EUROPEAN
COMMISSION

Brussels, 9.7.2014
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COMMISSION DECISION

of 9.7.2014

addressed to
- Servier S.A.S.
- Servier Laboratories Limited
- Les Laboratoires Servier
- Biogaran
- Krka, tovarna zdravil, d.d., Novo mesto
- Lupin Limited
- Mylan Laboratories Limited
- Mylan Inc.
- Niche Generics Limited
- Teva UK Limited
- Teva Pharmaceutical Industries Ltd
- Teva Pharmaceuticals Europe B.V.
- Unichem Laboratories Limited

relating to a proceeding under Article 101 and Article 102 of the Treaty on the Functioning of the European Union

AT.39612 – PERINDOPRIL (SERVIER)

(Only the English and French texts are authentic)

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AT.39612 – PERINDOPRIL (SERVIER)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union[1],

Having regard to Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty[2], and in particular Article 7 and Article 23(2) thereof,

Having regard to the Commission decisions of 2 July 2009 and 27 July 2012 to initiate proceedings in this case,

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1 OJ, C 115, 9/5/2008, p.47. Any reference to the European Union or its Member States in this Decision should be understood as not including Croatia, since Croatia was not a Member State of the European Union at the time of the investigated conduct, in the period from 2004 until 2009.

2 OJ L 1, 4.1.2003, p.1. With effect from 1 December 2009, Articles 81 and 82 of the EC Treaty have become Articles 101 and 102, respectively, of the Treaty on the Functioning of the European Union ("TFEU", hereafter also referred to as "the Treaty"). The two sets of provisions are, in substance, identical. For the purposes of this Decision, references to Articles 101 and 102 of the Treaty should be understood as references to Articles 81 and 82, respectively, of the EC Treaty where appropriate. The TFEU also introduced certain changes in terminology, such as the replacement of "Community" by "Union" and "common market" by "internal market". Where the meaning remains unchanged, the terminology of the TFEU will be used throughout this Decision.

Having given the undertakings concerned the opportunity to make known their views on the objections raised by the Commission pursuant to Article 27(1) of Regulation (EC) No 1/2003 and Article 12 of Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the Treaty,[3]

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Having regard to the final report of the hearing officer in this case,[4]

Whereas:

INTRODUCTION

(1) Perindopril is a so-called angiotensin converting enzyme (ACE) inhibitor used for the treatment of cardiovascular diseases e.g. high blood pressure. Once confirmed as a successful treatment for a patient in an initial trial period, the patient typically takes the medicine over many years and is unlikely to switch to an alternative medicine, even when these alternatives become significantly cheaper than perindopril due to generic entry.

(2) Perindopril became Servier's most successful product, with annual global sales for the years 2006 and 2007 exceeding USD 1 billion (making it a blockbuster drug),[5] accounting for approximately 30% of Servier's total turnover. According to Servier's own data (collected for the thirteen largest EU national markets), its average annual operating margins over the production and distribution of plain perindopril in the period 2000-2008 exceeded [90–100]* % in every year, making perindopril a highly profitable product.

(3) Generic entry for products like perindopril typically leads to two notable changes in the market. First, there is a significant decrease in prices[6] and secondly there are substantial volume shifts from the originator company to the generic companies. Servier therefore had strong incentives to delay generic entry for as long as possible.

(4) Servier started to devise, constantly update and implement its anti-generics strategy from the late 1990s onwards, if not before. Generic entry on the most important markets, such as the United Kingdom of Great Britain and Northern Ireland (hereinafter "the UK" or "the United Kingdom") and France, would happen, in principle, after the expiry of the perindopril compound patent – as extended by the supplementary protection certificate ("SPC") - in 2003/2005.[7] Servier pursued its objective to delay or prevent generic entry by making use of a great variety of instruments. This Decision does not qualify each and every one of these practices as infringements but they all form part of Servier's overall and comprehensive strategy

3 OJ L 123, 27.4.2004, p. 18.

4 OJ not yet published.

5 In FY2005, Servier reported the turnover of EUR [400–500]* million (USD [500–600]* million, based on the ECB exchange rate of USD/EUR 1.2042 on 30 September 2005) generated with the sales of plain perindopril in EU25 (ID7619).

6 For example, price drops of up to 90% were observed upon generic entry to the UK market. Please see section 6.4.1.4 for greater detail.

7 For the precise dates of SPC expiries, please consult Table 2 in section 4.1.1.2. Also, see paragraph (68).

against generic companies. They are thus relevant to fully understand the infringements described in the Decision. For the UK market, Servier noted on the eve of actual generic entry in July 2007, that its anti-generics strategy had been very successful: "**4 years gained = great success*".[8]

(5) The most important elements of Servier's anti-generic strategy can be summarised as follows. Between 2000 and 2005, Servier applied for and obtained a number of process and crystalline form patents, which Servier internally referred to as "**blocking patent"* or *"*paper patent"*. According to Servier's own assessment, some of them involved *"zero inventive activity"*.[9] The broadest protection resulted from the EP 1 296 947 patent (hereinafter "the '947 patent") for the "alpha crystalline form".[10] This patent was perceived by generic companies as the most significant obstacle to market entry. Ultimately it was annulled, first in certain national jurisdictions, like the Court of Appeal of England and Wales ("the Court of Appeal").[11] The European Patent Office ("EPO") also revoked the patent in May 2009.

(6) In the period from 2001 to 2009, there were a limited number of technologies for the production of perindopril that would not be covered by Servier's patents. Servier followed the market very closely. When Servier learnt that a producer of active pharmaceutical ingredients ("API") claimed to have found an alternative – possibly non-infringing - way to produce perindopril, Servier acquired these technologies and removed them as a competitive source from the market. In fact, Servier bought two technologies, one in 2001 from [company name and nationality]* and one in 2004 from Swiss company Azad. Servier purchased the latter with the explicit purpose to "*strengthen the defense mechanism"*[12] for perindopril. Through these acquisitions, Servier not only eliminated direct competition from the patent holders themselves but also removed them as a source of essential inputs (notably supplies of API, and licences) for other potential generic entrants. The generic companies noted on this practice: "*once an API manufacturer has got around the process patents, Servier has bought the company, sourcing API has been very difficult* ".[13]

(7) When Servier learnt about generic companies that were preparing for market entry (e.g., application for marketing authorisation), Servier tried to discourage them from proceeding by sending warning letters in which Servier made reference to its patent cluster including the paper patents. Servier also made use of litigation including injunction procedures. Moreover, Servier sought protection against generic entry by concluding five patent settlement agreements with the (most) advanced generic contenders: Niche/Unichem, Matrix, Teva, Krka and Lupin between 2005 and 2007. The settlements consisted of significant payments, or other inducements, to the generic companies, and the obligation for them not to challenge Servier's patents and not to enter the market (directly or indirectly) for a number of years. With one exception, the geographical scope of the settlements covered all EU Member States. The settlement with Teva concerned the UK only. The settlement agreements with Krka and Lupin also included an assignment (transfer) of certain patents to Servier. In total, Servier's payments to the generic companies exceeded EUR 120 million.

8 ID0116, p. 51.
9 ID9972, p. 78 – 119.
10 EP 1 296 947 would lapse in 2021.
11 See section 4.1.2.4.2.2.1.
12 ID0104, p.182.
13 ID0082, p. 70.

Niche noted on the transfer: *"Settlement was equivalent to over 10 year planned sales and 20 years planned gross profit"*.[14] One of Servier's internal documents dated 19 June 2006 and entitled *"Coversyl: Defense against generics - "Did it work?"* explicitly confirms that the patent settlements were part of Servier's anti-generic strategy.[15]

(8) Further, Servier developed a second generation product, which was based on a new salt, arginine instead of erbumine, and for which Servier had obtained patent protection until 2023. The second generation product is a bioequivalent, generic version of the first generation product but, due to the different molecular weight of the new salt, the second generation product is sold in different dosages (arginine: 2.5, 5 and 10 mg; erbumine: 2, 4 and 8 mg). Servier's strategy was to switch patients to the second generation product and withdraw its first generation product before generic versions could enter the market. Depending on the national regulatory regime, generic substitution was made impossible or limited. It is undisputed that the second generation product has no therapeutic advantages for patients over the first generation product. Internally Servier summarised its objectives: "**The purpose of this brief development (filing within a year), based on bioequivalence, is threefold: - Through its patent, to extend the duration of protection of Coversyl (2023). – To replace Coversyl immediately. – Not be substitutable by generics, in those countries where the latter would be already present at the time of launch"*.[16]

(9) The practices of patent acquisition and reverse payment settlements are considered to be violations of EU competition law. The reverse payment settlements amount to anti-competitive agreements pursuant to Article 101 of the Treaty. For this reason, this Decision is addressed to Servier as well as its contractual partners in the settlement agreements. The combination of the patent acquisition and the reverse payment settlements also amounts, in the Commission's assessment set out in this Decision, to an abuse of a dominant position by Servier pursuant to Article 102 of the Treaty.

(10) The first part of this Decision describes the parties (section 1), the procedure (section 2), the regulatory framework (section 3) and Servier's main practices (section 4). It provides an overview of all practices and then concentrates on the detailed description of a technology acquisition and reverse payment settlements. The second part of this Decision is dedicated to the assessment of the practices under Article 101 of the Treaty while the third part is dedicated to the assessment of the practices under Article 102 of the Treaty, including the analysis of the relevant markets and dominance.

[14] ID0025, p. 57.
[15] ID0105, p.172.
[16] ID0112, p. 32.

1 THE PARTIES

1.1 Servier

(11) The parent company of the Servier group is Servier S.A.S.[17] Servier S.A.S. is a financial holding company.[18] Its headquarters are at 50 rue Carnot, 92284 Suresnes cedex, France. It comprises a huge number of subsidiaries in and outside France directly or indirectly owned or controlled by Servier S.A.S. The various subsidiaries belonging to Servier S.A.S. are regrouped under five names: Les Laboratoires Servier, Servier Monde, Arts et Techniques du Progrès, Biofarma (the aforementioned subsidiaries are all private limited share companies)[19] and Servier International B.V.[20] Throughout the period between 1999 and 2009, Les Laboratoires Servier was a subsidiary of Servier S.A.S. within the Servier group.[21]

(12) Les Laboratoires Servier is a French pharmaceutical company specialised in the development of innovative (originator) medicines. Its main business consists of providing innovative medicines in the areas of diabetes, cancer, cardiovascular diseases and cerebral aging.[22] Les Laboratoires Servier's activities are grouped into four categories: "**promotion*",[23] "**production*",[24] "**generics*"[25] and "**medical information training*".[26] The headquarters of Les Laboratoires Servier are at 50 rue Carnot, 92284 Suresnes cedex, France.[27]

(13) Servier, in its reply to the Commission's request for information ("RFI") of 4 November 2009, advised that several other subsidiaries of Servier S.A.S. are relevant for this investigation.

(14) First, Servier referred to Servier Laboratories Limited, a subsidiary of Servier International B.V.[28] It is active in the area of promotion and distribution of pharmaceuticals in the UK. Second, Servier mentioned Biogaran, established in 1996, which is a wholly owned generic subsidiary of Les Laboratoires Servier[29] and whose distribution activity is almost exclusively limited to France.[30] […]*.[31] [...]*.[32] [...]*.[33]

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17 "**Servier S.A.S. is a simplified joint stock company* [société par actions simplifiée] *having a share capital of EUR 225,600, registered on 15 November 1985 with registration number 324 444 991 with the Register of Commerce and Companies of Nanterre. Its registered office is located at 50 rue Carnot, 92284 Suresnes cedex, France*". ID10673, p. 1.

18 ID5064, p. 9.

19 "**Simplified Joint Stock Company*" ("Société par Actions Simplifiée" or "S.A.S"), ID1632, p. 1.

20 ID1630, p. 1.

21 ID1631, p. 1.

22 ID0318, p. 1.

23 [Names of subsidiaries of Servier]*.

24 [Names of subsidiary of Servier]*.

25 Biogaran.

26 […]*.

27 ID10673, p. 2.

28 ID1630, p. 1.

29 ID7049.

30 ID4517, p.13.

31 ID1630, p. 1 and ID 0111, p. 6.

32 ID1151, p. 37.

33 ID0319, p. 1.

(15) The non-profit foundation under Dutch law, Stichting FIRS, has exclusive control over the management of Servier S.A.S.[34] Stichting FIRS (registration number 41205960) is located at Promenadeplein 125 – 2711 AB Zoetermeer, the Netherlands.[35] It was founded in 1986. Its objectives are (a) promotion of scientific research and its application in the area of pharmaceuticals, (b) development and continuity of the operations of the undertakings belonging to the group controlled by Servier S.A.S.

(16) Servier is an international undertaking, present in 140 countries.[36] According to Servier, the group devotes 25% of its turnover to R&D for new medicines.[37]

(17) The Servier group's annual global consolidated turnover for the business year starting 1 October 2012 until 30 September 2013 was EUR 4,189,012,000.[38] Contained in this figure is the turnover generated with generic products, which was EUR [1,100–1,200]* million for the same period ([20–30]* % of the global consolidated turnover).[39]

(18) In this Decision, and unless otherwise specified, companies of the Servier group will be referred to as "**Servier**".

1.2 Generic companies, which entered into a reverse payment settlement with Servier, and which are addressees of this Decision

1.2.1 Krka

(19) The Krka Group consists of the controlling company, Krka, d.d., Novo mesto (Slovenia), and a number of subsidiaries in and outside Slovenia (jointly referred to hereinafter as "Krka"). Krka is a pharmaceutical company registered in Slovenia.

(20) Krka's main business consists of the development, production, sale and marketing of human health products (prescription and self-medication pharmaceuticals and cosmetics), animal health products and health resort and tourist services. Production takes place in Slovenia, Poland, the Russian Federation, Croatia and Germany, while the remaining subsidiaries outside Slovenia are engaged in the marketing and/or sale of Krka products.

(21) Krka is specialised in the development, manufacturing and marketing of generic medicines. Its most important sales region is Central Europe with highest growth anticipated in Western Europe and overseas markets. Its total turnover in 2008 was around EUR 950 million, of which 82% related to prescription medicines.[40] In 2013 Krka reported a turnover of EUR 1,200,827,000 within the Krka Group.[41]

(22) In this Decision, and unless otherwise specified, companies of the Krka Group will be referred to as **"Krka"**.

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34 Such control results notably from the power to appoint and revoke the managers.

35 ID10673, p. 2. Source: The trade register of the Dutch Chambers of Commerce; ID2366, p. 1-2.

36 http://www.servier.fr/servier-dans-le-monde.

37 ID1631, p. 2 of 5.

38 ID1933.

39 ID10666, p. 1.

40 ID4955 - Krka annual report 2008, p. 7-9, 16. (http://www.krka.biz/media/doc/en/for_investors/2012/2008_Annual_report.pdf).

41 ID10642, p. 3.

1.2.2 Lupin

(23) Lupin Limited is the Indian-registered parent company of the Lupin Group of companies headquartered in Mumbai. Lupin (Europe) Limited was established in 2000 with the aim of developing contacts in Europe through which products manufactured by Lupin Limited could be commercialised.[42]

(24) Lupin (Europe) Limited was a branch of Lupin Limited until 5 June 2009, when it became a limited company, and thus a separate legal entity from Lupin Limited.[43] The primary activities of Lupin (Europe) Limited are sales of APIs and the supply of Lupin finished products (i.e., tablets, capsules, suspensions) in conjunction with the out-licensing of Lupin Limited's product marketing authorisation dossiers throughout Europe. In addition, Lupin (Europe) Limited has a small direct-to-market operation in the UK through which Lupin's finished products are sold in the retail pharmacy and wholesale sectors.[44]

(25) Lupin Limited's most recent global annual turnover was INR 111,671,200,000 (EUR 1,376,715,790) in the financial year which ended 31 March 2014.[45]

(26) In this Decision, and unless otherwise specified, companies of the Lupin Group will be referred to as "**Lupin**".

1.2.3 Matrix

(27) Matrix Laboratories Limited ("Matrix")[46] is a public limited company based in Hyderabad, India and listed on the major stock exchanges in India during the infringement period.[47] Matrix is engaged in four areas: (1) supply of APIs to international generic companies; (2) contract research and manufacturing APIs and intermediates for international generic companies; APIs for research-based pharmaceutical companies; and chemical development from lead optimization to commercial scale; (3) contract development and manufacture of finished dosage formulations; and (4) manufacture and marketing of antiretroviral APIs and finished dosage formulations. Matrix develops and manufactures a wide range of products for the domestic and international markets, including the European Union.[48]

(28) On 21 December 2006, a company[49] within the Mylan Laboratories Inc. group ("Mylan") acquired a 20% shareholding in Matrix. On 8 January 2007, this shareholding was increased to 71.5%[50] and from that date Mylan had a controlling interest in Matrix.[51] Following a further purchase of shares during 2009, Mylan's

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42 ID0434, p. 5.

43 ID4977, p.19.

44 ID0434, p. 5.

45 ID10693, p. 4.

46 Matrix Laboratories Limited changed its name to Mylan Laboratories Limited on 5 October 2011 (ID5387).

47 Matrix changed its name from Herren Drugs & Pharmaceuticals Limited to Matrix Laboratories Limited on 21 March 2001 (which had been a public limited company since 19 October 1992). In April 2003 Matrix merged with Medicorp Technologies India Limited, a publicly-listed manufacturer of API. ID0665, p. 4.

48 ID0665, p. 4-5.

49 MP Laboratories (Mauritius) Limited, ID5392, p.2.

50 ID5392, p. 2.

51 ID3308, p. 2 and ID4088, p. 8.

shareholding increased from 71.5% to 94.36%.[52] As of 22 August 2011, Mylan held 97-98% of Matrix's shares.[53]

(29) The global turnover of Matrix for the year ending 31 March 2013 was INR 58,205.06 million (EUR 831.234 million).[54] Matrix had, until recently,[55] two subsidiaries which sold perindopril in the EEA: Docpharma NV ("Docpharma")[56] and Apothecon BV ("Apothecon"). Both companies were acquired by Matrix in June 2005.[57] The global turnover of Mylan for the year ending 31 December 2013 was USD 6,909.143 million (EUR 5,202.668 million).[58]

(30) In this Decision, and unless otherwise specified, Matrix Laboratories Limited and all its subsidiaries as well as Medicorp Technologies India Limited for which Matrix Laboratories Limited is the legal successor will be referred to as "**Matrix**".

1.2.4 Niche/Unichem

(31) Niche Generics Limited ("Niche") is a company registered in the UK (company number 04353309). It is a medium-sized pharmaceutical firm based in the UK and Ireland, which undertakes the launch of and supply of generic pharmaceutical products for distribution in the UK, Ireland and the rest of Europe. Niche's main business activities are patents, regulatory affairs, solid-dose manufacture, quality control, marketing and sales. Niche's products are marketed directly in Ireland, via wholesalers in the UK and through partnerships with other generic companies in other countries in Europe.[59] Since December 2006, Niche is wholly owned by Unichem Laboratories Limited.[60]

(32) Niche's annual turnover for the fiscal year ending 31 March 2014 was EUR 12,440,682 (GBP 10,491,028).[61]

(33) On 15 April 2002, Niche bought the assets and trade of Bioglan Generics Limited. ("Bioglan"),[62] which was, at the time, the generic subsidiary of Bioglan Pharma Plc.[63] In order to fund the acquisition Niche entered into a loan agreement for GBP [0–2]* million with Unichem Laboratories Limited.[64] At that time, the latter owned 60% of Niche's shares, with the remaining shares being held by Niche's management team.[65]

(34) Unichem Laboratories Limited ("Unichem")[66] is an independent research and manufacturing pharmaceutical company registered in India with its own API plant

52 The increase in the shareholding became effective on 7 September 2009. ID5392, p. 4.
53 ID5392, p.3 and ID10830, p.1.
54 ID10685, p. 2.
55 Matrix does not own these subsidiaries since September 2010 (ID10830, p.1).
56 Docpharma "is primarily a distributor of pharmaceutical products in the Benelux region of Europe", 2008 Mylan Annual Report (Form 10-K), p. 4.
57 ID1452, p. 5.
58 ID10685, p. 2.
59 ID0383, p. 1.
60 ID0383, p. 1.
61 ID10817, p. 2.
62 ID3268, p. 1.
63 ID1577, p. 3 and ID2613, p. 3.
64 ID7454.
65 ID0383, p. 1.
66 Registered office is at Mahalaxmi Chambers 22, Bhulabhai Desai Road, Mumbai 400 026 India.

and finished-dose manufacturing unit. In 2002, Unichem established as a joint venture company Niche Generics Limited, controlled by Unichem.

(35) For the fiscal year ending on 31 March 2014 the turnover of Unichem was INR 11,334,479,000 which corresponds to EUR 139,687,731.[67]

(36) In this Decision, and unless otherwise specified, Unichem Laboratories Limited, including Niche Generics Limited which is under its control, will be referred to as "**Niche/Unichem**" (unless where information refers specifically to Niche or Unichem).

1.2.5 Teva

(37) Teva Pharmaceutical Industries Limited ("Teva"), with headquarters in Israel,[68] is a global pharmaceutical company that develops, produces and markets generic drugs covering all major treatment categories. Teva also produces APIs for its own pharmaceutical production as well as for third-party manufacturers. Teva has production facilities in Israel, North America, Europe and Latin America. Teva Pharmaceuticals Europe B.V. with headquarters in the Netherlands is a wholly owned subsidiary of Teva Pharmaceutical Industries Limited.[69] Teva UK Limited is a company incorporated in the UK and a wholly owned subsidiary of Teva Pharmaceuticals Europe B.V.[70] Teva operates in more than 50 countries in North America, Europe, Latin America and Asia and is among the largest generic pharmaceutical companies in the world.[71]

(38) During the last decade, Teva acquired/merged with several pharmaceutical companies. In this Decision, the most significant of these transactions was with Ivax in 2006. Ivax was a multinational generic pharmaceutical company, comprising several subsidiaries.[72] Ivax had engaged in independent efforts to enter the perindopril market. After Ivax's acquisition by Teva, Ivax's perindopril product development project was chosen and continued within Teva. Furthermore, in 2008, Teva acquired Bentley Pharmaceuticals, Inc., CoGenesys, Inc. and Barr Pharmaceuticals, Inc.[73] and, on 10 August 2010, the acquisition of Ratiopharm was completed.[74]

(39) The global annual turnover of Teva Pharmaceutical Industries Limited is USD 20,314 million (EUR 15,160 million) for year ending 31 December 2013.[75]

(40) In this Decision, and unless otherwise specified, companies of Teva Pharmaceutical Industries Limited will be referred to as "**Teva**".

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67 ID10817, p. 2.

68 Teva's executive offices are located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel.

69 ID5426, p. 3.

70 ID5426, p. 3.

71 ID0339, p. 10-13.

72 For an overview, see the Teva organizational chart: ID0339, p.13.

73 ID0339, p. 11.

74 http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-newsArticle&ID=1555528&highlight=.

75 ID10847, p. 2.

1.3 API producers that sold their enabling technology to Servier but are not addressees of this Decision

1.3.1 Azad

(41) Azad Pharma AG was founded in 2002 and is based in Toffen, Switzerland. Its main activities include the development of marketing authorisation dossiers, sale of licences of dossiers, and supplying finished pharmaceuticals to pharmaceutical resellers. Azad Pharmaceutical Ingredients AG develops processing methods for generic pharmaceuticals.[76] Azad Fine Chemicals AG is the group's API trading and marketing arm.[77]

(42) As all of these companies belong to Miba Holding AG[78] they shall be, for the purpose of this Decision, considered to form part of the same group of undertakings, and shall be jointly referred to as "**Azad**".

*1.3.2 [Company name]**

(43) [Company name]* is a [nationality]* company active in the manufacturing and marketing of APIs.[79]

[76] ID1112, p. 2, ID3343, p. 3.
[77] ID3343, p. 3.
[78] ID3343, p. 4.
[79] ID3293, p. 11.

2 PROCEDURE

2.1 Chronology of the Commission's investigation

(44) On 24 November 2008, the Commission started its *ex-officio* investigation with unannounced inspections[80] of the premises of Servier, Krka, Lupin,[81] Niche and Teva in various Member States.[82]

(45) Following the unannounced inspections, the Commission sent its first round of requests for information in January 2009.

(46) On 2 July 2009, the Commission decided to open formal proceedings against Servier for suspected breaches of the rules on restrictive business practices (Article 101 of the Treaty) and abuse of a dominant market position (Article 102 of the Treaty). The decision to open proceedings also applied to the generic operators Krka, Lupin, Matrix/Mylan, Niche and Teva.[83]

(47) The proceedings were opened with a view to adopting a decision in application of Chapter III of Council Regulation No 1/2003. [84]

(48) In August 2009, the Commission sent a second round of requests for information with questions relating to the inspection material. The second round was sent to 24 addressees in total, including companies that had not been addressed before and IMS Health ("IMS", a company providing healthcare data).

(49) Between 2009 and 2012, several state of play meetings took place with the main parties. Throughout the subsequent investigation a number of additional requests for information were sent to the main parties and to more than 30 additional companies on an individual basis. These were sent from December 2009 to June 2012. [85] Following Servier's refusal to reply to parts of simple requests for information dated 7 February and 18 April 2011 concerning the agreement between its subsidiary Biogaran, and Niche[86], the Commission adopted a decision pursuant to Article 18(3)

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80 ID4928, printed on 11 July 2011.

81 Lupin was also subject to the second inspection that took place in July 2009.

82 For the avoidance of doubt, the present investigation does not form part of the Commission's Pharmaceutical Sector Inquiry ("Sector Inquiry") which was concluded in July 2009. However, the knowledge the Commission acquired during the Sector Inquiry has allowed it to draw conclusions on the areas where Commission action based on competition law could be appropriate and effective.
For information on the competition inquiry into the pharmaceutical sector, the Final Report adopted by the Commission on 8 July 2009 can be found at:
http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.
See also IP/09/1098 (ID4989, printed on 14 July 2011).

83 ID829-834 and ID849. Moreover, on 27 July 2012, the Commission formally initiated proceedings against Teva Pharmaceuticals Europe B.V., Unichem Laboratories Limited, and Mylan Incorporated.

84 The present case meets the Commission enforcement priorities in applying Article 102 of the Treaty to exclusionary conduct as set in the *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty [now Article 102* of the Treaty*] to abusive exclusionary conduct by dominant undertakings*, OJ C 45, 24.02.2009, p.7-20.

85 From December 2009 to May 2012, Servier received 18 requests for information. The generic companies (Krka, Lupin, Mylan, Matrix, Niche, Unichem and Teva) received, in the same period between three and seven requests for information each. In total, 516 requests for information have been sent during the course of the investigation.

86 See sections 4.3.1.4.1.3 and 5.2.1.3.3.5.

of Council Regulation No 1/2003 requesting this information. Servier provided the requested information on 7 November 2011.

(50) On 27 July 2012 the Commission issued a Statement of Objections (referred to also as "the SO") to the parties.

(51) The parties submitted their written replies to the Statement of Objections between November 2012 and January 2013.[87] An interested party, the English Secretary of State for Health and others, submitted comments on the summary of the Statement of Objections.

(52) On 15 – 18 April 2013, a four-day Oral Hearing was held where all parties who had requested a hearing presented their views. The interested third party also attended the Oral Hearing. One of the sessions was held as a closed session at the request of Servier.

(53) In the course of July, September and October 2013 state of play meetings with all the main parties took place. In parallel, a limited number of additional requests for information were sent to Servier, Krka, Lupin and Mylan in 2013.[88]

(54) On 18 December 2013, the Commission granted access to evidence gathered or further disclosed after the Statement of Objections and sent a Letter of Facts to which all parties replied between 17 and 30 January 2014.[89] On 4 April 2014, the Commission sent Letters of Facts concerning solely the issue of parental liability to Mylan, Matrix, Unichem and Niche, to which they replied between 22 April and 5 May 2014.[90]

(55) The Hearing Officer issued his final report on 7 July 2014.

2.2 Main evidence relied on and procedural steps

(56) The main evidence relied on is the actual text of the agreements concluded between Servier and each of the generic undertakings concerned, and the text of the relevant technology acquisitions, together with documents found during the inspections, the companies' replies to requests for information and elements gathered for the market definition. These documents concern in particular the negotiation, conclusion and implementation of the agreements covered by this Decision.[91]

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87 Niche and Unichem replied to the Statement of Objections on 16 November 2012; Teva (Teva UK Limited, Teva Pharmaceutical Industries Ltd, Teva Pharmaceuticals Europe B.V.) replied on 16 November 2012; Krka replied on 5 December 2012; Lupin replied on 5 December 2012; Mylan (Mylan Inc. and Mylan Laboratories Limited) replied on 12 December 2012; and Servier (Servier S.A.S., Les Laboratoires Servier, Servier Laboratories Limited, Adir and Biogaran) replied on 14 January 2013.

88 In 2013, CEGEDIM (Centre de Gestion, de Documentation, d'Informatique et de Marketing) also received a RFI concerning data submitted by Servier; and in 2014, Mylan received two requests for information concerning solely the issue of parental liability.

89 Servier replied to the Letter on Facts on 31 January 2014 (ID10289, with Annexes 1 to 12, ID10292 to 10303; a separate reply was submitted on behalf of Biogaran (ID10288)); Mylan (ID10200), Krka (ID10202) and Teva (ID10204) replied to the Letter of Facts on 17 January 2014; Unichem (ID10221) and Niche (ID10220) replied on 21 January 2014; and Lupin (ID10241) replied to the Letter of Facts on 22 January 2014.

90 Unichem and Niche replied on 22 April 2014 (ID10590); and Mylan and Matrix replied on 2 May 2014 (ID10599).

91 These sources of evidence are mentioned only for ease of reference. The Commission relies on the entirety of the evidence presented in this Decision to prove the infringements identified in this Decision.

(57) During the inspections in 2008, a number of documents were identified for which Servier claimed *inter alia* that they were protected by Legal Professional Privilege (hereinafter "LPP"). Servier's claims for LPP were all subsequently resolved. On 10 June 2010, the Commission returned unopened two sealed envelopes to Servier, opened four sealed envelopes and added the latter content to the case file with Servier's consent. In addition, the Commission agreed to return some of the inspection documents and to remove them from the case file. Servier's lawyers confirmed in writing that, apart from the sealed envelope (for which the Commission took a decision later), their clients made no further claims regarding LPP in respect of the inspection documents.

(58) For one document in a sealed envelope, the Commission and Servier could not reach an agreement as to whether it was covered by LPP. On 23 July 2010 the Commission took a decision pursuant to Article 20(4) of Council Regulation (EC) No 1/2003 to open the sealed envelope. Servier did not challenge the decision. Subsequently the Commission added the document to the case file. It was a letter from Teva's Belgian lawyers to Servier's Belgian lawyers (later forwarded to and within Servier) in which Teva warned Servier that it would submit an antitrust complaint to the Commission regarding Servier's decision to switch from perindopril erbumine to perindopril arginine and to withdraw perindopril erbumine from the market in Belgium, which made generic substitution impossible[92], unless a mutually acceptable agreement was reached between the parties.

(59) The case file also contains a number of documents that were originally gathered from Servier in the context first of the Sector Inquiry (Case COMP/AT.39514) and secondly, during an investigation relating to the alleged provision of misleading and incorrect information (Case COMP/AT.39812). These documents were re-requested so that they could be included in the case file. Following initial hesitations, Servier decided to comply with the corresponding requests for information (see requests for information to Servier of 11 March 2010 and 18 April 2011) and submitted the requested documents. In this context, Servier questioned Commission's compliance with the principle of good administration and suggested that the Commission improperly used the information obtained within the framework of the Sector Inquiry for the present case.[93] As explained in paragraph (44), the present investigation does not form part of the Commission's Sector Inquiry. However, the knowledge the Commission acquired during the Sector Inquiry has allowed it to draw conclusions in the areas where the Commission's action based on competition law could be appropriate and effective. It is settled case-law that the Commission is not precluded "*from initiating an inquiry in order to verify or supplement information which it happened to obtain during a previous investigation if that information indicates the existence of conduct contrary to the competition rules in the Treaty*".[94] It must be stressed that the Commission did not introduce into this case of its own motion documents which it had obtained in the Sector Inquiry, but obtained those documents

92 See section 4.1.2.7.

93 ID10114, p. 655-656.

94 Joined Judgment in *Limburgse Vinyl Maatschappij and Others v Commission*, C-238/99 P, C-244/99 P, C-245/99 P, C-247/99 P, C-250/99 P to C-252/99 P and C-254/99 P, EU:C:2002:582, paragraph 301.

again in the context of the investigation of the present case.[95] The Commission therefore did not breach the principle of good administration.

(60) The Commission carried out an extensive survey on the prescribing patterns of cardiologists, general practitioners and hospitals in the four Member States selected for in-depth investigation: the UK, France, Poland and the Netherlands, pertaining to the time period 2000 to 2009. More than 300 replies were received and analysed (see section 6.4.5.7).

(61) In the replies to the Statement of Objections and in the replies to the Letter of Facts, certain parties alleged that their procedural rights had been infringed in the course of the proceedings. The Commission considers that the parties' procedural rights have been duly respected, and their requests handled timely and in compliance with the applicable procedures. Certain issues were addressed to the Hearing Officer for final resolution. Reference is made to the Hearing Officer's final report of 7 July 2014.[96] The parties' claims are also addressed in paragraphs (58) and (1200) of this Decision.

95 See in that respect Joined Judgment in *Limburgse Vinyl Maatschappij and Others v Commission*, C-238/99 P, C-244/99 P, C-245/99 P, C-247/99 P, C-250/99 P to C-252/99 P and C-254/99 P, EU:C:2002:582, paragraphs 302-306.

96 OJ not yet published.

3 REGULATORY FRAMEWORK

(62) The European pharmaceutical sector is highly regulated. The regulatory framework, which is based on international, national and European law, aims at removing obstacles to the free movement of medicinal products and ensuring their quality, safety and efficacy while stimulating innovation and ensuring access to affordable medicines. At European level, the main sets of legislation affecting the pharmaceutical industry that are relevant for the purposes of this Decision are: patent law, rules on marketing authorisation and the Convention on the European Pharmacopoeia. Rules concerning the price and reimbursement of medicinal products are also relevant to issues described in this Decision. Nonetheless, in this area, Member States are solely competent to regulate the prices and reimbursement levels of medicines sold in their territory, although such rules must abide by certain transparency, equality and accountability standards.

3.1 Patent system

(63) The pharmaceutical sector relies heavily on patents. A patent is a legal title protecting an invention, which can be a product or a process, by granting its holder the right to prevent third parties from making, using, offering for sale, selling, importing, distributing or stocking the product (including the product obtained directly by a patented manufacturing process) without the patent holder's consent.[97] The main objective of patent protection is to stimulate innovation by granting the inventor a period of exclusive use of the invention. At the same time, the publication of the invention required for obtaining the patent helps to disseminate knowledge and can be the basis of further innovative efforts also by third parties. The protection is time-limited, encouraging the inventor to bring the innovation to market as quickly as possible and providing incentives for the inventor to continue to innovate and develop further innovative products benefitting from patent protection. The maximum protection period granted by a patent is 20 years from the date of the patent application.[98]

(64) The European Patent Convention ("EPC") is an international treaty binding all EU Member States[99] as well as some other European countries (e.g. Switzerland, Norway) which establishes a common system of law for the grant of patents. It provides for a centralised procedure for the grant of European patents. At the time of the events, European patents were split after grant into a bundle of national patents. Once granted, a European Patent has the same effect and confers the same rights, subject to the same conditions, as would be conferred by a national patent. For process patents, the protection conferred by a European patent extends to products directly obtained by the process that is the subject-matter of the patent. After grant, European patents need to be validated in each Member State for which the patent was requested, by the submission of a translation, if the patent is not in one of the

97 A patent is therefore an intellectual property right ("IPR"). See Article 28(1) of the WTO Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS").

98 See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 116. In accordance with Article 3 TRIPS, Article 63 of the EPC provides that the term of a European patent is 20 years from the date of filing of the application.

99 The present Decision takes into account the dates of accession to the EPC by individual Member States, see for example footnotes 2821 and 2824.

official languages of that Member State. Any infringement of a European patent is dealt with under national law. Finally, under the EPC, contracting states have the option to provide for less protection than that conferred by the Convention to a published application for a European patent. Many Member States have exercised this option and only provide for reasonable compensation in the event of an infringement of a published patent application, often subject to the fulfilment of some conditions. In practice this means that the proprietor of a patent application cannot apply to a national court for an injunction in the event of an alleged infringement of a patent application. The only remedy available to the patent holder is a grant of damages reasonable in the circumstances.

(65) In the pharmaceutical industry, inventions relate for example, to new active ingredients, to new formulations of existing active ingredients or to new ways of producing or delivering active ingredients. All of these are, in principle, patentable. It is not a requirement of patentability that a new medicine is more effective in therapeutic action than an existing medicine.

(66) Patents covering new active ingredients can also be referred to as "primary", "basic" or "compound" patents. Subsequent patents covering, for example, new processes for the production of active ingredients are sometimes referred to as "secondary" patents.

(67) In accordance with Article 52(1) EPC, a patent will be granted if the following three criteria of patentability are met:

(a) The invention is new: An invention is new if it does not form part of the "state of the art". In Europe, this concept comprises everything made available to the public, in any shape or form, before the date of filing of the patent application. Such publicly available information is called "prior art".

(b) The invention involves an inventive step: A patent involves an inventive step if the invention, having regard to the state of the art, is not obvious to a person skilled in the art. In order to assess this, the EPO follows the "problem-solution approach", consisting of three stages of analysis. First, the closest prior art is determined.[100] Then the objective technical problem to be solved is established, based on the difference between the claimed invention and the closest prior art. Finally, the EPO considers whether the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to a skilled person.

(c) The invention is susceptible of industrial application: Being susceptible of industrial application simply means that the invention can be made or used in any kind of industry, including agriculture.

(68) In order to compensate for the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market, which reduces the period of market exclusivity to such an extent that it was considered insufficient to cover the investment into the research to discover the medicinal product, a SPC was created at the EU level.[101] The SPC

[100] The closest prior art is the combination of already known features which constitutes the most promising starting point for development leading to the claimed invention.

[101] Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, p. 1-5), replaced by Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1-10).

extends for a maximum of five years in the territory of a Member State the term of the basic patent protecting a medicinal product which has been subject to a MA before being placed on the market.

(69) European patents are open to opposition and appeal from third parties without any presumption by the EPO regarding their status.[102] The validity of patents can also be challenged in administrative procedures before the patent offices ("opposition procedures") or before national courts. The latter can also decide if a certain product infringes an existing product. Where this is the case, national courts or patent offices will reach their own view on the validity of the patent. As the European patent is a "bundle of patents", the annulment of a patent in a given national jurisdiction does not invalidate the patent in all other jurisdictions, even if the patent in the other jurisdictions is based on the same European patent granted by the EPO. By contrast, an EPO decision in opposition proceedings is retro-actively effective in all States where the opposed patent is valid.

3.2 Marketing Authorisation

(70) In the EEA,[103] medicinal products may only be placed on the market after they have obtained marketing authorisation ("MA"). This applies to all medicinal products, regardless of whether they are from originator companies or generic companies. The main objective of marketing authorisation procedures is to ensure the quality, efficacy and safety of medicinal products put on the market.

(71) MA procedures are completely harmonized under Union law.[104] There are four different routes to obtaining an MA which result in the issue of three different types of MA: (i) a national only MA, (ii) a mutually recognised MA or (iii) a community authorisation. These routes determine the procedures, processes and timelines used in progressing an application for a new MA in accordance with EU legislation. Once granted, the authorisation will be classified as nationally authorised, mutually recognised or centrally authorised.[105] The centralised procedure results in a MA that is valid for the entire EEA and is granted by the Commission following a scientific evaluation by the European Medicines Agency ("EMA"). The scope of the centralised procedure has been extended over the years and now also applies to some generic products. By contrast, the Mutual Recognition Procedure ("MRP") and the Decentralised Procedure ("DCP") rely on the principle of mutual recognition. The MRP must be used when a product is already authorised in at least one Member State on a national basis and the marketing authorisation holder wishes to obtain an MA in at least one other Member State.

(72) The Member State that has already authorised the product (known as the Reference Member State ("RMS")) submits an evaluation of the product to other Member State/s (known as Concerned Member States ("CMS")) which are asked to mutually

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102 See Final Report of the Pharmaceutical Sector Inquiry, paragraph 286.

103 Norway, Iceland and Liechtenstein which together with the EU28 form the EEA have agreed to adopt, through the EEA agreement, the existing body of Union law on medicinal products.

104 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67-128), as amended, and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1-33).

105 See www.hma.eu.

recognise the MA of the RMS. The CMS will then issue a MA permitting the marketing of the product in their territory.

(73) If no national MA has yet been granted, an applicant can use the DCP allowing the submission of applications in several Member States simultaneously. In the DCP, the RMS does the initial evaluation of the product and issues a draft assessment report. The CMS either agree with the RMS's evaluation or ask further questions/raise objections if there are public health issues. At the end of the procedure each Member State will issue a MA permitting the marketing of the product in their territory.[106]

(74) For new originator medicines, detailed results of pharmaceutical (physio-chemical, biological or microbiological) tests, pre-clinical (toxicological and pharmacological) tests and clinical trials must be submitted when the MA application is made. As an exception, where MA is requested for a generic product of an originator's medicinal product which has been authorised for a specified period, the generic applicant is not required to provide the results of pre-clinical tests and clinical trials. Instead, the competent authority can rely on the results of tests and trials submitted in the MA application for the originator product (the 'reference product'). The generic company then simply files for an "abridged application" in which it has to demonstrate that its product has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product and to show bioequivalence with it, by conducting bioavailability studies.[107] The period during which competent authorities cannot rely on the pre-clinical tests and clinical trials submitted in support of the MA application for the originator's product is the so-called “data exclusivity period”.[108]

(75) The rules on patents and on data exclusivity provide different and parallel sources of protection for originator medicinal products, which may or may not overlap. In most cases, however, the data exclusivity period expires before the expiry of the relevant patents (including SPCs).[109] It is important to note that in such situations, competent authorities are not prevented from granting a MA to generic products because the reference product is protected by a patent (whether a product, formulation or process patent). MA decisions are taken on the basis only of scientific criteria regarding the quality, safety and efficacy of the medicinal product, and following an evaluation of

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106 The DCP was introduced by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30/04/2004, p. 34–57) which entered into force on 30 October 2005.

107 For this purpose different salts of API are considered to be the same API, unless they differ significantly with regard to safety and/or efficacy (see Article 10(2) (b) of Directive 2001/83/EC).

108 Formerly, there were data exclusivity periods of 6 or 10 years depending on the Member State. They were harmonised by Directive 2004/27/EC to a period of 10 years. In accordance with the new rules, competent authorities may process an abridged application after 8 years from the date of the first MA of the reference product. The generic product cannot, however, be marketed before the expiry of a period of 10 years from the first MA of the reference product. The latter period is often called the 'marketing exclusivity' period. However, these periods of protection do not apply to reference medicinal products for which the initial application for MA was submitted before the date of transposition of Directive 2004/27/EC (30 October 2005) which is the case for Servier's product Coversyl. Consequently, the relevant data exclusivity periods are those of 6 or 10 years depending on the Member State of authorization (see, Final Report of the Pharmaceutical Sector Inquiry, footnote 271) with no 'marketing exclusivity' period being available.

109 As regards the four Member States that are the subject of in-depth investigation of effects under Articles 101 and 102 of the Treaty in the present case, the data exclusivity period expired on 22 June 1998 in the UK, France and the Netherlands and on 22 July 1998 in Poland. The last reported expiry of the data protection period was in February 1999. ID2365, p. 6 - 7.

the risk-benefit balance of the product. Factors such as the fact that the reference product is covered by a patent cannot be invoked by competent authorities in order to refuse, suspend or withdraw a MA to a generic product.[110] Once a generic has obtained an MA it can launch onto the market, provided other national legal requirements such as obtaining price approval and reimbursement status have been satisfied. In principle, a generic company can decide to launch its generic product without waiting for the originator's relevant patents to expire or attempting to invalidate them. It is in these cases that one generally speaks of launch 'at risk' as the generic may still be prevented from entering the market or may subsequently have to be withdrawn pursuant to a court order/injunction, if it infringes a valid patent.

(76) EU legislation[111] permits the use of a Drug Master File ("DMF") procedure when the active substance manufacturer is not the applicant for a product MA. A DMF is a document containing the information required to demonstrate that the quality of the active substance is adequately controlled by the specification proposed by the applicant. The applicant must, therefore, collaborate with the person submitting a separate DMF to ensure that all relevant information required is supplied. Furthermore it must be ensured that the applicant's part of the DMF contains all the information needed for the applicant to take full responsibility for the preparation, including the suitability of the active substance (as supplied) for the intended route of administration. It is not a requirement to present information on the active substance in the form of a separate DMF. The information may also form part of the application for the MA to place a medicinal product on the market. Three types of active substances may be described in a European DMF: (i) new active substances still covered by a patent, not described in the European Pharmacopoeia or in the pharmacopoeia of a Member State, (ii) active substances off-patent, not described in the European Pharmacopoeia or the pharmacopoeia of a Member State and (iii) active substances described in the European Pharmacopoeia or in the pharmacopoeia of a Member State when prepared by a method liable to leave impurities not mentioned in the pharmacopoeia monograph and for which the monograph is inappropriate to adequately control their quality.

3.3 The European Pharmacopoeia

(77) The European Pharmacopoeia was established by an international convention of the Council of Europe.[112] The purpose of the European Pharmacopoeia is to provide recognised common standards for use by health care professionals and others concerned with the quality of medicines. The European Pharmacopoeia is therefore a single reference work for the quality control of medicines in Europe. The European Pharmacopoeia is formed of monographs on particular medicines prepared by their manufacturers and approved by expert groups within the pharmacopoeia administrative body. Once approved, the monographs are published and are updated regularly. The monographs contain specifications concerning the qualitative and

110 See, Article 81 of Regulation 726/2004, as amended, and Article 126 of Directive 2001/83, as amended. See also, Final Report of the Pharmaceutical Sector Inquiry, point 336.

111 Annex I to Directive 2001/83/EC as amended by Directive 2003/63/EC, Part I, section 3.2 Content: basic principles and requirements, paragraph 8 (OJ L 159, 26.6.2003, p. 61) now renamed as 'Active Substance Master File' – ASMF. In this Decision, reference will be made to the DMF.

112 Convention of the elaboration of the European Pharmacopoeia, Strasbourg, 22 July 1964. As of 18 April 2007 the Convention had been signed by 36 states and by the EU.

quantitative composition and the tests to be carried out on these medicines, the raw materials used in production and the intermediates of synthesis.

(78) European Union Directives 2001/82/EC[113] and 2001/83/EC[114] on medicines for human and for veterinary use, set out the mandatory character of European Pharmacopoeia specifications on medicines for marketing authorisation applications.[115]

(79) The official standards published by the European Pharmacopoeia provide a legal and scientific basis for quality control during the development, production and marketing of medicines. All producers of medicines or substances for pharmaceutical use therefore must respect the quality standards of the European Pharmacopoeia.

(80) The European Pharmacopoeia coexists with national pharmacopoeia, which issue common quality standards for medicines at national level.

3.4 Pricing and Reimbursement

(81) In many Member States a medicinal product can only be marketed after a decision on the price and reimbursement status has been taken. The pricing decision determines the commercial terms of access to the market in a particular country. These policies aim to ensure (1) that patients have access to the necessary medicines and originator companies have adequate incentives to continue innovating and (2) that health budgets remain under control in order to ensure sustainability of the health system. In order to preserve incentives for further innovation, Member States typically accord high price levels for innovative medicines. Whilst breakthrough drugs should generally attract a premium, "me too" products[116] often also attract very high prices. Perindopril, as one of the last drugs developed amongst the ACE inhibitors, is an example of this.

(82) Even in Member States in which prices are not officially fixed, indirect price controls exist through reimbursement decisions. If no reimbursement is offered for an expensive product facing competition, or it is subject to a very significant co-payment, a significant share of patients may refrain from using such a medicine.

(83) Pricing and reimbursement decisions must be taken within the timeframe set by the Transparency Directive.[117] Once the pricing and reimbursement decisions have been taken, the product can be launched onto the market. Details on the pricing and reimbursement status of perindopril are set out in section 6.4.

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113 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1-66).

114 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67-128).

115 This was codified in Annex 1 to Directive 2003/63/EC.
- Introduction and general principles, (5): "with respect to the quality part (chemical, pharmaceutical and *biological) of the dossier, all monographs including general monographs and general chapters of the European Pharmacopoeia are applicable"*
- Chapter 3.2 (5): "*The monographs of the European Pharmacopoeia shall be applicable to all the substances appearing in it…"*

116 "Me too" product refers to a medicine that uses an identical therapeutic mechanism of action as an existing medicine.

117 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, (OJ L 40, 11/02/1989, p. 8-11).

4 PRACTICES UNDER INVESTIGATION

(84) In this part, the Commission describes in detail the facts underlying the technology acquisitions (see section 4.2) and reverse payment settlements (see section 4.3) under investigation. The detailed description of the main practices is preceded by an overview of the different practices and underlying strategies, with a particular emphasis on Servier's overall strategy to delay generic entry.

4.1 Overview of practices and underlying strategies

(85) This section begins with an overview from product discovery to commercialisation of perindopril in the European markets. Subsequently, it describes Servier's late lifecycle strategy, including its anti-generic elements, and its implementation. The Commission's factual description in this Decision of Servier's strategy against generic entry into the perindopril market is without prejudice to the legality of those practices of Servier which are not assessed in sections 5 (reverse payment patent settlements) and 8 (technology acquisitions and reverse payment patent settlements) of this Decision, which are the ones found to infringe Union competition law in this Decision.

4.1.1 Discovery, development and commercial launch of perindopril

4.1.1.1 Description of the product

(86) Perindopril is a medicine originally developed by Servier/Adir and marketed under the principal brand names of Coversyl and Prestarium.[118] With global sales exceeding USD 1 billion (EUR 800 million) in 2006 and 2007, perindopril was Servier's most successful product to date and constituted a blockbuster.[119] Perindopril is used primarily in the area of cardiovascular diseases for the treatment of hypertension and heart failure.

(87) Perindopril is designed to work by inhibiting the action of a body compound called *angiotensin converting enzyme* ("ACE"). It allows blood vessels to relax and widen. The overall effect of this is a reduction in blood pressure and hence perindopril can be used to lower high blood pressure (hypertension). Due to its specific mode of action, perindopril is called an ACE inhibitor.

(88) Perindopril's API, i.e. the biologically active chemical substance which provides for the desired therapeutic effects, takes the form of a salt. Currently there are two different salts of perindopril registered and marketed: *tert-butylamine* (also known under the name of *erbumine*,[120] which is the term used in this Decision) and *arginine.* As will be shown below, the two salts have the same therapeutic indications and are considered bioequivalent. For the purpose of the current investigation, it is important to note that the synthesis process of perindopril *erbumine* as applied by Servier led to the salt in its crystalline form.[121] In particular, the product contained so-called "alpha crystallines", which apparently had already been the case before Servier filed for the alpha crystalline patent in 2001.

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118 Please see section 6.2 for further details.

119 For the value of the EU sales of perindopril, see footnote 5.

120 See, for example, ID0053, p. 89.

121 ID0375, p. 1 - 2.

(89) Perindopril tablets are generally available in three dosages (perindopril *erbumine* 2, 4 and 8 mg and perindopril *arginine* 2.5, 5 and 10 mg). Servier has also produced combination products based on perindopril *erbumine* or *arginine* in combination with other active substances: *indapamide* and *amlodipine* treating cardiovascular diseases. However, perindopril based combination products are not the focus of the present investigation.[122]

(90) In the context of this investigation, Servier claims to be in competition with other cardiovascular drugs, specifically those produced by Pfizer (amlodipine), Sanofi-Aventis (ramipril and irbesartan), Bristol-Myers Squibb (irbesartan), Merck Sharp & Dohme (enalapril, lisinopril and losartan), Astra Zeneca (lisinopril), Novartis (valsartan, valsartan+hctz) and other pharmaceutical products. The alleged competitive constraints are assessed in section 6.5.

(91) A particularity of perindopril, like many other long term treatments, is that it is taken over a number of years. Once confirmed as a successful treatment for a patient in an initial trial period, the patient typically takes the drug over many years and is unlikely to switch to an alternative, even when the purported alternative becomes available at significantly lower prices. In economic terms this corresponds to the low price-elasticity of demand. In the absence of a loss of efficacy, the occurrence of new side effects or the launch of a truly superior treatment (which was not the case during the period investigated), the patients will continue to take the same medicine, as doctors and patients are reluctant to go through a new trial period with an uncertain outcome. This was also confirmed by the extensive market survey carried out by the Commission.[123]

4.1.1.2 Discovery and initial patent protection

(92) ACE inhibitors were first discovered in the early 1970s. It was regarded as one of the major advances in cardiology, particularly in the treatment of hypertension and heart failure, in coronary artery disease or in nephropathy.[124] The first ACE inhibitors, e.g. captopril, received a marketing authorisation for the treatment of hypertension in 1981.

(93) Servier reports that the molecule of perindopril was discovered by a group of inventors at Servier's research centre. The invention was described in European patent EP0049658[125] (perindopril compound patent). This patent was filed by Adir, a member of the Servier group, on 29 September 1981.

(94) In the 1980s, in addition to the compound patent, Servier obtained protection for the key processes required in the industrial preparation and synthesis of perindopril. These five patents are summarised in Table 1 below.

122 See also section 6.3.1.
123 See section 6.4.5.7.
124 ID3842, p. 1.
125 ID3843, p. 1 – 20.

Table 1: Servier's initial patents on perindopril

Patent number	Filing date	Content	Applicant	EPO Status	Patent Expiry
EP0049658	29/09/1981	Substituted amino diacids, their preparation and pharmaceutical preparations containing them	ADIR (Servier)	Granted 25/04/1984	29/09/2001
EP0308339	16/09/1988	Process for the industrial preparation of perhydroindole - 2(2S,3aS,7aS)-carboxylic acid, use in the preparation of carboxyalkyl dipeptides	ADIR (Servier)	Granted 31/03/1992	16/09/2008
EP0308340	16/09/1988	Process for the synthesis of N-alkylated alpha-amino acids and their esters, use in the synthesis of carboxyalkyl dipeptides	ADIR (Servier)	Granted 04/02/1991	16/09/2008
EP0308341	16/09/1988	Process for the industrial synthesis of perindopril and for its principal synthesis intermediates	ADIR (Servier)	Granted 05/11/1990	16/09/2008
EP0309324	16/09/1988	Process for the preparation of N-alkylated amino acids and their esters, use in the synthesis of carboxyalkyl dipeptides	ADIR (Servier)	Granted 04/02/1991	16/09/2008

Source: http://www.epoline.org and ID3842, p. 3.

(95) As shown in Table 1, the perindopril compound patent was due to expire in September 2001. Due to the granting of SPCs,[126] patent protection was prolonged in a number of Member States with the exception of Spain, Greece and Portugal. Table

[126] For details on the Council Regulation (EEC) No 1768/92 of 18 June 1992 creating supplementary protection certificates (SPCs) for medicinal products, see Report on the Pharmaceutical Sector Inquiry, p. 131-133.

2 below indicates the dates of expiry of the SPCs in the Member States where Servier's compound patent was valid.

Table 2: Patent and SPC expiry dates for compound patent EP0049658 in the EU

MS	Patent Expiry	SPC Expiry	MS	Patent Expiry	SPC Expiry
AT	29/09/2001	22/06/2003	IT	29/09/2001	13/02/2009
BE	29/09/2001	22/06/2003	LU	29/09/2001	22/06/2003
DE	29/09/2001	22/06/2003	NL	29/09/2001	22/06/2003
FR	29/09/2001	22/03/2005	SE	29/09/2001	22/06/2003
UK	29/09/2001	22/06/2003	PL	n/a	n/a

Source: ID3842, p. 3.

(96) The SPC extensions varied across the EU as a result of different legislation in Member States prior to the introduction of the European SPC rules. Servier explains that: *"*These different expiry dates of patent EP 49658 depend on the national laws on Supplementary Protection Certificates (SPC) existing before the entry into force of the Regulation on SPCs in Europe. 29 September 2001 corresponds to the first expiry date of patent EP0049 658 in several countries of the European Union and 13 February 2009 corresponds to the expiry of the SPC in Italy, which is the latest expiry date of the term of protection for patent EP 0049 658 through SPC"*.[127][128]

(97) Servier, in its reply to the RFI of 6 August 2009, states that after they were granted, the four process patents indicated in Table 1 above were never subject to any opposition before the EPO.[129] Servier also explains that in countries such as Spain, Portugal and Greece, where Servier did not have a compound patent and therefore only the manufacturing process was protected, the process patents were never questioned by generics in order to enable generic market entry.[130] In the same submission, Servier goes on to state that *"*Consequently, our belief was that these patents could not easily be invalidated*".[131] However, as evidenced by the presentation for the Sector Management Meeting in Paris on 19 June 2006, Servier did not seem confident to rely solely on the protection offered by these process patents, specifically as generic companies might find alternative processes to manufacture perindopril.[132] Additionally, as set out further below, these process patents were subject to separate litigation proceedings in the UK between Servier and Niche; and Servier and Krka.

127 ID1151, p. 27.

128 More details are provided by Servier in its reply to the Commission RFI of 9 April 2009: *"*The European Regulation on SPCs (1768 of 18/06/1992) has been applied to the following states: AT, BE, DE, DK, FI, GB, IR, LU, NL, SE and has made it possible to obtain an SPC expiring on 22/06/2003. This European Regulation was not applicable to ES, GR and PT. In France French Law No 90-510 of 25 June 1990, predating the entry into force of the European Regulation, has resulted in an SPC expiring on 22 June 2005. And the Italian law on SPCs No 349 of 19 October 1991 predating the entry into force of the European Regulation has resulted in an SPC expiring on 13 February 2009"*, ID2365, p.7.

129 ID1151, p. 22.

130 ID1151, p. 22.

131 ID1151, p, 22 – 23.

132 ID0032, p. 176 – 183.

4.1.1.3 Marketing authorisation and indications

(98) Perindopril *erbumine* tablets (2 and 4 mg) for the treatment of hypertension *(traitement de l'hypertension artérielle)* obtained an MA in Europe between 1988 and 1989. The first MA was registered in France on 22 June 1988 which was followed by registration in Belgium, Germany, Italy, the Netherlands, the UK, Denmark, Greece, Ireland and Portugal.[133] A new therapeutic indication for cardiac insufficiency *(insuffisance cardiaque symptomatique*) was approved several years later e.g. in 1992 in France. In 2006, the French authorities also approved a new indication for the treatment of coronary heart disease ('**stable coronary heart disease: reduction of the risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation*'), which is the third and, currently, last indication for perindopril. In addition, there are several countries where perindopril was also authorised for the treatment of stroke.[134]

(99) Additionally, with the exception of the UK (where the MA was obtained on 12 June 2002), Servier registered perindopril *erbumine* 8 mg in all Member States during 2003 and 2004 using the national marketing authorisation procedure.

(100) The French MA for perindopril *arginine* was obtained in November 2004. Servier used the abridged marketing authorisation intended for generic products, as it considered perindopril *arginine* to be a bioequivalent (i.e. generic) version of perindopril erbumine. The MA through the MRP was granted in 26 Member states in April 2005. However, the product launch did not take place until much later (e.g. 2009 in France).[135]

4.1.1.4 Commercialisation

(101) Between 1989 and 2004, as shown in Table 3, Servier launched all available different dosages of perindopril *erbumine* in the four Member States selected for in-depth investigation in the present case. On the basis of the information provided by Servier in its reply to the Commission's RFI of 16 January 2009, the table contains the launch dates for the four Member States:

Table 3: Perindopril erbumine launch dates

Member State	Coversyl 2 mg	Coversyl 4 mg	Coversyl 8 mg
FR	01/01/1989	01/01/1989	23/04/2007
UK	01/03/1990	01/03/1990	07/11/2002
NL	01/07/1989	01/07/1989	23/05/2003
PL	n/a	01/10/1992	01/02/2005

Source: ID9974, p. 957 – 959.

(102) Following the launch of perindopril erbumine in the EU in 1989 until around 2000, Servier's strategy concentrated on the marketing of its products in Europe, with expansion to the rest of the world, for the two main indications, hypertension and cardiac insufficiency. The general strategy for perindopril focussed mainly on promotion measures and developing new indications. This is explained in key strategy documents from 1998 to 2001.[136] The strategy comprised high profile

133 ID2365, p. 6.
134 See section 6.2.2.
135 See also section 4.1.2.7.
136 ID9974, p. 972; ID9974, p. 1062; ID9974, p. 1107.

studies which were published in medical journals (see below sections 6.2.10.1 - 6.2.10.2 for more information on relevant studies). In 1998, 16 clinical studies and 5 pharmacological studies were to be carried out around the world with the aim of ensuring the visibility of the product in international publications, seminars and congresses.[137] Visits to specialist cardiologists, general practitioners and hospital services aimed at raising the profile of perindopril on the market were an essential element in Servier's promotion strategy.

4.1.2 Main elements of Servier's anti-generic strategy

(103) Perindopril was from the beginning of its commercialisation in Europe a very successful product for Servier. Over time, it became Servier's best-selling product. In the financial year 2000/2001, after approximately ten years on the EU market, perindopril achieved a turnover of EUR [400–500]* million, representing [20–30]* % of Servier's turnover.[138] Perindopril's turnover continued to grow steadily over the following years and attained a worldwide turnover of up to EUR [800–900]* million,[139] [30–40]* % of Servier's total turnover.

(104) According to company data collected for the thirteen largest EU markets, Servier's average annual operating margins over the production and distribution cost of plain perindopril in the period 2000-2005 exceeded [90–100]* % in every year of the period concerned. Even if one deducts all other costs reported by Servier, perindopril enjoyed very significant profit margins ranging from [20–30]* % up to [60–70]* % depending on the year.

(105) Numerous strategy documents regarding perindopril present this product therefore as the guarantee of Servier's positive forecasts in the short, medium and long term. For example, according to Servier's Strategic Plan for the period 2002/2003 until 2011/2012: *"*Coversyl remains the guarantee of our long-term development and, as such, will remain one of the top priorities throughout the duration of the Plan"*.[140] In addition, Servier expected that perindopril "*will remain (its) dairy-cow-product*" in the period 2005 to 2008.[141]

(106) Generic entry for products like perindopril typically leads to two notable changes in the market. First, there is a significant decrease in prices charged to consumers and secondly substantial volume shifts from the originator company to the generic companies can be observed. This explains Servier's incentives to protect perindopril against generic entry.

(107) From the end of the 1990s and in the early 2000s, Servier progressively devised a strategy aimed at preventing or at least delaying generic entry after expiry of the perindopril compound patent. The strategy consisted of a variety of measures that were constantly adapted to take into account market developments.

(108) For the purpose of establishing a solid protection framework for perindopril, Servier organised regular internal meetings entitled "*Protection Coversyl"*. These meetings were generally attended by high level Servier management including the CEO and members of the legal and patent departments. Yearly reports (*"*Monitoring of the*

137 ID9974, p. 1032.
138 ID0117, p. 46 – 49.
139 See Table 10, and cited source.
140 ID0117, p. 46 – 49.
141 ID0034, p. 111.

Medicine") on perindopril setting out the main aspects of Servier's commercial, development and regulatory strategy were also prepared. Considering the product's place in Servier's portfolio there was consensus that: *"*The "Protection Coversyl" project deserves special attention in view of the position of the product in the Company's portfolio. It is now the main product in terms of both total revenue and growth".* [142]

(109) The first overall protection strategy is set out in a communication[143] of 9 November 1999 from [company name]*[144] staff to [employee name and function with Servier]* in preparation for one of the "*Protection Coversyl"* meetings. The document describes the main measures to be undertaken to extend the lifecycle of perindopril in the following way: *"*1- Process patents, intermediate patents [...] (i.e. the creation of patent clusters) .2- European Pharmacopoeia monograph […] (i.e. the raising of technical entry barriers); 3- A new pharmaceutical form with clinical added value" (i.e. the switch to a second generation product)"* (i.e. the switch to a second generation product). [145] This strategy was later complemented by other strategies.

(110) All of these practices are described in the subsequent subsections in the following order: (1) filing a patent cluster (section 4.1.2.1), (2) publication of perindopril monograph in the European Pharmacopoeia (section 4.1.2.2) (3) acquisition of alternative technologies and accompanying IPRs (section 4.1.2.3) (4) patent disputes and patent settlements (section 4.1.2.4) (5) distribution agreements with friendly generics (section 4.1.2.5), (6) […]* practices (section 4.1.2.6), and (7) selective switch to the arginine salt (section 4.1.2.7). The description of these practices is without prejudice to their legality under Union competition law.

(111) Before examining the individual strategies, it is important to refer to an internal presentation at Servier's Sector Management Meeting in Paris on 19 June 2006. This document offers a contemporaneous overview of Servier's defence strategy against generic entry as well as a description of the successes of the measures already taken. The presentation is entitled "*Coversyl: Defense against generics"* and notes that there is *"No absolute weapon"*, but rather a *"Sum of complementary actions"* required.[146] Another Servier presentation bearing the same date makes an account of such actions, which included patents for *"incremental improvements"*, process patents for active ingredients and intermediates, stricter purity specifications and quality criteria, tightening specifications and analytical methods in the monographs, warning letters, letters to authorities (*"re dubious quality origin of data products")* and infringement actions, as well as the ensuing patent settlements. Under the title *"Did it work?"* the presentation lists a number of examples of generics' incapacity to come onto the market, which includes a reference to the court case in the UK and the patent settlements with Niche and Matrix. The overview of Servier's defence against generics also referred to Teva as a partner only days after the Teva Settlement Agreement had been concluded. [147]

142 ID0111, p. 27 – 29.
143 ID0111, p.6.
144 *Institut de Recherches Internationales Servier*.
145 ID0111, p. 6.
146 ID0032, p. 177.
147 ID0105, p. 159-186.

(112) From an *ex post* perspective it seems that Servier was satisfied with its anti-generic strategy. In handwritten minutes from a Servier internal meeting, the company took note of the unfavourable judgment of the High Court of Justice of England and Wales ("the High Court") which annulled the '947 patent, thereby opening the market for generics.[148] Typically, a patent annulment is a moment triggering negative comments as generic entry can no longer be legally prevented. However, the document mentions that the SPC expired in the UK in 2003 and that Servier had won 4 years of additional protection, which was celebrated as a big success ("**[…] 4 years gained = great success*"). Moreover, it is also mentioned that due to the functioning of the European patent system, only the sales in the UK were at stake ("**European patent = objections raised only in the UK*") suggesting that Servier was continuing to benefit from perindopril sales in these other markets.

4.1.2.1 Creation of a patent cluster

(113) Ongoing R&D effort resulting in new patents on, for instance, new forms of an active substance, device or diagnosis, or on the processes of producing an existing drug, device or technology is generally pro-competitive where it leads to a more pharmacologically efficacious active substance, therapy, diagnosis or treatment, or a more cost-efficient production process for making it. It is, moreover, legitimate to patent such innovations and to defend the resultant patents.

(114) Servier knew that its compound patent for perindopril would expire in the period 2003-2005 in most Member States including its largest markets (France and the UK) when the SPC would expire. Thereafter Servier could only rely on the patent protection conferred by its process patents; EP 0308 339 ("patent '339"), EP 0308 340 ("patent '340") and EP 0308 341 ("patent '341"), which described the specific processes by which Servier produced perindopril. However, Servier also knew that these process patents would not afford absolute protection against generic entry considering that alternative non-infringing production processes might exist or could be developed.

4.1.2.1.1 The so-called "paper patents"

(115) In 1999, Servier therefore began to contemplate how to increase the patent protection for perindopril and considered that the filing of new patents would be its best option. In a letter of 8 October 1999, [employee name and function with Servier]*, at the time posted in [company name]* (a subsidiary of Servier) and later a [employee function with Servier]*, explained that *"*[g]enerics of Coversyl may be launched, provided that Perindopril is synthesised by a synthesis route which is different from that described in our process patents"* and stressed the need to file blocking patents ("**blocking patents*") to create a patent cluster of process patents around perindopril ("**a cluster of process patents around the molecule*").

(116) The relevant extracts from this letter read: "*[…] *As we have already mentioned, it would be entirely appropriate to file blocking patents on other synthesis processes using alternative ways to create a cluster of process patents around the core patent. As the patent applications are only published 18 months after filing, the ideal situation would be that a publication of the new process patents is made before October 2001 so that third parties are informed thereof. This means that these new applications must be filed by no later than March 2000. Given this very short time,*

[148] ID0116, p. 51.

we must try to do everything possible to try to draft as quickly as possible new patent applications on these alternative routes".[149]

(117) The same message is found in other internal documents for perindopril from 1999 and thereafter,[150] which explicitly identify the strategic objective of neutralising the arrival of generics ("**Develop a strategy to neutralise the arrival of generics*"), specify how this is to be achieved ("**All synthesis routes that can potentially be industrialised should be blocked by blocking patents*"), and, subsequently, refer to the existence of blocking patents.[151] In late 2000 this strategy was also described as seeking protection through a "*maze of patents*".[152]

(118) The patenting strategy devised and implemented by Servier therefore consisted of filing as many blocking patents as possible. The patents covered all aspects associated with the molecule, its synthesis, production processes, polymorphic forms, etc. As shown in Table 4, Servier was successful in establishing a dense network of patents around perindopril.

(119) Table 4 provides an overview of Servier's main perindopril-related patents applied for or granted by the EPO in addition to the compound patent and the process patents mentioned in paragraph (113)). Most patents were filed from 2001 to 2005, as can be deduced from the expiry date (which occurs 20 years after filing).[153]

(120) Servier also applied for national patents in those European countries that were not EPC member states at the time of the filings.[154] For example, Servier made applications covering its alpha-crystalline form of perindopril *erbumine* (corresponding to the '947 patent) in Hungary (HU 225340), Poland (P348492), Slovakia (PP 0149-2003), the Czech Republic (PV 2003 -357), Bulgaria (BG 107 532) and Estonia (P200300001).[155] The same happened for several other EPO applications concerning perindopril that were filed in the period 2001 to 2004.[156] In the course of this investigation Servier did not, however, report any national patent applications that would go beyond the simple replication of the corresponding EPO applications.[157] Accordingly it is sufficient to discuss the protection at EPO level.

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149 ID0111, p. 5.

150 ID0111, p. 5; ID10079, p. 867; ID9974, p. 631; ID9974, p. 783; and ID9974, p. 791 "**Monitoring of the Medicine*" for the years 2004 – 2008.

151 ID9974, p. 689.

152 ID0036, p. 158.

153 Servier's EP patents filed in the period 2001-2005: EP1268398, EP1272454, EP1268424, EP1256590, EP1279665, EP1333026, EP1338591, EP1403277, EP1403275, EP1323729, EP1319668, EP1321471, EP1348684, EP1354874, EP1354875, EP1354876, EP1367061, EP1362864, EP1367063, EP1367062, EP1380590, EP1380591, EP1362845, EP1371659, EP1403278, EP1400531, EP1420028, EP1422236, EP1420029, EP1420030, EP1603558, EP1861367, EP1753720, EP1296947, EP1294689, EP1296948, EP1636185, EP1675827, EP1345605, EP1467750, EP1729739. Source: ID0363.

154 For example, Bulgaria, the Czech Republic, Estonia and Slovakia joined the EPO on 1 July 2002, while Poland on 1 March 2004.

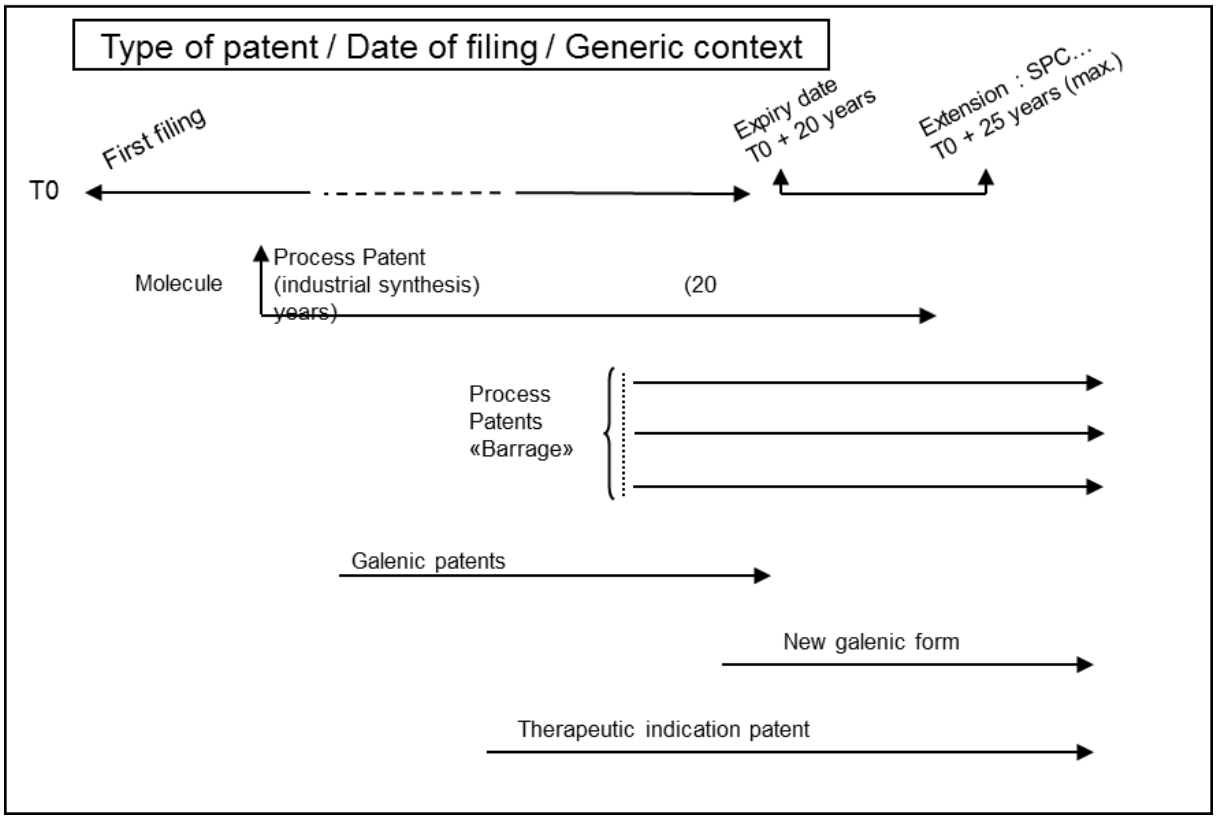
155 All the patent applications in question bear the same filing date of 6 July 2001. The patents were granted in Bulgaria on 16 May 2006, in Hungary on 17 August 2006, in the Czech Republic on 23 January 2007, in Slovakia on 23 April 2007 and in Poland on 24 March 2010. See also Table 6 for information on the relevant invalidation proceedings. ID0119, p. 29; ID3842, p. 2-4; ID5828; and ID7836, p.53.

156 Most of national patents were applied for in Poland that joined the EPO later than the other concerned states.

157 ID0363.

(121) The importance of filing *"*blocking"* patents as an essential element of the defence mechanism is further described in Servier's internal presentations. For example, Figure 1[158] below offers a complete picture of Servier's overall patenting strategy and highlights the role of the "*barrage*" patents in the protection framework.

Figure 1: Servier's patent filing strategy in a generic context



Source: ID9972, p. 140.

(122) In this context, contemporaneous evidence[159] reveals that, of the 33 process patents (mostly patents for synthesis routes), 21 were described by Servier internally as *"*blocking"* patents or *"*paper patent"*.[160] Three of these 21 process patents were in addition characterised as involving *"*zero inventive step"*.[161] As shown in Table 4, these patents were, however, granted by the EPO.

158 ID0115, p. 39.

159 ID9972, p. 78 - 119.

160 Servier argued in its reply to the Statement of Objections (Annex 00-03, paragraph 15, ID9054, p. 5) that "*this was simply an internal short-hand"* for patents *"inventive on paper, but their technological value is not assured*". However the use of the term "**blocking (paper)*" appears rather self-explanatory. The sentence "**The process does not work according to [employee name of Servier]* (paper patent)*" on patent EP1272454 also indicates not that the value of this "**paper patent*" is "*not assured*" but simply that it does not work.

161 Servier argued in its reply to the Statement of Objections (Annex 00-03, paragraph 17, ID9054, p. 5 - 6) that this was due to the fact that "*Servier's application had faced a challenge by the examiner about possible lack of an inventive step*", as can be seen in the "**Procedure*" section of the document. It is however noted that several other patents in the list do not have the label "**Zero inventive step*" when they have similar information in the "**Procedure*" section (e.g. EP1348684 , EP1367063, see ID9972, p. 78 – 119).

Table 4: Overview of Servier's process patent applications

Patent No	Application date	Blocking patent – Zero inventive step – Other remarks	Grant date
EP1272454	10/04/2001	*"*Paper patent"* *"*The process does not work according to [employee name of Servier]* (paper patent)"*	23/05/2007
EP1338591	28/02/2003	*"*Blocking patent (paper)"*	26/10/2005
EP1403277	28/02/2003	*"*Blocking patent (paper)"* *"*Younger brother of9490-P6"*	05/10/2005
EP1403275	28/02/2003	*"*Blocking patent (paper)"* *"*Younger brother of9490-P6"*	19/10/2005
EP1323729	12/03/2003	*"*Blocking patent (paper)"*	03/11/2004
EP1319668	12/03/2003	*"*Blocking patent (paper)"* *"*Younger brother of9490-P9"*	27/10/2004
EP1321471	12/03/2003	*"*Blocking patent (paper)"* *"*Younger brother of9490-P9"*	04/05/2005
EP1348684	9/04/2003	*"*Patent resulting from a study [subsidiary of Servier]* which was actually carried out; refusal to submit the patent to a widened research report;"*	08/03/2006
EP1354874	15/04/2003	*"*Blocking patent (paper)"*	24/11/2004
EP1354875	19/05/2003	*"*Blocking patent (paper)"*	24/11/2004
EP1354876	13/06/2003	*"*Blocking patent (paper)"*	27/04/2005
EP1367061	30/06/2003	*"*Blocking patent (paper)"* *"*Zero inventive step"*	04/01/2006
EP1362864	30/06/2003	*"*Blocking patent (paper)"* *"*Zero inventive step"*	25/04/2007
EP1367063	31/07/2003	*"*Blocking patent (paper)"*	23/08/2006
EP1367062	31/07/2003	*"*Blocking patent (paper)"* *"*Younger brother of9490-P18"*	30/08/2006
EP1380590	29/08/2003	*"*Blocking patent (paper)"*	06/09/2006
EP1380591	29/08/2003	*"*Blocking patent (paper)"*	16/11/2005
EP1371659	29/08/2003	*"*Blocking patent (paper)"* *"*Younger brother of9490-P21"*	12/10/2005
EP1420028	19/11/2003	*"*Blocking patent (paper)"*	21/02/2007
EP1422236	19/11/2003	*"*Blocking patent (paper)"* *"*Younger brother of9490-P26"*	14/02/2007
EP1420029	10/12/2003	*"*Blocking patent (paper)"* *"*Zero inventive step"*	20/02/2008

Source: Servier's internal document ID9972, p. 78-119[162] (undated)

(123) Furthermore, minutes of one of Servier's internal meetings held on 22 January 2003, show that Servier continued throughout the lifecycle of perindopril to develop and

[162] Servier was not able to trace back the date of the document but reports that is probably from 2001/2002 (ID3842, p. 14)

file patent applications which were themselves considered internally as *"*blocking*" patents. The minutes categorise as such 31 synthesis process patent applications. For those patent applications Servier proposes filing with the EPO as a purely editorial task – i.e. without conducting any patentability studies or any laboratory trials: "**Purpose of the meeting: […] to establish a list of 'reasonable' synthesis processes of perindopril or of its synthesis intermediates, which will be the subject of 'blocking' patent applications. […] The 31 corresponding patent applications, which will be subjected neither to patentability studies nor to laboratory tests, will have to be drafted and filed as soon as possible (as early as February 2003 for the first), the aim being to obtain the publication of a first 'wave' of these applications in June 2003"*.[163]

4.1.2.1.2 The '947 patent

(124) Servier filed a patent application for a crystalline form of perindopril on 6 July 2001. The European patent EP 1 296 947 (the '947 patent) was granted by the EPO[164] on 4 February 2004.[165] It relates to the crystalline alpha form of perindopril and the process for its preparation. The objective for filing the '947 patent was to extend the protection of perindopril in the Member States that were EPO members at the time of filing until 2021.[166]

(125) The '947 patent is one of Servier´s most controversial patents. In its annulment decision the Court of Appeal ruled the '947 patent "*is invalid. And very plainly so. It is the sort of patent which can give the patent system a bad name*".[167] The EPO revoked the '947 patent by decision of 6 May 2009 – reversing an earlier decision of the Opposition Division of 26 July 2006 which rejected nine oppositions filed against the patent.

(126) The '947 patent plays a key role in the present investigation. Almost all generic companies cited[168] the '947 patent as the Servier patent which most constrained the development of their generic perindopril[169] (Teva,[170] Ratiopharm,[171] Sandoz,[172] Niche,[173] Generics UK,[174] Krka,[175] Stada[176]). Also, most patent litigation concerned the '947 patent and, consequently, the patent settlements.

(127) The investigation has not found any direct evidence that Servier internally considered the '947 patent invalid when filing the patent application. However,

163 ID7330, p. 14 - 15 (p. 15 is further disclosed in further access to file in ID10070).

164 For more details on the EPO see section 3.1.

165 Source: EPO.

166 Servier also applied for national patents corresponding to the '947 patent in those European countries that were not EPC member states at the time of the filings, see paragraph (120).

167 Judgment [2008] EWCA Civ 445, Case No A3/2007/1715, paragraph 9 (ID5149).

168 In their respective replies to the Commission's RFI of 5 August 2009.

169 ID1039, p. 33.

170 See section 4.3.2.2.

171 ID1481, p. 22.

172 Sandoz lists in addition 9 Servier patents "of most relevance to Sandoz's development of generic perindopril" ID1480, p. 13-14.

173 Niche lists in addition the EP '948 polymorph patent, ID1577, p. 6-7.

174 Generics UK (Mylan) provides a comprehensive list of constraining Servier patents. ID1499, p. 1 - 4.

175 Krka mentions in addition two product patents (EP 1294689 and EP 1296948) as well as several process patents (EP 309324, EP 1333026, EP 1279665, EP 1272454, EP 1268424, EP 1268398, EP 1256590) which had constrained them. ID1307, p. 76.

176 Stada list in addition EP 1279665. ID1034, p. 9-10.

contemporaneous documents seem to indicate that Servier was uncertain that it could successfully enforce or defend the patent. For example, despite the favourable decision that Servier obtained from the EPO's Opposition Division on 27 July 2006 to maintain the amended '947 patent, in March 2007 Servier anticipated "**an unfavourable decision"* in the proceedings against Apotex before the High Court, which could result in the annulment of the '947 patent, and envisaged to discontinue the litigation.[177] Moreover, when Servier had to decide whether to appeal the decision of the High Court (which had annulled the '947 patent in the UK) [employee name and function with Servier]* explains in an email[178] dated 11 July 2007 to Servier's legal department: "**I am also convinced that the revocation of the patent will be confirmed on appeal: we have almost no chance/ sorry for being so realistic!"*[179]

(128) The view of many generic companies was that the '947 patent was not valid. They had a shared opinion that the '947 patent did not meet the patentability criteria. This said, a degree of uncertainty as to the legal outcome existed, both, on Servier's side, and on the generic companies' side. Such uncertainty existed before and after the intermediate decision of the EPO Opposition Division on 27 July 2006.[180] However, despite the uncertainty, many generic companies considered that they had valid (even strong) arguments against the '947 patent and decided to start proceedings against the validity of the patent. And, after the decision of 27 July 2006, several generic companies persisted, and appealed the EPO decision.

(129) In 2004, ten generic companies filed opposition proceedings against the '947 patent at the EPO.[181] These ten included all companies with which Servier later concluded patent settlements. In addition, the validity of the '947 patent was challenged in several national jurisdictions (see sections 4.1.2.4.2.2. and 4.1.2.4.2.3).

4.1.2.2 Tightening technical rules (European Pharmacopoeia)

(130) […]*. As indicated above, the internal communication[182] of 9 November 1999 from [staff members of a subsidiary of Servier]* to [employee name of Servier]* describes this as one of the main measures to be undertaken to extend the lifecycle of perindopril: "**2- European Pharmacopoeia position paper"*.

(131) The European Pharmacopoeia is a single reference work for the quality control of medicines in Europe. Several legal texts make the European Pharmacopoeia

177 ID0102, p. 266.

178 ID0116, p. 143.

179 ID0116, p. 143. [Employee name of Servier]* stated in Servier's reply to the Statement of Objections (Annex 00-03, paragraph 32, ID9054, p. 10 - 11) that regarding this email *"[her] view of the prospects of success of the appeal was based primarily on the fact that some issues are difficult to appeal to the English Court of Appeal"*. It is nonetheless noted that Servier chose to continue the litigation despite this opinion "*as there is always some chance of success, even if only modest*". Servier was allegedly concerned that "*withdrawal of the appeal would have damaged Servier's prospects of success, and thus the investments already made in defending the patent, in [other] jurisdictions*". [Employee name of Servier]*'s contemporaneous email in fact indicates "*the filing of the appeal is interesting to create some uncertainty concerning the final decision, in particular in view of the proceedings in Europe and to postpone payment of the damages that will be sought by Apotex"*.

180 See, for example, Servier's reply to the Statement of Objections, section 5.2.2.5, ID9053, p. 140 – 143.

181 For further details on the opposition procedure, see section 4.1.2.4.2.1.

182 ID0111, p. 6.

mandatory.[183] The official standards published by the European Pharmacopoeia provide a legal and scientific basis for quality control during the development, production and marketing of medicines. Demonstrating compliance with these standards is a necessary part of the marketing authorisation dossier for a medicine.

(132) As explained in section 3.3, all pharmaceutical companies that want to commercialise a product in the EU must, therefore, respect the quality standards for a medicine as established in the European Pharmacopoeia. […]*. In relation to the inclusion of the perindopril monograph in the European Pharmacopoeia, an email of 9 November 1999 to [employee name and function with a subsidiary of Servier]* from [name of a subsidiary of Servier]* (a subsidiary of Servier) considers that *"*It would be ideal if the standards announced led to the use of protected processes"*.[184] The key perindopril strategy document[185] for 2002 describes the *"*stricter standards of purity of perindopril (variation type I no. 14)"* and the *"registration of the perindopril monograph in the European Pharmacopoeia (publication in Pharmeuropa in January 2002)"* as a protective measure against generic entry.

(133) The perindopril monograph was published for the first time in the European Pharmacopoeia in January 2002. A period for comments ran until April 2002. The *"Perindopril, tert-butylamine salt"* monograph was adopted in November 2002 and, as reported by Servier, became official and applicable in January 2004.[186]

(134) Contemporaneous evidence based on Servier's annual strategy documents, notably "**Monitoring of the Medicine"*, shows that Servier's commercial strategy for perindopril foresaw additional protection through the *"*Publication in June 2003 of the perindopril monograph, tert-butylamine salt in the European Pharmacopoeia (application in January 2004)"*.[187]

(135) Servier explains that several variations to the marketing authorisation dossiers were submitted to adapt the authorisation to the monograph as well as two revisions of the latter. According to Servier, the first revision was published in November 2004 and became applicable in January 2006. Servier clarifies that it was a minor change that did not require the modification of the specifications.[188]

(136) The second revision was adopted in November 2006 and became applicable in January 2008. Servier explains[189] that this revision aimed at "**control of the related substances in order to provide a more robust method and one that is easier to use"* and that *"*Fundamentally, the specifications remained the same"*.

(137) In Krka's view as stated in its reply to the Commission's RFI of 5 August 2009,[190] the high purity standards laid down in the perindopril monograph meant that API producers and generic companies had to spend a lot of time and effort on the development of "*the analytical method and for development of active substance with less than 0.10% of individual isomer*". Moreover, Krka explains that *"[…] it was*

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183 Directive 2001/83/EC, as amended, on medicines for human use, maintains the mandatory character of European Pharmacopoeia specifications on medicines for marketing authorisation applications. See also section 3.3.

184 ID0111, p. 6.

185 ID9974, p. 758.

186 ID2365, p. 25; ID7325, p. 360.

187 "**Monitoring of the Medicine*" for Coversyl: ID9974, p. 697.

188 ID2365, p. 26.

189 ID2365, p. 26. Servier reply to the Commission RFI of 9 April 2010.

190 ID1307, p. 74.

impossible to purchase any quantities of active substance complying with the strict Ph. Eur. Requirements on the world market which definitely prolonged the time of our development– for most of the would/could be suppliers this barrier were [sic] *too high and their products have not matched strict Ph. Eur. requirements for purity of perindopril – even if they had avoided alpha patent, they would have met also Ph. Eur. requirements for purity of perindopril".*

(138) Consequently, Krka considers the perindopril monograph in the European Pharmacopoeia as the second most significant market barrier. The company explains in the same submission that:

"There were not many industrial processes which enabled manufacturing of perindopril having the required purity. Krka was one of rare companies at that time which achieved to develop, and has also patented, a processes for synthesis of perindopril of the required purity.

We cannot really estimate time and costs to overcome this barrier. Development of the product having a Phar. Eu. quality was not an easy barrier to overcome, according to our opinion. In fact, majority of R&D costs can be considered as costs for overcoming these also this [sic] *barrier".*[191]

4.1.2.3 Acquisition of enabling technologies that would have allowed for generic entry

(139) From 2001 onwards, Servier also entered into agreements to acquire relevant alternative technologies for the production of perindopril and the accompanying IPRs. The acquisitions meant that these technologies were no longer available for generic operators seeking to enter the market with a form of perindopril that was not patent protected by Servier.

Importance of alternative enabling technologies

(140) Servier had filed and obtained an array of patents protecting perindopril. Some generic companies or producers of advanced pharmaceutical intermediates and APIs were nevertheless trying to develop alternative methods to produce perindopril or to obtain different crystalline forms of perindopril which were not patent protected. Non-infringing technologies available for the manufacture of perindopril were, in any case, limited and required substantial investment and research by the generic companies.

(141) Servier monitored the activities of its generic competitors which it perceived as a potential threat and started to consider strategies that would eliminate competition stemming from these alternative technologies. A 2006 presentation at the Sector Management Meeting by [employee name of Servier]* entitled *"Coversyl: Defense against generics*" refers to "*Process patents for active ingredients and intermediaries"* as part of the *"Protective measures against generics*".[192] Further, Servier regularly monitored the perindopril API market. The same presentation[193] includes a list of API producers of which Servier was aware at the time and categorises them with a *"(-)"* or *"(+)"* next to the name of the company.

(142) The generic companies were aware of Servier's activities and internally expressed concern about them. For example, an internal Ivax/Teva communication from

191 ID1307, p. 57 - 58.
192 ID0105, p. 166.
193 ID0105, p. 173.

3 October 2005 reports: *"The position with Perindopril is very complicated in terms of patents- particularly process patents which affect API manufacturers. This is partly why everyone is late (once an API manufacturer has got round the process patents Servier has bought the company, sourcing API has been very difficult"*.[194] In other words, the generic companies perceived Servier as acquiring all alternative supply sources, which rendered market entry difficult. Generic companies also recommended to each other not to disclose their respective API sources to Servier. Another internal Ivax/Teva email of 10 August 2005 states: *"In any conversations with Servier, it is important that they are not given the name of our APIs supplier. The general Industry consensus is that Servier will attempt to take out API sources"*.[195]

(143) Servier explains the reasons behind the acquisition of various alternative technologies for the production of perindopril developed by generic firms and the accompanying IPRs differently. In its reply to the Commission's RFI of 6 August 2009 Servier stated:[196]

*"*Patent applications were purchased in order to improve our manufacturing processes and thus increase production capacity while optimising production costs. The improvements we are seeking are mainly on three levels of the production process: […]**.*

The amounts invested in the purchase of these patent applications resulted from negotiations with the companies holding these rights and the evaluation of our internal experts".

(144) However, in contrast to this, the 2004 contract concluded with Azad (one of the potential API suppliers) states that Servier purchases Azad's patent applications and know-how in order to *"strengthen the defense mechanism for its own alpha, beta and gamma forms of Perindopril"*.[197] Another example of Servier's use of IPR acquisitions to reinforce the defence mechanism against generics can be found in the negotiations with Sandoz for the potential sale of know-how relevant to perindopril. In the Heads of Agreement with Sandoz, Servier committed to purchase the IP rights from Sandoz provided that Sandoz's product 1) was stable (including no transformation of amorphous form into a crystalline form), 2) could be produced on industrial scale, 3) did not breach Servier's patents. In other words, […]*.

Description of main agreements relating to alternative technologies

(145) Servier concluded, in particular, two agreements, one with [company name]* and one with Azad, which removed alternative technologies from the market and which are briefly described here (for further details on these agreements see section 4.2; for patent acquisitions related to respective patent settlement agreements with Krka and Lupin see sections 4.3.3 and 4.3.4).

4.1.2.3.1 [Company name]*

(146) Servier's first acquisition of alternative technologies was concluded on […]* 2001. The [company name and nationality]* sold its patent application ([…]*) and a

194 ID0082, p. 70.
195 ID0358, p. 545.
196 ID1151, p. 24.
197 ID0104, p.182.

"chemical dossier" for perindopril API to [subsidiary of Servier]*,[198] an entity belonging to the Servier group ("the [company name]* Agreement").[199] The patent was later granted to [subsidiary of Servier]*.[200] In consideration for the transfer, Servier paid [company name]* a total amount of USD [5–15]* million.[201]

(147) In its reply to the Commission's RFI of 6 August 2009, Servier indicates that it obtained Patent […]* for the purpose of optimising the synthesis of perindopril: *"*optimisation of the synthesis […]* to finally obtain tert-butylamine salt […]*"*.[202] Servier explains that *"*The lesson of […]* has enabled us to develop a more productive […]*."*[203]

(148) However, from internal documents (e.g. the aforementioned 2006 document summarising the anti-generics strategy or the "*Monitoring of the Medicine*" for 2008[204]) it appears […]*. At the time of the acquisition, negotiations with Teva regarding supplies of perindopril took place. The contractual relationship between [company name]* and Servier continued beyond 2001, affecting [company name]*'s incentives to develop other alternative technologies.

4.1.2.3.2 Azad

(149) Servier's second acquisition was concluded on 9 November 2004. It agreed a *"Patent application and related international extensions and know-how transfer and assignment agreement"* ("the Azad Agreement")[205] with the Swiss company Azad. Having acknowledged that the Azad patents did not infringe Servier IP rights,[206] Servier agreed to purchase Azad's patent applications and know-how in order to *"strengthen the defence mechanism for its own alpha, beta and gamma forms of Perindopril"*. The know-how to be transferred to Servier included 4 synthesis routes for the manufacturing of perindopril. Servier committed to pay the amount of EUR 13,374,243[207] to Azad for the assignment.

(150) According to Azad, as a consequence of the assignment the company stopped all activities involving perindopril in December 2004, immediately upon the conclusion of the agreement with Servier.[208] This also meant that Azad was no longer a potential source of API for generic companies. Azad had to pay damages to Teva (USD [0.5–1.5]* million) and Arrow (USD [seven digit figure]) because they were not supplied with perindopril API.

4.1.2.4 Patent disputes and reverse payment patent settlements

(151) Between 2003 and 2008, Servier engaged in a number of patent disputes with its generic competitors. This was done through warning letters, preliminary injunctions

198 […]* (ID1151 p.37).
199 ID2366, p. 110 - 117.
200 Priority filing date: 24.07.2001, publication date 12.03.2003, source: https://register.epo.org/application?number=EP02016262.
201 Including 5% withholding tax.
202 ID1151 p. 37.
203 ID1151, p. 37.
204 […]*, see ID9974, p. 699.
205 ID0104, p. 180 - 297.
206 ID0104, p. 182.
207 Following the exchange rate applied to the 1st instalment paid on 1 September 2004 (USD/EUR 1.2711), this sum amounts to roughly USD 17 million as stipulated in the draft Agreement of 22 October 2004 (see above).
208 ID1112, p. 7.

and court actions. As a result, there was no single generic producer that could enter the market without being challenged in one way or another.

(152) During the period concerned, Servier sent warning letters to practically all generic challengers and entered into litigation in certain Member States with a number of generic companies that were preparing to launch generic versions of perindopril. In addition, Servier defended itself against several generic companies that had initiated opposition procedures before the EPO. The main subject matter of the litigation as well as the opposition procedure was the '947 patent. Litigation with Niche[209] and Krka[210] also related to Servier's process patents, '339, '340 and '341.

4.1.2.4.1 Sending of warning letters and requests for interim injunctions

(153) Generally when Servier received information on a possible launch of generic perindopril, it sent warning letters to the generic companies concerned with the aim of deterring them from launching the product.[211] These warning letters often invoked as many as thirty five patents, including those that Servier internally qualified as "*barrage patents"* and patents with "*zero inventive activity"* (for the list of those patents see section 4.1.2.1.1). Servier made clear that it would exhaust all means to defend its product.

(154) Between 27 February 2006 and 7 November 2008, Servier sent fifty-two warning letters[212] to different generic companies that had considered entering parts of the EU market with a generic version of perindopril. In general Servier referred to a (planned) market registration for a generic version of perindopril in a Member State of which it had been informed. In a warning letter dated 7 November 2008 sent to Actavis[213] concerning the Finnish market, Servier refers to 35 patents. Internally Servier identified three as having no inventive value and 17 were explicitly *"barrage"* patents. The same patents were invoked in warning letters sent to Ranbaxy[214] and Briz[215] concerning the Latvian market.

(155) During 2007 and 2008, Teva received warning letters from Servier in the Czech Republic (5 March 2007),[216] Lithuania (19 December 2007),[217] Ireland (22 July 2008), Belgium (18 April 2008), Denmark (28 January 2008)[218] and in Italy (15 December 2008). Servier warned Teva that its generic version of perindopril could infringe approximately thirty of Servier's patents including the '947 patent and the process patents, which included the so-called *"*blocking"* patents as described in section 4.1.2.1.1. Servier thus continued to enforce the '947 patent in the Member States where the '947 was still in force after the UK court had annulled this patent.

(156) In a number of cases where the warning letter did not produce the desired results, Servier sought an injunction. In its reply to the Commission's RFI of 9 April 2010,

209 Court case number HC04C02097.

210 ID1723, p. 4.

211 Servier confirmed in its reply to the Statement of Objections (Annex 00-03, paragraph 34, ID9054, p. 11) that "*such letters do also act as a form of warning to the would-be market entrant*".

212 ID0110, p. 34-215 (the warning letters concerning markets outside the EU have not been counted but are in the case file).

213 ID0110, p. 34.

214 ID0110, p. 40.

215 ID0110, p. 43.

216 ID0350, p. 507.

217 ID0344, p. 65.

218 ID0344, p. 19.

Servier provided the following Table 5 containing an overview of all the preliminary injunctions launched by Servier against generic companies in the EU.

Table 5: Perindopril – preliminary injunctions in Member States

Country	Opposing party	Date of the injunction	Case number	Outcome
Belgium	NV Teva Generics Belgium	28/11/2008	C08/00206	Granted 17/12/2008 Repealed 06/05/2009
Hungary	Krka Hungary	30/05/2006	3.Pk.22.330/2006/16	Rejected 13/10/2006
	Extractum Pharma Actavis Hungary	13/07/2009	3.Pk.24.032/2009 8Pkf.25.037/2010/4 (appeal)	Rejected in first instance (14/09/2009) Appeal accepted 04/02/2010: Action sent back to the first instance (pending)
	Gedeon Richter	01/12/2009	3.Pk.26.732/2009	Rejected in first instance (17/02/2010) Appeal filed 12/03/2010, pending
Netherlands	Katwijk Farma	07/12/2007	299953/KG ZA 07-1450	Rejected 30/01/2008
United Kingdom	Krka Polska/Krka dd	01/08/2006	HC 06 C 03051	Granted 03/10/2006 Settlement 02/11/2006
	Apotex Inc. / Apotex Pharmachem Inc / Apotex Europe Limited / Apotex UK Limited	01/08/2006	HC 06 C 03050	Granted 03/08/2006 Repealed 09/07/2007

Source: ID2365, p. 18.

4.1.2.4.2 Litigation and opposition procedures

(157) Between June 2004 and June 2009, in parallel to the EPO proceedings, Servier was party to twenty-five court cases involving perindopril.[219] Litigation proceedings concerning the '947 patent took place in different Member States with a number of generic companies that were preparing to launch a generic version of perindopril.

4.1.2.4.2.1 Opposition procedures before the European Patent Office

(158) The '947 patent was granted by the EPO on 4 February 2004. Ten generic companies filed opposition proceedings against this decision reflecting the broader perception by generic operators that the patent was without merit and had to be removed to permit effective generic entry into perindopril. The opponent companies were: Química Sintética S.A., Norton Healthcare LTD (Teva), Glenmark Pharmaceuticals Limited, Polpharma, Mieszkowska, Hetero Drugs, Ratiopharm, Niche Generics, Lupin Limited and Krka. The three latter companies withdrew from proceedings after signing their respective settlement agreements with Servier.[220]

(159) Explicit internal documentation denoting Servier's knowledge of the invalidity of the '947 patent has not been found. However, a number of circumstances seem to

219 ID0746, p. 1 - 4.

220 See sections 4.3.1, 4.3.3 and 4.3.4.

indicate that Servier was uncertain that it could successfully enforce or defend the patent. For example, although the protection granted by the '947 patent was until 2021, in internal documents[221] and certain warning letters,[222] Servier appears to consider 2008 (the expiry date of the main process patents '339, '340 and '341) as the most significant date for the loss of exclusivity. Also Servier was initially reluctant to enforce the '947 patent, as transpires from the litigation with Niche – Niche's lawyer noted: "*They seemed remarkably reluctant to risk suit on the 947 patent*".[223] – or the litigation with Ivax, which was suspended and allowed Ivax market entry pending the EPO proceedings on the '947 patent.[224] Finally, following the annulment of the patent in the UK courts and when reflecting whether to appeal, Servier's patent department director noted: *"*I am also convinced that the revocation of the patent will be confirmed on appeal: we have almost no chance/ sorry for being so realistic!"*[225]

(160) The oppositions before the EPO were admitted on 6 December 2004. During the proceedings, the opponents raised a number of grounds for the opposition: lack of novelty (Article 54 EPC), lack of inventive step (Article 56 EPC) and insufficiency of disclosure (Article 83 EPC).

(161) The lack of novelty arguments were based mainly on Servier's '341 patent.[226] This patent related to an industrial method for the preparation of the tert-butylamine salt of perindopril (the industrial synthesis of perindopril). The generic companies also relied on one of Servier's scientific publications, dating from 1988, which referred to the process in question and Servier's international patent application WO 01/58868. This patent application had a priority date 6 April 2000, i.e. three months before the priority date of the '947 patent (6 July 2000). The opponents argued that due to the fact that this international application was continued in Europe (the Netherlands was the designated country), this document formed part of the state of the art according to Article 54 (3) EPC. Finally, the opponents claimed that the older version of perindopril also contained the alpha form.

(162) During the oral proceedings held on 27 July 2006, Servier filed[227] a new set of claims replacing the original set of claims as granted.[228]

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221 E.g. ID9974, p. 145, 159, 193, 268, 270, 335, 479, 482 (pages further disclosed in further access to file in ID10071, ID10072, ID10073, ID10074, ID10075, ID10076, ID10077 and ID10078, respectively). These documents show, in a very consistent manner over a period of four years, that Servier's launch strategy for the perindopril family was based on the assumption that product exclusivity would be lost in 2008. It is not contested that other documents, such as referred to by Servier (reply to the Statement of Objections, paragraph 224, ID10114, p. 128), indicated that crystalline form patents expire in 2021. However, the commercial strategy of Servier internalised the risk of loss of exclusivity as a material consideration as of 2008. ID0112, p. 27 and 33.

222 E.g. ID0466, p. 58.

223 ID0025, p. 131.

224 ID0345, p. 233; ID1323, p.1 - 5.

225 As explained an internal email from Servier's Patent Director to the legal department dated 11 July 2007; ID0116 p. 143.

226 See Table 1.

227 Source: EPO.

228 The amendment of the claims of the '947 patent comprised combining original claims 2 and 5 (establishing a specific cooling regime) into a new claim 2 (which relates to a method for the preparation of the alpha crystalline form of the tert-butylamine salt of perindopril according to claim 1). In particular, the amendment introduced by Servier added in the patent description the expression *"*the tert-butylamine salt of perindopril thus obtained is in the form of easy-to-filter individual sticks"*, Furthermore, Servier incorporated the following characteristic for the process *"*which can be obtained by a process whereby a solution of tert-butylamine salt of Perindopril is refluxed in ethyl acetate, then*

(163) The EPO's Opposition Division concluded that Servier's new set of claims for the '947 patent was within the terms of the EPC, hence the patent was maintained in the amended form.

(164) From 14 to 21 November 2006, all except one of the original opponents appealed[229] against the decision of the Opposition Division[230] before the EPO's Technical Board of Appeal ("TBA"). Niche had withdrawn from the opposition procedure on 9 February 2005. Krka and Lupin had to formally withdraw from the appeal on 11 January 2007 and 5 February 2007 respectively following their settlement agreements with Servier. The appellants requested that the decision of the Opposition Division be overturned.

(165) Although the '947 patent, as upheld by the Opposition Division, ran until 2021, an internal Servier document from 2008 considered that "**the Coversyl range is normally protected from generics until 2010 thanks to a case won on 27 July 2006 against the generic companies. Nevertheless we are not completely protected from generics […]*".[231] Servier's confidence that its patent would also be upheld by the TBA and would thus only lapse in 2021 does not transpire from this statement.

(166) The oral hearings before the TBA took place on 5 and 6 May 2009. The UK Court (at first instance) and the Dutch Court decisions had been delivered by that time, both annulling the '947 patent. Those decisions were submitted by the appellants and taken into account by the TBA.[232]

(167) On 6 May 2009, the TBA decided to revoke the '947 patent.[233] It accepted the experiments performed by the appellants and their arguments and concluded that,[234]

*"*Given the evidence provided by the claimants and the fact that the tests of the respondent are not such as to cast doubt on it, the Board concludes that the crystalline form α [alpha] is the inevitable result of the 3D example of the document (1), that is to say, there is no "grey area" and there is no reasonable doubt in this respect".*

(168) With regard to the amendment introduced by Servier: "**the tert-butylamine salt of perindopril thus obtained is in the form of easy-to-filter individual sticks*", the TBA stated that this was anticipated by the '341 patent and therefore, it did not find novelty either.

(169) As a result of the TBA decision, the '947 patent was revoked throughout Europe with the exception of the countries where Servier had applied only for a national patent[235].

(170) On 30 November 2009, Servier introduced a request for a revision of the TBA's decision before the EPO Enlarged Board of Appeal. On the basis of an alleged violation of its right to be heard during the earlier proceedings, Servier sought the annulment of the decision and the opening of new appeal proceedings. On

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cooled down to a temperature of between 55 and 65°C, at a rate of between 5 and 10C/h, then to ambient temperature, until full crystallisation". (ID1734, p. 17-18) (Decision of 6 May 2009 of the TBA).

229 Appeal T1753/06-3301.

230 The Decision of 27 July 2006 was published on 21 September 2006.

231 ID0105, p. 158.

232 ID1734, p. 17 - 18.

233 Decision published on 29 September 2009; ID1734, p. 1 - 75.

234 ID1734, p. 55.

235 See paragraph (120).

6 May 2010, the Enlarged Board of Appeal rejected Servier's appeal as manifestly unfounded.[236]

4.1.2.4.2.2 Patent litigation in the UK and patent settlements

(171) In the UK, as shown above in section 4.1.1.2, Servier's perindopril compound patent protection/SPC expired in June 2003. From that time, Servier monitored the UK market regularly *"to look for the entry of generic versions of its branded products"*.[237]

(172) Servier's market intelligence often managed to identify potential entrants before market authorisations were granted, despite the confidential status of the authorisation process. For example, in a document dated 8 September 2003 prepared by the consultancy firm [company name]* for Servier, it was reported that research had been carried out at the UK regulatory agency, the Medicines and Healthcare products Regulatory Agency ("MHRA"), to establish *"if any applications for generics to the Perindopril had been lodged since the previous research. There was speculation about a possible new application at the end of June or the beginning of July 2003. As at 4 September 2003, there have been no new applications for the active substance Perindopril. It is confirmed that the only applications currently registered at the MHRA are the original registration and the subsequent renewals for Servier Laboratories Limited"*.[238]

(173) When Servier was alerted that a generic company was in the advanced stages of preparing the launch of a generic version of perindopril, it generally launched patent infringement proceedings and/or interim injunctions to stop the commercialisation of the product (see sections 4.3.1 and 4.3.3 as regards Niche/Unichem and Krka, respectively). Servier also defended itself against actions to revoke its patents launched by the generic (see section 4.3.4 as regards Lupin) or applied for a stay of the national proceedings pending the decision of the EPO (see below as regards Teva).

(174) In the UK, Servier concluded patent settlement agreements with five companies: Niche/Unichem, Matrix, Teva, Krka and Lupin. The settlements essentially consisted, on the one hand, of payment of significant amounts of money, or another significant value transfer, to the generic companies, and, on the other hand, the obligation for the generic companies not to enter the market for a period of time and not to challenge the patents. With one exception (Teva), the settlements had a geographic scope covering the entire EU (or even wider). Teva also entered into an agreement whereby it would distribute in the UK an authorised generic that would be supplied by Servier.

(175) Section 4.3 provides a detailed factual overview of the aforementioned five settlement agreements that ended a challenge to Servier's patent position in the UK. Servier however failed to settle all litigation in the UK. Namely, patent litigation between Servier and Apotex, the only generic company with which Servier did not conclude a patent settlement agreement in the UK, led to the annulment of the '947 patent by the UK Courts, as described in the following subsection.

236 ID4988, EPO.
237 ID1172, p. 2 - 3.
238 ID0034, p. 455.

4.1.2.4.2.2.1 Apotex

(176) Apotex had applied for and was granted 15 marketing authorisations by the MHRA for generic perindopril in various doses. On this basis, on 28 July 2006, Apotex launched generic perindopril "at risk" in the UK.[239]

(177) On 1 August 2006, Servier launched infringement proceedings against Apotex[240] before the UK courts. The former claimed infringement of the '947 patent and applied for an interim injunction. Apotex launched a counterclaim for annulment of Servier's '947 patent. Apotex essentially claimed lack of novelty and obviousness because of the '341 patent. Apotex's cross-application for summary judgment on the basis that the '947 patent was invalid was not successful because Servier demonstrated, in the view of the Court, a sufficient prospect of defending the patent at trial. Pending trial, on 8 August 2006, Servier obtained an interim injunction against Apotex,[241] preventing it from importing, offering to sell or selling its perindopril but allowing it to fulfil contractually binding orders existing as at 3 August 2006. In the short period between 28 July 2006 and 8 August 2006, Apotex sold perindopril valued at GBP 4 million.[242]

(178) The reasons for launching infringement proceedings against Apotex were explained in a witness statement by [employee name of Servier]*:[243]

"On receiving information about Apotex launch of generic perindopril, Servier had to decide whether to instruct our UK lawyers to seek injunctive relief against Apotex or whether to proceed with the launch of our generic product via Teva and […]. If Servier committed itself to launching its generic product, the entire perindopril market would become generic and it would therefore be extremely difficult, if not impossible, for Servier to regain its pre-generic market position. The resulting downward price spiral and lost market share would have been very damaging to Servier. Therefore in conjunction with our UK lawyers […], it was decided to make an application to seek injunctive relief against Apotex before launching with our competing generic products. [Servier] informed Teva that [they] would not supply them with Servier product until further notice"

(179) Already during the trial, by March 2007, Servier was anticipating an unfavourable decision in view of recent tests demonstrating insufficient novelty of the crystalline form. Servier was inclined to discontinue the litigation and thus renounce the '947 patent in the UK. Servier's options for the Apotex litigation were henceforth based on "*discontinuance rather than settlement*".[244] However, Servier did finally not discontinue the Apotex litigation.

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239 ID1591, p. 16.

240 Les Laboratoires Servier & Anor v Apotex Inc & Ors [2007] EWHC 1538 (Pat) (11 July 2007). Available at: http://www.bailii.org/cgi-bin/markup.cgi?doc=/ew/cases/EWHC/Patents/2007/1538.html&query=Servier+and+Apotex&method=boolean

241 ID1591, p. 16.

242 ID242, p. 343.

243 This statement was provided in the context of a trial in 2008 for award of damages to Apotex. ID1172, p. 10.

244 ID0102, p. 266.

(180) On 6 July 2007, almost a year after the EPO Opposition Division had confirmed its validity, the High Court found the English part of the (EP (UK) 1296947) patent invalid.[245]

(181) Claim 1 relating to the crystalline form of perindopril erbumine was held by Mr Justice Pumfrey to lack novelty ("*in my judgment, claim 1 of the patent is anticipated by 341*")[246] and inventive step over the '341 patent ("*Assuming, therefore, that the process which Servier have been running since 2000 is obvious in the light of 341, and if that produces form α[alpha], then the product of that process is an obvious product to produce and it is in form α[alpha]. It was an obvious product to produce at the publication date of 341. This renders the patent invalid*").[247]

(182) Equally, the process claims, contained in the '947 patent, were considered lacking inventive step: *"The process claims 2 to 7 are merely a recital of typical process conditions, and on the assumption that it is possible to repeat 341 in the manner described and either produce a material which does or does not fall within the claim, then it cannot be suggested that any of the conditions in these claims are conducive to success. They accordingly lack any inventive step and must be invalid"*.[248] The judge granted permission to appeal to the Court of Appeal although it considered that there was no appealable issue, following precedent to the effect that permission should be granted in special circumstances.[249] The judge rejected the application made by Servier to continue the interim injunction against Apotex pending the appeal. [250] However, it ordered the interim injunction to continue for a few days to give Servier time to apply to the Court of Appeal to continue it. That application was refused by the Court of Appeal.[251] Thus the injunction was lifted and Apotex entered the market, a year after it had been forced to withdraw as a result of the injunction granted by Judge Mann.

(183) The witness statement of one of Servier's solicitors would appear to indicate that Servier knew of the existence of the alpha crystalline form claimed in the '947 patent long before the patent was filed: *"regarding Servier's knowledge of the polymorphic form of its perindopril before 9 March 2000, Servier considered it proper to make an immediate admission that the active pharmaceutical ingredient in Servier's perindopril product, Coversyl, marketed under marketing authorisation number 5815/0001 since about 15 December 1989, is the alpha crystalline form claimed in the Patent* ['947]*"*.[252]

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245 ID1591, p. 16 and 22. As a result the launch of perindopril by Apotex was delayed by a year.

246 See paragraph 39 of the judgment.

247 See paragraph 40 of the judgment.

248 See paragraph 40 of the judgment.

249 See page 64 of the transcript, Exhibit 3 to Annex 00-03 to Servier's reply to the Statement of Objections: *"I am satisfied, for the reasons I have expressed in the judgment which I have already delivered, that there is no argument for appeal here. I granted permission to appeal because I do not think that it is right to impose upon the Court of Appeal the burden of placing itself in the same position as I was on all the material available, before deciding whether permission should be granted or not."*

250 If Servier applied to the Court of Appeal for an interim injunction then the interim relief granted by Judge Mann would continue, provided that Servier applied to the Court of Appeal for an expedited hearing on the interim relief and that both that application and the appeal were prosecuted expeditiously (See, transcript of Judgment, page 65, Exhibit 3 to Annex 00-03 to Servier's reply to the Statement of Objections).

251 ID 5149, p.2.

252 ID0371, p. 50.

(184) In handwritten minutes from a high-level management (Comex) meeting within Servier, reference was made to the unfavourable judgment for Servier. However, the document mentions that the SPC expired in the UK in 2003, that Servier acquired experience and won 4 years ("**[…] 4 years gained = great success*"). Moreover, Servier noted that due to the European patent system, only the UK patent was contested ("**European patent = objections raised only in the UK*"). Despite "losing" the '947 patent, which was highly controversial and had led to a number of settlements, Servier still considered the extension of exclusivity beyond 2003 by virtue of the patent as a "**great success*".

(185) Following the decision at first instance, and consistently with the appreciation of the trial judge, Servier had doubts about the likelihood of winning on appeal. [Employee name and function with Servier]* explains in an email to Servier's legal department dated 11 July 2007: "**I am also convinced that the revocation of the patent will be confirmed on appeal: we have almost no chance/ sorry for being so realistic!"*[253] The weighing of arguments in favour of appealing is contained in the same email: *"*The decision to appeal must therefore be taken circumspectly: the filing of the appeal is interesting to create some uncertainty concerning the final decision, in particular in view of the proceedings in Europe and to postpone payment of the damages that will be sought by Apotex"*. Despite the concerns expressed by [employee name of Servier]*, Servier eventually lodged appeal against the judgment on 27 July 2007.[254]

(186) On 9 May 2008,[255] the Court of Appeal confirmed the High Court's decision and declared the '947 patent invalid in its entirety for lacking novelty, as it was anticipated by the '341 patent. Specifically, the Court of Appeal was convinced that the process known from the '341 patent and used to prepare perindopril *erbumine* would have inevitably led to the formation of the alpha form.

(187) Lord Justice Jacob explained:[256]

"*The upshot of all this is that were the patent valid, Servier's monopoly in practice would last until 2020. But, as the Judge held and we confirm, it is invalid. And very plainly so. It is the sort of patent which can give the patent system a bad name. I am not sure that much could have been done about this at the examination stage. There are other sorts of case where the Patent Office examination is seen to be too lenient. But this is not one of them. For simply comparing the cited prior art ('341) with the patent would not reveal lack of novelty and probably not obviousness. You need the technical input of experts both in the kind of chemistry involved and in powder X-ray diffraction and some experimental evidence in order to see just how specious the application for the patent was. The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest.*

It is right to observe that nothing Servier did was unlawful. It is the court's job to see that try-ons such as the present patent get nowhere. The only sanction (apart, perhaps, from competition law which thus far has had nothing or virtually nothing to say about unmeritorious patents) lie in an award of costs on the higher (indemnity) scale if the patent is defended unreasonably".

253 ID0116, p. 143.
254 ID3842, p. 15.
255 ID5149.
256 Judgment [2008] EWCA Civ 445, Case No A3/2007/1715, paragraphs 9 and 10 (ID5149).

(188) During the summer of 2008, Servier sought to settle with Apotex "*[…]**" but no agreement was reached.[257] New litigation commenced and on 13 October 2008, Apotex was awarded damages of GBP 17.5 million based upon a figure of GBP 74 million as the estimated sales during the period when the injunction was in force. Apotex had originally claimed GBP 27 million.

(189) Servier applied to the Court of Appeal to reopen the damages enquiry in June 2008. Servier in its submissions of 21 March 2011[258] informed the Commission that "**Mr Justice Norris refused to grant Servier permission to reopen the proceedings to invoke these arguments. Servier appealed against this refusal and obtained from Lord Justice Jacob (i) conversion of the judgment into a provisional decision and (ii) the right to file a plea on the merits before the High Court. The arguments were exchanged on both sides and the pleadings took place in the week of 14 March 2011"*.

(190) Following the permission granted to Servier by the Court of Appeal to amend its defence, Servier included a public policy argument. Servier's argument was based on the *ex turpi causa* rule, i.e. that Apotex was not allowed to recover damages since it infringed a valid Canadian patent by manufacturing and selling perindopril in Canada. On 29 March 2011, Justice Arnold of the High Court (Chancery Division, Patents Court) indicated that the *ex turpi causa* rule should apply and ordered Apotex to repay Servier the sum of GBP 17.5 million.[259]

(191) It is important to mention that Apotex was the only generic company involved in litigation in the UK with which Servier did not conclude a settlement and the litigation continued until the Court's decision was delivered. Although there was "**an indication that Apotex might perhaps consider a settlement*", at least as of March 2007, Servier envisaged discontinuance rather than settlement of this litigation because, according to [employee name of Servier]* "**[…] we anticipate a decision unfavourable to us in the context of proceedings in the UK*".[260] The litigation was neither settled, nor discontinued, and the judge ruled against Servier annulling the '947 patent.[261]

(192) To conclude this section, it is interesting to note that in order to rule on Apotex's damages claim the judge examined the settlement agreements concluded by Servier with Teva, on the one hand, and with Krka on the other. As regards the agreement with Teva, the judge's interpretation of Servier's conduct was that *"Servier thus paid AG2 [AG2 is Teva] approximately £[0–20]* million to keep it out of the market"*.[262]

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257 ID1591, p. 17 - 18.

258 ID3842, p. 16.

259 Les Laboratoires Servier & Anor v Apotex Inc & Ors [2011] EWHC 730 (Pat) (29 March 2011). Available at: http://www.bailii.org/ew/cases/EWHC/Patents/2011/730.html

260 ID0102, p. 266

261 ID3442, p. 6. Servier claims that there were no contacts between Servier and Apotex relating to the UK procedure, and that such contacts only related to the Canadian proceedings (reply to the Statement of Objections, paragraphs 233-234, ID10114, p. 130-131). However, the quote, which explicitly mentions "**the UK court*" shows that at a certain moment there was an indication that Apotex could envisage a settlement, and that Servier was aware of this. This is consistent with the fact that, at least until March 2007, settling Apotex litigation was also amongst valid options for Servier (see paragraph (179)).

262 For the full quote see paragraph (810); ID4962, paragraph 23, Les Laboratoires Servier & Anor v Apotex Inc & Ors [2008] EWHC 2347 (Ch) (9 October 2008). Available at http://www.bailii.org/cgi-bin/markup.cgi?doc=/ew/cases/EWHC/Ch/2008/2347.html&query=apotex&method=boolean#disp18

4.1.2.4.2.3 Litigation in other Member States

4.1.2.4.2.3.1 Katwijk Farma B.V

(193) Apotex was also active in the Netherlands through its subsidiary Katwijk Farma B.V.[263] From an exchange of internal Servier emails in November 2007,[264] it appears that Apotex was preparing to launch generic perindopril in the Netherlands. Apotex had registered its generic perindopril in the Z-Index and fixed a price for the 2, 4 and 8 mg dosages.[265] Servier's employees discussed the need to urgently launch injunction proceedings to prevent the commercialisation of Apotex's product ("**We are doing everything to obtain this injunction from the court. Katwijk's lawyers will be notified tomorrow of our action*").[266]

(194) On 13 November 2007, Katwijk Farma initiated an annulment action[267] against Servier, seeking revocation of the Dutch part of the '947 patent on the grounds of lack of novelty and inventive activity. On 7 December 2007, Servier commenced preliminary injunction proceedings[268] against Katwijk Farma before the District Court of The Hague.[269] This action concerned the alleged infringement of the '947 patent following the grant of marketing authorisations for Katwijk generic perindopril.[270] Shortly thereafter, on 13 December 2007, Apotex/Katwijk launched its generic version of perindopril.[271]

(195) On 30 January 2008, in the injunction proceedings, the Court dismissed Servier's claims. Servier appealed against this decision one month later.[272]

(196) On 11 June 2008, the Dutch courts annulled the '947 patent for the Netherlands in parallel proceedings with Pharmachemie (see below). In light of this decision, on 24 June 2008, Servier and Katwijk Farma concluded an agreement[273] to withdraw from the proceedings on the merits and from the appeal proceedings[274] if the judgment of 11 June 2008 became final and conclusive. Servier also agreed to pay EUR [100,000–200,000]* to Katwijk Farma to cover the costs of litigation.

(197) This settlement consisted merely of an agreement by both parties to withdraw from the proceedings and did not contain any market entry limitations for the generic company. Katwijk had already launched its generic version of perindopril at the time of the settlement and continued to market the product after the settlement was reached.

263 Apotex bought Katwijk Farma in April 2004. In October 2008, the name Katwijk Farma was changed to Apotex NL BV.
264 ID0102, p. 246 - 249.
265 ID0102, p. 250 - 251.
266 ID0102, p. 246 - 249.
267 Case Number 2007/3982.
268 Case Number 299953 KG ZA 07-1450.
269 ID2365, p. 11.
270 ID2365, p. 11.
271 ID1591, p. 13.
272 ID0746; ID0350, p. 1427.
273 ID0118, p. 18 - 19.
274 ID2365, p. 11.

4.1.2.4.2.3.2 Pharmachemie B.V./Teva

(198) On 15 August 2007, Pharmachemie B.V. (a Teva subsidiary) filed a revocation action against the Dutch part of the '947 patent at the Court of The Hague.[275] On 4 September 2007, Pharmachemie submitted a Writ of Summons,[276] arguing that the '947 patent was invalid on the grounds of lack of novelty and of inventive step and for non-reproducibility.[277]

(199) On 11 June 2008, the Court of The Hague annulled the '947 patent for the Netherlands.[278] The Court held that the process described in the '947 patent lacked inventive step and did not present any advantages over the process contained in the '341 patent.

(200) On 7 October 2008, Servier appealed to the Court of The Hague. However, Teva explains that Servier did not submit a Statement of Grievances and the case was put on the Court's dormant case list.[279]

4.1.2.4.2.3.3 Other litigation

(201) Table 6 below lists other litigation proceedings reported by Servier in the EU/EEA. Most of the actions brought by the generic companies (except Teva's action in Belgium) were reportedly revocation actions.[280]

275 ID0345, p. 315.
276 Case number 2007/3171.
277 ID 2519, p. 9.
278 ID2519, p. 9.
279 ID 2519, p. 9-10.
280 ID2365, p. 9 - 10.

Table 6: Patent litigation in other Member States

Date	Launching party	Patent	Court	Against	Status of the action
17/08/2007	TEVA Pharmaceuticals CR	CZ 297672 (*)	Prague	Servier	Patent revoked – 06/2010
15/11/2007	Apotex CR	CZ 297672 (*)	Prague	Servier	Patent revoked – 06/2010
12/12/2008	Glenmark Pharmaceuticals (Europe)	CZ 297672 (*)	Prague	Servier	Patent revoked – 06/2010
6/05/2008	Ivax Pharmaceuticals, sro	PP 149-2003	Bratislava	Servier	Pending
17/12/2008	Glenmark Pharmaceuticals (Europe)	PP 149-2003	Bratislava	Servier	Pending
12/09/2006	Servier	EP '947	Paris	IDD/Apotex	Invalidated 6/05/2009 (#)
20/11/2007	Doc Generici	EP '947	Rome	Servier	Invalidated 6/05/2009 (#)
9/02/2009	TEVA	EP '947	Rome	Servier	Invalidated 6/05/2009 (#)
20/08/2008	Servier	EP '947	Brussels	Ranbaxy	Invalidated 6/05/2009 (#)
31/07/2008	Teva Generics/Pharma Belgium	EP '947	Anvers	Servier	Procedure cancelled
28/11/2008	Servier	EP '947	Anvers	NV Teva Generics Belgium	Invalidated 6/05/2009 (#)
12/12/2008	Glenmark Pharmaceuticals Ltd	BG 64868	Sofia	Servier	Pending
27/01/2009	Química Sintética	EP '947	Barcelona	Servier	Invalidated 6/05/2009 (#)
30/05/2006	Servier	HU 225340	Budapest	Krka Hungary Ltd	Settled – 16/11/2006
10/04/2008	Actavis Hungary Kft	HU 225340	Budapest	Servier	Pending
30/03/2009	Ranbaxy	HU 225340	Budapest	Servier	Pending

Note: situation on 21 March 2011

(*) CZ 297 672 is a national equivalent to the '947 patent [ID0350, p.231]

(#) The date on which the '947 patent was invalidated by the EPO TBA.

Source: ID3842, p. 3-4, ID2365, p. 9-10.

(202) To conclude, it is interesting to note the costs Servier identified regarding litigation on perindopril. Servier reported that the total external cost of litigation with Apotex (interim injunction proceedings, main proceedings, appeal proceedings and proceedings to establish damages to Apotex) amounted to EUR [1–25 millions]*. The proceedings with Ivax/Teva, which were stayed at an early stage, and then settled, cost EUR [100,000–200,000]*. Adding the costs reported for other litigation procedures (Niche, Krka) the aggregate cost of perindopril litigation in the UK for Servier reportedly amounted to EUR [1–25 millions]*. The costs of the EPO

opposition procedure amounted to EUR [50,000–75,000]* and of the procedure before the EPO Technical Board of Appeal to additional EUR [25,000–50,000]*.[281]

4.1.2.5 Distribution agreements with "friendly generics"

(203) From 2005 to the present day, Servier has concluded distribution agreements for generic perindopril in the UK and other Member States with several generic firms.[282] The agreements generally grant the generic companies the right to distribute a so-called "authorised generic". These arrangements can lead to a controlled generic entry as the generic company, in return, normally promises not to sell other generic versions, while the originator may retain a degree of control over certain commercial parameters (for example, date of launch, quantities, prices etc.). Entry by authorised generics was referred to by Servier as a "*nuclear weapon*". The strategic use of friendly generics was made clear in the instruction: "*be prepared (registration, production*)", "*but launch only in case of absolute necessity"*.[283]

(204) Servier concluded ten distribution agreements in total with the generic companies, including: Teva (see section 4.3.2.5 for the description of this agreement), Docpharma, and Orifarm. All of the agreements concern the commercialisation of perindopril in the contractual territory with exclusive supply by Servier.[284]

(205) The distribution agreements with Teva and another generic company (both relate to the UK market) were seen by Servier as an efficient tool to maintain a *"good income from perindopril"* and keep volumes if generic entry took place.[285]

4.1.2.5.1 [Company name]* / [Company name]* / Mylan

(206) On 15 December 2005, Servier entered into an agreement ("the [company name]* Agreement")[286] with [company name]* entitled "**Licence agreement*", relating to France, the UK and the Netherlands, amongst others. [company name]* was the parent company of [company name]*. In May 2007 [company name]* was acquired by the generic company Mylan. None of the companies now belonging to the Mylan group developed their own perindopril product.

(207) In the UK, [company name]* intended to launch a generic version of perindopril sourced from Servier in mid-2006 according to the terms of the licence granted by Servier. Following the interim injunction against Apotex,[287] the product was only launched in 2007.

(208) Other subsidiaries of Mylan also acted as local distribution partners for Servier. In the Netherlands, [subsidiary of Mylan]* launched generic perindopril sourced from Servier in April 2008. Both Mylan SAS in France and [subsidiary of Mylan]* in Belgium were expected to commence distributing generic perindopril sourced from Servier by the end of 2009 at the time of Mylan's reply.[288]

281 ID1144, p. 1, ID1151, p. 23.
282 ID4539, p. 1 - 2.
283 ID0032, p. 179.
284 ID4539, p. 1 - 2.
285 ID0033, p. 53.
286 ID1496, p. 15.
287 See section 4.1.2.4.2.2.1.
288 ID1496, p. 16.

4.1.2.5.2 [Company name]*

(209) [Company name]*'s correspondence with Servier dating from August to October 2008 refers to a "*gentleman's agreement*" between Servier and [company name]*, under the terms of which [company name]* received a marketing authorisation for generic perindopril launch in several Member States. This took the form of the conclusion of distribution agreements between Servier and the French company ([…]*) and the Irish one ([…]*), both subsidiaries of [company name]*.[289]

(210) On 6 November 2008, Servier and [company name]* signed a *'Non-exclusive Distribution Agreement"*. Servier appointed [company name]* to be the distributor in Ireland of perindopril 2, 4 and 8 mg from the "*First Distribution Date"*. This term is defined as the earliest of the following three dates to occur: (1) a date notified by Servier in writing, (2) the date of revocation of the '947 patent in Ireland or (3) one month before the expiry of the '947 patent in Ireland. [Company name]* would buy all of its requirements for perindopril from Servier and would commercialise perindopril under the trademark […]*.

(211) Servier and [company name]* concluded a *"*Contract for the transfer of the capacity of marketing authorisation holder*"[290] on 22 June 2009 with a duration of three years. Servier agreed to supply [company name]* with perindopril 2, 4 and 8 mg to be distributed by the latter under its own layout in France.

4.1.2.6 […]* practices in France

(212) In September 2008, Sandoz was the first generic producer to enter the French market with generic perindopril *erbumine*.[291] Its perindopril had an amorphous (non-crystalline) form and hence it was free of the alpha crystals covered by the '947 patent.

(213) […]*.[292]

(214) […]*, it should be noted that in 2007/2008, when discussing with Sandoz a possible IPR transfer (see section 4.2.2.8.4.), Servier had already acknowledged that Sandoz's perindopril product did not infringe Servier's patents. In Servier's internal assessment dated 4 January 2008, it recognised that (i) *"the product [of Sandoz] possesses the chemical and stereochemical quality comparable to that of Servier", (ii) "the synthesis route applied does not appear to use the route of Servier" and (iii) "the product [of Sandoz] presents an amorphous structure "*.

(215) On 22 December 2008, Sandoz formally[293] drew Biogaran's attention to the fact that it was aware of its activities and asked that they be stopped. Biogaran denied Sandoz's allegations.

(216) Despite its significantly lower price and the general incentives for pharmacists to dispense generics present in the national system, generic perindopril did not gain a very significant share of the French market. By 2009 Sandoz's product (which was introduced before Servier had switched from the erbumine salt to the arginine salt) accounted for only 8.4% of total sales.

289 ID1151, p. 29.
290 ID1136, p. 1 - 18.
291 IMS Data.
292 ID1464, p. 2.
293 ID1464 (*Sommation interpellative*).

(217) In April 2009, Servier discontinued selling perindopril *erbumine* and replaced it with perindopril *arginine*. The switch seemed to transfer practically all of Servier's sales from the former to the latter. In October 2009 the French authorities, namely the Economic Committee of Healthcare Products (*Comité économique des produits de santé*, "CEPS"), decided to lower the price of Servier's perindopril by 15%. The 13-month delay between Sandoz's generic entry and the said price decrease conflicts with the official position of the French Ministry of Health. The Ministry explained in its reply to the Commission's request of 7 April 2010 that *"*the ministerial guidelines state that CEPS implements a price cut of 15% to the reference medicinal product as from the marketing of the first generic"*. Servier claims it is unable to explain the underlying reasons why CEPS took so long to adapt the price.[294]

4.1.2.7 Selective switches to arginine salt (2nd generation product)

4.1.2.7.1 Servier's strategy for a second generation product

(218) The introduction of a second generation product was another important element anticipated to extend the lifecycle of perindopril. The following subsections describe different aspects of the switch to the *arginine* salt carried out by Servier as part of its anti-generic strategy. [295]

(219) Servier initially concentrated on the development of an extended release version known as project S5492 *("*extended-release perindopril tert-butylamine")*. In its internal presentation from 2000 entitled *"Why are we making such a fuss about it?"*,[296] one slide states: *"What about generics? Synthesising perindopril is going to be difficult for them. All complementary means to forbid them to reach the market will have to be used. We will have to transfer our turnover to S 5492 ASAP"*. However, project S5492 was eventually abandoned.[297]

(220) From 2002 onwards, Servier's internal documents indicate that the development and launch of a second generation product in the form of project S6490 (perindopril with *arginine* salt) was considered as the principal weapon with which to fight generic entry. One example is the strategy paper: *"*Monitoring of Project 2002/1 "DESS" 6490: (arginine)*"[298] dated 4 October 2002 which stresses the importance of protecting perindopril through the development of the *arginine* salt. With reference to the S6490 project, the document states:

"**The purpose of this brief development (filing within a year), based on bioequivalence, is threefold: [i] Through its patent, to extend the duration of protection of Coversyl (2023). [ii] To replace Coversyl immediately. [iii] Not be substitutable by generics, in those countries where the latter would be already present at the time of launch*".

(221) It is therefore evident that the introduction of the *arginine* salt before the arrival of generic versions of erbumine was an essential element of Servier's action plan to

294 ID2433, p. 3.

295 In addition to the four Member States subject to in-depth investigation of effects under Articles 101 and 102 of the Treaty(France, Netherlands, Poland and the UK), this section contains information related to other Member States such as Belgium, Denmark, Italy, Ireland and Romania which has been considered relevant to offer a more accurate report of Servier's activities in relation to the switch from perindopril *erbumine* to perindopril *arginine*.

296 ID0036, p 156 - 161.

297 ID1151, p. 35.

298 ID0112, p. 32.

prolong the lifecycle of perindopril. The strategy was based on the specificities of national substitution rules. Due to its different molecular weight, *erbumine* is sold in dosages of 2, 4 or 8 mg, whilst *arginine* is sold in dosages of 2.5, 5 and 10 mg. Depending on the national substitution rules, pharmacists cannot dispense a generic version of perindopril *erbumine* if the prescription specifies tablets with different dosages.

(222) Another strategy document dealing with protection measures against generics concludes that "**The registration of arginine salt is a defence tool to extend the life cycle of Coversyl*".[299]

4.1.2.7.2 No added therapeutic value of the arginine salt

(223) The *arginine* salt was meant to replace the *erbumine* salt on the basis of claims relating to its improved shelf-life and stability.

(224) In an internal email of 14 March 2008 (concerning its submission to the UK marketing authorisation body for Coversyl Plus *arginine*), Servier reveals its awareness of the lack of added therapeutic value of the new salt: *"It is going to be very difficult to justify that the alternative agents [perindopril erbumine] are not comparator medicines [generics] and, since they will be cheaper, we would have to make a full submission. Since there is no cost or effectiveness advantage, it seems unlikely that the new salt could justify a place ahead of alternatives".* [300]

(225) In Servier's internal document entitled *"Coversyl protection",*[301] the replacement of the *erbumine* with the *arginine* salt is mentioned as generating new patent protection and a shift of dosages (from 2, 4 and 8 mg to 2.5, 5 and 10 mg). The document describes the *arginine* salt as being more stable: *"one single packaging for all the climatic zones (tablet container)", "No specific storage conditions" and "Shelf-life can be extended to 3 years"*. However, in an email dated 14 October 2008 an Associate Project Manager CV Risk, at Servier explains: *"There is not really clinical benefits for the patients because Coversyl arginine is bioequivalent to old Coversyl. […] This stability [of arginine salt] is proved by the one more years of shelf life vs the old salt. So the advantage is not (only) financial"*.[302] It is evident that Servier was aware of the lack of added therapeutic benefits of the new product and that it would not bring any cost savings to the state. An undated internal Servier presentation refers to perindopril *arginine* as a *"*New form without IMSP [Improvement in the Medical Service Provided] (expected saving compared with the existing form)*" which is, however, "**likely to impede or block generic entry (generic price applied on the outgoing patent of the existing form)*".[303]

(226) Furthermore, Teva's external lawyers sent a letter[304] to Servier's external lawyers on 29 August 2008 in which they wrote: *"In addition, the "benefit" which it [*perindopril *arginine] is said to possess is, in practical terms, of little interest to patients and clinicians as the shelf life for perindopril erbumine was two years - a period which is considered to be perfectly acceptable for pharmaceutical products"*. Also, the following email submitted as part of Teva's reply to the Commission's RFI of

299 ID0112, p. 33.
300 ID0034, p. 10.
301 ID0105, p. 264.
302 ID0033, p. 31.
303 ID0112, p. 22.
304 ID2503, p. 3.

16 January 2009 refers to the letter from the Danish Medicine Agency: *"In the two formulations the two salts of perindopril correspond to the same amount of the active substance of "perindopril". For instance, 2 mg of perindopril tertbutylamine correspond to 1.669 mg of perindopril and 2.5 mg of perindopril arginine corresponds to 1.6975 mg of perindopril. Consequently, there ought to be no difference in the effect whether one or the other of the two different salts are used, when the content of the active substance is generally the same. We can confirm that the manufacturer of the original product has documented this in its application for the product in another salt".*[305]

(227) Perindopril arginine's better thermodynamic stability meant it needed a single kind of packaging for all climatic zones and it had an extended shelf life (three years instead of two) and had no particular storage conditions.[306] According to Servier, this lead to an improvement in terms of logistics (stock management for manufacturers and wholesalers).[307] Servier adds that perindopril *arginine* represented *"*the share of sales made in the tropical countries around the world represents one fifth of global sales"* and 37% of European sales between 2007 and 2008.[308]

(228) However, Servier also acknowledges that "*did not claim that Perindopril arginine has, with regard to the therapeutic effects for patients (secondary effects included), a superior medical effect when compared to perindopril erbumine, as mentioned in the transparency file submitted to the French Haute Autorité de Santé (French National Health Authority) in November 2007: "The benefit/risk ratio [of coversyl arginine] is unchanged compared to that of coversyl [tert-butylamine]"*".[309]

4.1.2.7.3 Patent protection and marketing authorisation

(229) Servier applied for a European patent for the *arginine* salt on 17 February 2003. The patent[310] (EP 1 354 873 B, the '873 patent) was granted on 14 July 2004 and will expire on 17 February 2023.

(230) On 13 April 2005, Teva filed an opposition to the '873 patent.[311] Oral proceedings were held on 25 September 2008, at the end of which Teva was unsuccessful. Teva reports[312] that the Opposition Division did not accept its arguments that the patent lacked sufficiency and inventive step. Teva explains that, in particular, the Opposition Division was "*of the opinion that Teva had not demonstrated that the prior art directed the skilled person to identify the arginine salt of perindopril as being superior to the prior art erbumine salt*". On 22 December 2008, Teva filed an appeal against the decision.[313] However, Teva withdrew its appeal on 8 May 2012 and the '873 patent was maintained.[314]

(231) With regard to the MA, the registration of perindopril *arginine* was based on bioequivalence studies with perindopril *erbumine,* and was a line extension application through the MRP for the entire EU with the exception of Romania (where

305 ID0344, p. 58.
306 ID4517, p. 7.
307 ID4517, p. 7.
308 ID4517, p. 9.
309 ID4517, p. 6.
310 ID0354, p. 1223 - 1236.
311 ID0345, p. 223.
312 ID2519, p. 7.
313 ID2519, p. 7.
314 Source: EPO.

it was registered nationally).[315] Servier relied on clinical and pre-clinical data from the perindopril *erbumine* marketing dossier.[316] The procedure started with an abridged submission in France in October 2003.[317] The fact that Servier used the abridged application route is evidence that Servier considers perindopril *erbumine* and *arginine* as bioequivalent.[318] In other words, perindopril *arginine* can be linked to a generic version of perindopril *erbumine*.

(232) The French marketing authorisation was granted on 25 November 2004. Through the MRP, Servier obtained MA in 26 other Member States in April 2005.

4.1.2.7.4 Commercialisation

(233) The decision to launch perindopril *arginine* in the different Member States appears to be linked to the regulatory framework for generic substitution. In *"*Coversyl Monitoring of the Medicine 2008*"319 it is reported that "**the decision to replace on the market the current form of Coversyl (tert-butylamine salt) with this new patented formulation (arginine salt) will be taken on a case-by-case basis, according to the local legislation on substitution*".

(234) Servier explicitly lists as one advantage of the salt switch that *"Pharmacist's substitution of one salt by another one is currently not permitted in a certain number of countries"*.[320] More specifically, Servier explains that generic substitution at the pharmacy level is hindered due to the new dosages (rather than the salt switch in itself*): "*[…] However we are not completely protected from generics. The launch of Coversyl arginine will protect us against the potential generics of Coversyl because pharmacists cannot substitute medicines with different dosages"*.[321]

(235) Servier put significant effort and resources into the switch from *erbumine* to *arginine*. The timing of the switch (between 2006 and 2008) and the withdrawal of perindopril *erbumine* were often described as crucial, complemented by aggressive detailing as described in internal documents. From the beginning, the strategic goal of quickly replacing perindopril *erbumine* with *arginine* appears to have been an important element in the action plan to prolong the lifecycle of perindopril. For example, as early as 2002, according to the minutes of an internal meeting held on 21 June 2002,[322] "**[p]roject S 6490 only makes sense if Coversyl arginine salt immediately and totally replaces Coversyl tert-butylamine salt on the market: [annuls and replaces]*".

(236) In relation to the change of dosage, Teva's regulatory team considers that *"There will potentially be a great deal of confusion caused by the 'new' strength and this could be used by Servier to inhibit generic competition. If the erbumine salt (Coversyl) was pulled from the market it could be seen as being anticompetitive"*.[323]

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315 ID2365, p. 24.

316 ID4517, p. 6

317 ID0105, p. 265 - 266.

318 The different salts of an active substance are considered to be the same substance for purposes of the abridged application unless it is shown that they differ significantly in properties with regard to safety and/or efficacy (See the Judgment in Generics (UK) and Others, C-368/96, EU:C:1998:583, paragraph 36; and Article 10(2)(b) of Directive 2001/83/EC as amended).

319 ID9974, p. 699. Signed by [employee name of Servier]*.

320 ID0105, p. 270.

321 ID0105, p. 158.

322 ID0104, p. 34 - 36.

323 ID0350, p. 910.

(237) The introduction of perindopril *arginine* in the EU markets started in 2006 in Poland. It was followed by a staggered introduction of the different dosages in various Member States. In some countries both salts, *erbumine* and *arginine*, were commercialised in parallel for a short period of time until the full replacement of the old salt by the new one had been completed. By mid-2008, the *arginine* salt was sold in several Member States. It maintained the brand name with the addition of the type of salt: 'Coversyl Arginine'. Servier's internal document "**Coversyl Monitoring of the Medicine 2008*", indicates that on 1 July 2008, perindopril *arginine* had been launched in 17 Member States (Bulgaria, Lithuania, Cyprus, Czech Republic, Denmark, Finland, Greece, Hungary, Ireland, Italy, Latvia, the Netherlands, Poland, Portugal, Romania, Slovenia and Slovakia).[324]

(238) Besides the regulatory framework for generic substitution, the successful introduction of perindopril *arginine* in the different Member States depended to a large extent on whether generics had already entered the market with generic perindopril *erbumine*.[325]

Conclusion with respect to Servier's second generation product

(239) The launch of perindopril *arginine* is considered by many generic competitors as the most important non-patent barrier for the introduction of generic perindopril.[326] Teva refers to "*evergreening"* among the non-patent barriers to enter the perindopril generic market. Teva specifically mentions the example of the successful switch to perindopril *arginine* in Ireland which hampered generic entry and impacted the sales of its own generic version: *"Although the product was formally launched in November 2008, Teva has achieved no sales, as Servier had moved the market to the arginine version"*.[327]

(240) Teva also points out that *"[…] It is Teva's experience that generic substitution was not possible in cases where Servier launched the arginine product before generic entry (such as Denmark, Ireland and Belgium). For Teva it was really possible to gain significant shares of sales only where it was able to launch a generic perindopril product before Servier switched to arginine (such as the UK and Spain)"*.[328]

(241) As Teva mentions, the UK was one of exceptions to the successful launches of perindopril *arginine*. Servier launched perindopril *arginine* there in April 2008 when generic perindopril had already been on the market for several months. By April 2008, sales of Coversyl (erbumine salt) were reduced to a small fraction of the historic levels.

(242) It can be concluded that the main objective of the introduction of perindopril *arginine* was to deny generic substitution due to the different dosages of the new product. As explained, in many Member States pharmacists cannot substitute, for example 2 mg of perindopril *erbumine* for 2.5 mg of *arginine* even though the actual amount of the active principle is unaffected.

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324 ID9974, p. 699.

325 ID1346, p. 26, see also section 6.4 for further information on the switch to perindopril arginine in France, the Netherlands, Poland and the UK.

326 ID1481, p. 14; ID1042, p. 9; ID1034, p. 6 (in Ireland).

327 ID1346, p. 9.

328 ID1346, p. 25.

4.1.3 Conclusion

(243) In the majority of the EU/EEA markets, sales of perindopril were controlled exclusively by Servier until 2008/2009. This was specifically the case until the expiry of the main process patents, '339, '340 and '341 in 2008 and the revocation of the '947 patent by the EPO Technical Board of Appeal on 6 May 2009. Prior to these events, generic entry took place on a limited number of markets e.g. when Krka started supplying its perindopril under the Prenessa brand in certain Member States around 2006[329] or when launches at risk and/or successful litigation led to effective generic entry on the UK and Dutch markets in 2007.

(244) Overall Servier expressed great satisfaction with its anti-generic strategy protecting perindopril as evidenced in a number of documents. Reference is made once more to the statement relating to the market entry of generics in the UK (where entry was first possible in Western Europe), Servier noted: *"*4 years gained = great success"*.[330]

(245) In this context, it should be noted that in late March 2011, the UK Department of Health ("NHS") launched a damages court action against Servier before the High Court in case HC11C01423 claiming approximately GBP 220 million in damages due to the delays caused to generic entry by Servier's allegedly anticompetitive practices.[331]

4.2 Acquisition of IPRs

*4.2.1 [Company name]**

(246) In September 1999, [company name]*, a small [nationality]* API company, started development of perindopril API by using a different production process from those patented by Servier. By 2001, when there were still almost no other companies developing generic perindopril API (the only other developer was Medicorp/Matrix), [company name]* was at an advanced stage of development of the API. [Company name]* considers that its API did not infringe any of Servier's patent rights in force at the time. In […]*, [company name]* filed for a process patent for this API. [Company name]*, a company cooperating with [company name]*, was publicly offering the [company name]* API and entered into advanced cooperation negotiations with a generic company in that regard. [Company name]* also informed Servier of [company name]*'s project. Following that, on […]* 2001, Servier and [company name]* concluded an agreement on the sale of the patent application and a "chemical dossier" for perindopril API ("the [company name]* Agreement"). The [company name]* Agreement effectively ended any independent development of perindopril based on the [company name]* API. Subsequently, [company name]* was turned into an API supplier to Servier. This chapter presents the underlying facts in more detail.

4.2.1.1 [Company name]*'s development of perindopril API

(247) [Company name]* is a company active in the manufacturing and marketing of APIs. In September 1999, [company name]* started a project "*with the objective of investigating and developing a technically viable process respecting third-party*

329 ID8386, p. 5, 61-63.
330 ID0116, p. 51.
331 ID5250. Case No HC11C01423, Secretary of State for Health v Servier Laboratories Ltd.

intellectual property rights enabling the industrial manufacture of Perindopril Erbumine API".[332]

(248) The first stage of R&D was carried out at […]* (approximate cost EUR [25,000–50,000]*, time employed [0–30]* months, one full-time chemist) and at [company name]*'s own laboratories (cost EUR [50,000–75,000]*, time employed [0–30]* months, one full-time chemist).[333]

(249) [Company name]* created a process on a small scale (10 g) in February 2001. On this scale, the process was robust and reliable and yielded quality perindopril erbumine. The cost efficiency of the perindopril production process was at that time not yet a consideration. Subsequently, [company name]* continued work on a scale-up to industrial manufacturing quantities at a viable cost.[334]

(250) The next stage consisted of development/manufacturing pilot batches (two batches of 1 kg and two batches of 6 kg amounting to 14 kg in total). During this stage various intermediate substances were also developed and produced. The approximate cost of perindopril API at this stage was EUR [10,000–20,000]* per kg.[335]

(251) According to [company name]*, during this development process, no third party intellectual property encumbering the process was found, despite extensive research.[336]

(252) On […]*, [company name]* filed patent application […]* with the [nationality]* Patent and Trademark Office (EPO publication number […]*). The process developed by [company name]* only related to perindopril erbumine salt in alpha crystalline form.[337] However, when [company name]* developed its process and filed its patent application, no patents or patent applications claiming polymorphic forms of perindopril erbumine were in the public domain.[338]

(253) Since the mid-to-late 1990s, [company name]* had entered into cooperation agreements with [company name]*, another [nationality]* API producer, for the provision of certain services relating to logistics and administration management[339] or of commercial/marketing services, whether technical or involving the representation of products produced by either of the two companies.[340] No collaboration between the companies concerning the development of perindopril API was reported in a reply to a RFI.

(254) [Company name]*'s reply to the RFI of 12 December 2010 confirmed that *"[u]nder the terms of its collaboration with [company name]*, [company name]* has been able to market the possibility of sourcing perindopril to its customers, but [company name]* has sole responsibility for supply and development of the product. As part of those marketing activities, [company name]* has on various occasions queried*

332 ID5625, p. 4.
333 ID5625, p. 9.
334 ID5625, p. 4.
335 ID5625, p. 10.
336 ID5625, p. 6.
337 ID5625, p. 5.
338 ID5625, p. 6. The application for the '947 patent was only published in November 2001.
339 ID5625, p. 2, ID5459, p. 6, ID3304, p. 4.
340 ID2882, p. 6 - 7.

[company name] about the status of the product for the purposes of carrying out its marketing activities"*.[341]

(255) [Company name]* featured [company name]*'s perindopril in its product offer and initiated discussions with Teva concerning the supply/development of perindopril on the basis of [company name]*'s API. In spring 2001, Teva and [company name]* entered into negotiations with respect to a draft memorandum of understanding.[342]

(256) Roughly during the same period, according to [company name]*, initial contacts were established between Servier and [company name]*. After [company name]* revealed the source of the API, Servier initiated discussions for potential acquisition of [company name]*'s "*research efforts in this field*".[343]

(257) The discussions between Teva and [company name]*, contacts between Servier ([subsidiary of Servier]*) and [company name]* and the ensuing agreement between [company name]* and Servier, all of which concerned [company name]*'s API, will be presented in the subsequent paragraphs. [Company name]* was also contacted in August 2003 by Ratiopharm, who had understood that [company name]* *"deals with the API Perindopril"* and inquired about the API, formulation and project status.[344]

4.2.1.2 Teva's discussions with [company name]*

(258) In 1999, Teva entered into negotiations with [company name]* for the development and the supply of perindopril API. This led to the exchange of a binding draft memorandum of understanding for the development and supply of perindopril erbumine ("MoU")[345] in the first half of 2001. [Company name]* confirmed it "*had initial discussions with Teva regarding the possibility of an […]* supply agreement with Teva for the perindopril API*".[346] It appears that [company name]* was carrying out these negotiations on behalf of [company name]*.[347] The basic idea of the arrangement was that Teva would get access to [company name]*'s API for eventual commercial exploitation but in the meantime would assist in the development of the API itself.

(259) The preamble of the draft MoU[348] states that Teva was in the process of developing an EU registration dossier for 2 and 4 mg formulations of perindopril erbumine API manufactured by [company name]*. The key provisions of the draft are the following:

- […]* supplies: Teva would purchase the product from [company name]* for [EU territories]*[349] for […]* commercial use. […]*.
- Product development: […]* Teva would agree to provide […]* no later than September 2001.[350]

341 ID3293, p. 4 - 5.

342 ID2481, p. 2; ID3304, p. 5. [Company name]* also mentioned that it provided limited supplies of intermediates used in the production of perindopril erbumine API to [company name]*.

343 ID5625, p. 7.

344 ID1487, p. 238. Ratiopharm provided a copy of its email query sent to [company name]*, which was apparently left without any response.

345 ID2481, p. 2.

346 ID3304, p. 6.

347 ID4999, p. 3.

348 ID2477, p. 2 - 5.

349 Hungary was amongst 10 Member States acceding the EU on 1 May 2004.

- […]*[351] […]*[352], […]*.
- The MoU would be in force for [5–10]* years after Teva's first commercial purchase of perindopril API from [company name]*. […]*.[353]

(260) An email chain provided by Teva shows that Teva and [company name]* were still in discussions on 19 June 2001. In this email, [employee name]* of [company name]* commented on certain elements of the draft MoU. A subsequent internal email of Teva observed that certain provisions of the draft needed to be improved, […]*. In addition, the email recommends that […]* should be removed.[354]

(261) In reply to the Commission's question on Teva's timeline for possible development and marketing of perindopril based on API supplies from [company name]*, Teva estimated "*that the development of a generic version until regulatory submission would have taken approximately 2 years assuming the API would have been available"*. Teva's reply allowed for potential additional delays given "*the nascent nature of the relationship with [company name]**", including the absence of any material for testing, [company name]*'s "*abrupt termination*" and the generally unpredictable nature of pharmaceutical development.[355]

(262) Teva was unable to provide any signed versions or written responses to the above letter and draft MoU. According to Teva, "*[i]n July 2001 [company name]* suddenly ceased contact with Teva*".[356] This is reflected in the following email from Teva to [company name]* dated 11 July 2001: "*I understand that the Perindopril deal with Teva is not any more in your interest. Am I right? if i am wrong, please make quick progress to conclude the deal since each delay in the development makes the deal much less attractive for us. if I am correct please confirm that this is the situation, it is okay with us and we will take our own decisions regarding that Issue*" (emphasis added).[357]

(263) [Company name]*'s reply to the RFI of 10 December 2010 claims the reasons for [company name]*'s discontinuation of the negotiations were as follows:[358]

"1. [Company name] could not guarantee supplies of the product at that time (*[company name]* *understands that the product was still under development); and*

2. Teva had requested […], which would not have been acceptable to [company name]*, the party who would ultimately supply the product;*

3. In the latter stages of the negotiations, [company name] understands that Servier had already approached [company name]* to begin discussions regarding sale of*

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350 According to Teva's explanations, it was not aware of any work undertaken on that development schedule before [company name]* withdrew from the discussions. (ID3624, p. 4).

351 The Commission notes that if the agreement had been concluded, the second part of the price formula would have led to a self-contradictory outcome for all the situations in which […]*.

352 Ibid.

353 ID2477, p. 2 - 5.

354 ID3447. The draft was broadly aligned with previous correspondence between Teva and [company name]* dated 21 May 2001 (ID2477, p. 1).

355 ID3624, p. 4.

356 ID2481, p. 2.

357 ID3448.

358 ID3304, p. 6.

the IP, and [company name] had informed [company name]* that the company's focus would shift to that transaction.*

As a result of these factors, these discussions were never progressed seriously, and although a draft memorandum of understanding was created, no commercial deal was ever reached".

(264) [Company name]* confirmed that [company name]* informed [company name]* of its discussions with Teva. [Company name]* in principle showed interest in supplying API to Teva, in due course, although commercial production was not yet ready.[359]

4.2.1.3 Conclusion of the agreement between Servier and [company name]*

(265) In its reply to the RFI of 14 July 2010, [company name]* explained that it was contacted by Servier in early 2001. According to [company name]*, Servier inquired as to whether [company name]* was involved, or cooperated, in a project to produce perindopril API. [Company name]* denied this but pointed to [company name]*'s project. Consequently, Servier contacted [company name]* for further discussions.[360]

(266) It is noteworthy that an internal presentation by Servier of June 2006[361] discussing Servier's defense against generics, under the title "*Did it work?*", mentions that the first announcement of generic launch took place in early 2001 (the document mentions no corresponding actual entry). Timewise, this corresponds with contacts between [company name]* and Servier concerning [company name]*'s API.

(267) The discussions between Servier and [company name]* actually commenced towards the end of March 2001 and went on until July 2001, when an agreement on price was reached and preparations for a draft agreement started. Servier pursued the discussions and the subsequent acquisition through its wholly-owned subsidiary [subsidiary of Servier]*,[362] which was also at the source of the patent-related strategy initiated in 1999 described above. [Subsidiary of Servier]* will hereafter be generally referred to as Servier.

(268) The agreement for the sale of the patent application and a "chemical dossier" for perindopril API was formally concluded by [subsidiary of Servier]* and [company name]* on […]* 2001.[363]

(269) According to the preamble, [company name]* had developed a "chemical dossier" and applied for a patent for bulk API of perindopril, and Servier wished to purchase these "*in order to obtain the REGISTRATION and distribution of a pharmaceutical specialty containing PERINDOPRIL and manufacturing in the TERRITORY*".

(270) Pursuant to clause II, the subject-matter of the agreement is the sale of [company name]*'s patent application […]* to manufacture the API and the related "chemical dossier" to Servier.

(271) The patent application number corresponds[364] to publication number […]* "*[...]**" (the patent was granted to Servier in […]* but revoked […]*[365]). […]*.

359 ID4999, p. 3.
360 ID2882, p. 6, ID3304, p. 7.
361 ID0105, p. 172.
362 See sections 1.1 and 9.2.
363 ID2366, p. 110 - 117.
364 Priority filing date: […]*, publication date: […]*, source: […]*.

(272) "Chemical dossier" is defined in clause I of the agreement as consisting in "any and all data, information, technical documentation […] in relation to the [bulk active ingredient] and necessary or useful for the REGISTRATION of the pharmaceutical specialty containing the [bulk active ingredient] and manufacturing of the [bulk active ingredient]".

(273) In consideration for the transfer, Servier committed to pay [company name]* a total amount of USD [5–15]* million[366] (including [5–10]* % withholding tax), of which [80–90]* % was to be paid upon remittance of the dossier. In addition, Servier committed not to file legal actions against [company name]* for patent infringement prior to the effective date of the agreement.

(274) Clause III of the [company name]* Agreement contains extensive warranties by [company name]*, namely that:

– […]*;

– […]*;

– […]*;

– […]*;

– […]*;

– […]*;

– […]*.

(275) In addition, [company name]* also claimed that, as part of the [company name]* Agreement, it continued with the process and the development of the API, scaling up the process to an industrial scale of around [40–60]* kg.[367] This led to a continued relationship between [company name]* and Servier, which will be further described below.

(276) It should be added that Servier did not list this agreement, or provide a copy thereof, in its reply to question 12 the Commission's RFI of 16 January 2009, which required Servier to list all patents/patent applications which were acquired or licensed by Servier from 1998 onwards, and to send complete copies of such agreements.[368] The existence of this agreement came to the attention of the Commission only after it had asked additional specific questions in its RFI of 6 August 2009 based on an indication detected in inspection documents found at Servier's premises.[369]

(277) Once confronted with the omission, Servier described this as an "*oversight*". It claims that it nonetheless mentioned [company name]* in its reply to question 62 of the RFI of 6 August 2009.[370] Question 62 explicitly referred to the patent application acquired from [company name]*.

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365 See ID4683. According to this decision, the closest prior art consisted in the process for preparation of indolapryl, which had similar di-peptide chemical structure as perindopril. This process was the subject matter of a [nationality]* patent […]*, which was not held by Servier or [company name]*.

366 Approximately EUR [10–15 million]* at an average monthly exchange rate of USD/EUR 0.9111 for 9/2001 (ECB data).

367 ID5625, p. 4 - 5.

368 ID0364.

369 ID9972, p. 89; ID0110, p. 14.

370 ID3842, p. 31.

4.2.1.4 The parties' explanations for the rationale of the [company name]* Agreement

(278) Servier, the purchaser of the patent application, provided the following explanations regarding the nature of the acquired patent and its consideration for concluding the agreement:[371]

*"*European patent […]* filed on […]* was granted on […]*.*

The priority application was filed on […] by [company name]*, which assigned its rights to [subsidiary of Servier]* in accordance with the agreement signed on […]*/2001. The status of the patent is attached herewith.*

[...].*

The desired objective is the optimisation of […].*

The lesson of this patent has enabled us […].*

[…]".*

(279) In addition to the patent application, Servier also acquired the chemical dossier, the contents of which (laboratory note books, for the most part) were listed as an annex to the agreement.[372] Servier stated, however, that it did not have access to these laboratory note books prior to the conclusion of the [company name]* Agreement.[373]

(280) Servier provided a more detailed explanation in its reply to the RFI of 7 February 2011, according to which the [company name]* patent allowed it […]*. Perindopril erbumine is nowadays […]*.[374]

(281) According to Servier, the […]* savings […]*. Servier estimates that the savings […]* amounted to around EUR [50–75]* million for the period 2005 - 2011, as compared to 2004/2005 costs based on […]*. It also projected EUR [25–50]* million of additional savings in the three years to come.[375] However, no contemporary supporting evidence that such savings have actually been achieved or confirming their extent has been submitted by Servier.

(282) Servier has submitted a 2009 document entitled "*Assessment and prospects for development of the Perindopril production process*" ("*Assessment*") in response to the RFI of 16 January 2009,[376] and created during Servier's deadline for reply to that RFI.[377] The document refers to capacity constraints and [30–40]* % higher costs for the newly introduced arginine salt compared to the cost of perindopril erbumine. According to the document, cost reductions had been achieved as a result of […]* by "*our R&D teams*". The document sets out similar cost reduction calculations (same API prices) as those described in Servier's above reply, arriving at the conclusion that in six years of commercial exploitation, EUR [75–100]* million would be saved. The document did not, however, mention the [company name]* technology. Servier only

371 ID1151, p. 36 - 37.
372 See e.g. ID5121.
373 ID5064, p. 4.
374 Erbumine salt is decomposed to isolate perindopril in the free acid form which is then salified with arginine to form perindopril arginine API. ID3842, p. 23.
375 ID3842, p. 24.
376 ID0376.
377 ID3842, p. 25.

claimed that the […]* is based on the […]* in its reply to the RFI of 7 February 2011.[378]

(283) In reply to a subsequent RFI of 18 April 2011, Servier clarified that while the [company name]* technology provided precious indications on […]*, it did not provide for an operational method in view of Servier's industrial constraints (the [company name]* method used […]*, which is considered dangerous for stocking and use). This reportedly prompted Servier to change one of the reagents ([…]*) and accordingly amend its (originally [company name]*'s) patent application.[379]

(284) An undated presentation entitled "**10-year plan 2004-2014 [subsidiary of Servier]**" pointed to an expected strong growth for perindopril (including the switch to perindopril arginine) and the corresponding increase in production volumes. According to the presentation, this expectation justified investments in the production of perindopril and rendered the roll-out of […]* indispensable (productivity and cost were mentioned amongst relevant factors).[380]

(285) To achieve the abovementioned cost reduction, Servier states that the improved production process, reportedly based on […]*, has been in place for commercial production since 2006/2007.[381]

(286) In reply to the RFI of 18 April 2011, Servier provided information on the evolution of its internal costs for the production of perindopril API.[382] In the period 1996-2004, the cost per kg of perindopril erbumine API was EUR [1,000–2,000]*, which increased to around EUR [2,000–3,000]* in 2004/2005 and then decreased to around EUR [1,000–2,000]* in 2005/2006 and around EUR [1 300-1 700] in the period since 2006. The reported cost of perindopril arginine API fell from around EUR [2,000–3,000]* in 2005/2006 to EUR [1 700-2 100] by 2010.

(287) According to the abovementioned "**Assessment**",[383] further savings could be achieved on the basis of the acquired Krka WO 2005/113500 patent, yet it is mentioned that this would still require "**huge development work**". The document is even less specific concerning the Lupin WO 2005/037788 patent, which would be reportedly "**of great help for the success of this future optimisation**".

(288) It is noteworthy that the "**Assessment**" was drafted on 12 February 2009, i.e. during the period for reply to the underlying Commission's RFI of 16 January 2009.[384] This document is therefore not contemporaneous with any of the patent acquisitions, including the aforementioned [company name]* patent. However, Servier stated that no other similar studies or feasibility studies prepared prior to the patent acquisitions exist.[385] However, when asked if feasibility studies, including cost studies, were

[378] ID3842, p. 25.
[379] ID4517, p. 4.
[380] ID5068.
[381] ID3842, p. 24, ID4517, p. 4.
[382] ID4517, p. 3.
[383] ID376, p. 7.
[384] ID3842, p. 25.
[385] ID3842, p. 25. In Annex 13-01 to its reply to the Statement of Objections, ID9066, Servier provided two studies, one from early 2002 and the other from late 2003 to early 2005, to support the idea that the [company name]* technology was […]*. Nevertheless, such documents are posterior to the acquisition and thus cannot be considered as contemporaneous elements assessing, prospectively, the technical feasability – let alone the overall desirability and profitability – of acquiring and using this technology. Such an absence is conspicuous given the sum paid for the acquisition (USD [10–15]* million).

carried out in relation to another patent acquisition, [employee name and function with Servier]* concerning perindopril, stated in his oral explanations during the Commission's inspection at Servier premises on 25 November 2008: "**I find it hard to imagine that there is no clause […] which specifies that any contract signed takes effect without such analyses having been made"*.[386] While the question specifically referred to the assignment of Krka's patent applications, the answer is, in view of its general nature, relevant for any other patent acquisitions by Servier examined in this Decision.

(289) In its reply to the RFI of 4 October 2010, [company name]* presented the following considerations for entering into the agreement with Servier:[387]

"At the time the negotiations commenced, [company name] was a very small company (with only around 15 employees at the time) in a very precarious financial situation. [Company name]* perceived this as an opportunity to obtain a capital injection. Without such an injection of capital, the future of the company would have been more than uncertain, and in fact it might very possibly no longer exist. In addition, given that the agreement included the ability for [company name]* to continue its innovation efforts in this space, it was also regarded as positive from a business perspective.*

It should also be noted that Servier was not purchasing a finalised product or process from [company name], but instead was purchasing the results of [company name]*'s initial research into an alternative manufacturing process. As the process at that stage had not been fully developed to an industrial scale, it was by no means certain to [company name]* that its efforts would have resulted in an opportunity to compete in the marketplace for provision of the API concerned. Indeed, although [company name]* had applied for patent protection over its process, it was also not clear if this application would withstand challenge at a later date.*

In particular, given that its initial process development had led to a high cost method of production, it was by no means clear that, even if [company name] had been technically successful in its development, the end result would have been economically viable".*

(290) Furthermore, [company name]* explained how it approached the valuation of the rights transferred to Servier:[388] "*First, [[company name]*] attempted to see the acquisition from the perspective of the larger company and, second, [company name]* looked for the possibility of being able to continue manufacturing the API for Servier (which ultimately it did as part of a new product from Servier based on the new Arginine Salt, for which Servier later indicated that [company name]*'s API would be an input)*".

(291) [Company name]* also acknowledged that "*[t]he offer of [5–15]* million USD for the work undertaken represented a significant financial windfall for [company name]**".[389]

386 ID3443, p. 13.

387 ID5625, p. 7.

388 ID3293, p. 8. (initially ID5625, p. 7, the second point was later modified by [company name]* in reaction to a query by the Commission).

389 ID5625, p. 8.

4.2.1.5 Continued relationship between Servier and [company name]* after the [company name]* Agreement

(292) It follows from the information provided by [company name]* that the relationship between [company name]* and Servier went beyond the mere transfer of IPR as agreed in the [company name]* Agreement of 3 September 2001. [Company name]* was in further discussions with Servier from November 2001 onwards concerning "*the sale of [company name]*'s research efforts in this area, and agreeing a continuation of its innovation efforts in manufacturing"*.[390]

(293) As already mentioned in paragraph (275), [company name]* affirmed that *"as part of the agreement, [company name]* continued with the process and the development of the API, scaling up the process to an industrial scale (around 50 kg). […] Servier has however not played any role in the development of [company name]*'s manufacturing process"*.[391] Thus, while Servier changed […]* (and amended the acquired patent application accordingly),[392] [company name]* kept to its originally developed technology.[393] However, [company name]* understood the production cost following this process to be "very high", at least in comparison with Servier's cost for the API production.[394] [Company name]* maintained that its "alternative production method has never been competitive in price terms with Servier's".[395]

(294) According to [company name]*, "*the development of an alternative manufacturing process for perindopril was not interrupted and [company name]* has, at present, a highly robust process industrially speaking*".[396] Accordingly, […]*.

(295) As regards Servier, it appears […]* [company name]* […]* in […]*, [company name]*'s […]*: "**The [company name]* patent application […]*, and on the other to the supplement included in […]*, the result of the work […]* by Servier"*.[397]

(296) The continued development of [company name]*'s manufacturing process was, even after Servier's acquisition of [company name]*'s patent application, based on the transferred technology to which [company name]* formally no longer had any rights. Yet, Servier did not grant any formal licence or other waiver of its rights – [company name]* did not receive any formal assurance from Servier. [Company name]* has stated in this regard that "*as it was developing the process for, and ultimately*

390 ID5625, p. 6.

391 Servier argues (paragraphs 2022 to 2024 and 2036 of its reply to the Statement of Objections, ID10114, p. 564 and 567) that Servier made a *"*decisive contribution […] to the optimisation of the [company name]* technology"*, thus contradicting this statement by [company name]*. However, other elements of Servier's reply to the Statement of Objections seem to confirm [company name]*'s position that it continued development on its own: *"*After the acquisition by Servier of [its] technology [[company name]*] freely continued its research work in agreement with Servier"* (paragraph 2127, ID10114, p. 581); *"*the cooperation enabled Servier to secure an independent source of viable, good quality API "* (paragraph 2130, ID10114, p. 581, emphasis added); "**This fact is confirmed by [company name]*'s statements and by the contemporary documents*" (paragraph 2133, ID10114, p. 581). Indeed, even the documents provided by Servier in support of this claim of a "**decisive contribution*" (Annex 13-02 to the Servier reply, ID9066) illustrate a situation where [company name]* develops and produces independently to sell the API to Servier, who provides feedback on quality like any client.

392 See paragraph (283).

393 ID4999, p. 5.

394 ID5625, p. 5.

395 ID4999, p. 3.

396 ID5625, p. 5.

397 ID3842, p. 33. This is also confirmed by Servier's spontaneous submission of an expert testimony, which indicates that Servier […]* (ID10631).

supplying API to, the rights holder, no formal assurance was regarded as necessary".[398] [Company name]* was unable to provide any supporting documents.[399] According to Servier, "**[Company name]* was authorised to exploit the technology concerned in the context of the orders placed by Servier*".[400] No further documentation explaining the legal basis of this "**authorisation* " was provided by Servier.

(297) Also, the agreement for the subsequent supply of the API to Servier (and to undertake the necessary further R&D even after Servier acquired [company name]*'s process) was – according to the parties – of an informal nature, "*based on purchase orders and invoices only"*,[401] although it generated a significant income over a number of years compared to [company name]*'s overall turnover.

(298) Specifically, [company name]* and Servier, through its subsidiary [company name]*, maintained a relationship for the supply of perindopril erbumine API produced by [company name]* following the process it developed, as an […]* Servier's […]*.[402]

(299) Servier explained that, as perindopril was a major product for the company, it was important to secure supplies of the API in case of an industrial breakdown. [Company name]* was seen as best placed to ensure the continuity of supplies in case of need or to complement possibly insufficient production capacities. This was the reason why, on the one hand, Servier assisted [company name]* in obtaining a European Pharmacopoeia Certificate ([…]*) and, on the other hand, maintained a business relationship with [company name]*.[403] Table 7 below shows that [company name]* was supplying commercial batches of perindopril erbumine API long before this Certificate was obtained; according to Servier, these batches were used for the development and the production of […]*.[404]

(300) Accordingly, [company name]* sold all its reported production of the API from 2002 - 2010 to Servier (specifically, to its subsidiary [company name]*).[405] The quantities and income from [company name]*'s sales of perindopril erbumine API to Servier were reported as follows:[406]

398 ID3293, p. 9.
399 ID3293, p. 8 - 9.
400 ID3842, p. 36.
401 ID3293, p. 9.
402 ID5625, p. 5.
403 ID3842, p. 34.
404 ID5064, p. 5.
405 ID5625, p. 10-11.
406 ID5625, p. 10-11. Price ranges based on the Commission's own calculations.

Table 7: [Company name]*'s perindopril API supplies to Servier

Year	Kg	API income	API € per kg	Year	Kg	API income	API € per kg
2001	0	0	-	2006	[650-700]	[4.0-4.1 million] EUR	[5,000-7,999]
2002	[150-200]	[1.6-1.7 million] USD	[8,000-12,000][407]	2007	[500-550]	[2.8-2.9 million] EUR	[5,000-7,999]
2003	[200-250]	[1.8-1.9 million] USD	[5,000-7,999][408]	2008	[550-600]	[2.9-3.0 million] EUR	[5,000-7,999]
2004	[100-150]	[650,000-750,000] EUR	[5,000-7,999]	2009	[400-450]	[2.2-2.3 million] EUR	[5,000-7,999]
2005	[400-450]	[2.1-2.2 million] EUR	[3,000-4,999]	2010	-	-	-

Source: ID5625, p. 10-11.

(301) For the sake of comparison, the cost of Servier's in-house production of perindopril erbumine was approximately in the region of EUR [0–5,000]* per kg.[409] [Company name]* added that, in view of the reduced volumes of its API sales of perindopril erbumine to Servier, it understood "*that the API manufactured by [company name]* has never been commercialised as a generic finished product*".[410]

(302) Thus, [company name]* supplied a total of [2,950-3,350] kg of perindopril erbumine API to Servier and received payments totalling approximately EUR [18-18.9] million. Combined with the payment stemming from the [company name]* Agreement (approximately EUR [5–15]* million), the total amount of perindopril-related payments from Servier to [company name]* amount to roughly EUR [28.9-29.8] million for the period 2001-2009. The total turnover of [company name]* in its entire production of API ([…]*) amounted to EUR [75–100]* million in the period 1997-2010.[411]

(303) [Company name]* claimed it "*has not had any commercial dealings with any company other than [subsidiary of Servier]* in respect of the perindopril API*". Although it made a series of offers to potential clients throughout 2010, it had not received any request for perindopril API from any other pharmaceutical company.[412]

(304) At the same time, however, [company name]* recognised in a later reply that the sale of its process technology was a limitation for [company name]*'s ability to supply the API to third parties. "*After signing the agreement, any supply of API based on this process would therefore have been "at risk" absent a license to or waiver of those rights by Servier*". [Company name]* would only be free to sell API if it had developed a new alternative process not covered by other parties' IPRs, which was not the case.[413]

407 At an average yearly exchange rate of 0.9456 USD/EUR for 2002 (ECB data).
408 At an average yearly exchange rate of 1.1312 USD/EUR for 2003 (ECB data).
409 ID4517, p. 3.
410 ID5625, p. 5.
411 ID5625, p. 3, 10, 11.
412 ID5625, p. 11.
413 ID3293, p. 9.

(305) [Company name]* confirmed that it never started a new project for the development of alternative perindopril API technology: "*Given the ongoing development and supply relationship with Servier, and the difficulties associated with developing a new process in the light of the ['947] patent application, there would have been no commercial sense in [company name]* developing an alternative process*".[414] [Company name]* noted that the new development process, if similar to the development of the transferred API technology, would take approximately 2 years.[415] This would in addition, however, need to take into account the changes in, for example, the company's freedom to operate, which was affected by the '947 patent.

4.2.2 Azad

(306) On 9 November 2004, Servier and Azad concluded an agreement ("the Azad Agreement"), in which Servier's aim to "*strengthen the defense mechanism for its own alpha, betha and gamma forms of Perindopril*" was explicitly recognised. This chapter presents the underlying facts in more detail.

(307) In its replies to the RFIs of 5 August 2009,[416] and of 10 December 2010,[417] Azad,[418] provided clarifications and contemporaneous documents (agreements, Court submissions, an invoice), but no internal Azad documents. Azad itself has given a minimal amount of information about its initial research and development of perindopril as well as subsequent events.

4.2.2.1 Azad's development of perindopril API

(308) From the available information, it transpires that Azad developed perindopril at its own risk and expenses. Azad also generated its own know-how. Azad was developing delta and epsilon polymorphic forms of perindopril erbumine not covered by Servier's patents, for which a patent application had been filed[419] on 24 June 2003 (publication number EP1636185; the EPO patent was granted in January 2012).[420] Azad was commercially developping the delta form of perindopril.

(309) The initial research for Azad was carried out at the Institute of Organic Chemistry of the University of Zurich, which also produced initial laboratory batches of perindopril API.[421] Azad explained that, during the development period, it used Cilag[422] as a contract process developer for its perindopril project and as a contract manufacturer for two perindopril intermediates.[423]

(310) According to Azad, it started to produce, through a contract API manufacturer in Taiwan (China Chemical Synthesis Industrial Co., Ltd, Taiwan, or "CCSB"), pilot and industrial batches of the perindopril API[424] in 2004. However, API purchases by

414 ID4999, p. 5.
415 ID4999, p. 5.
416 ID1112.
417 ID3343.
418 See section 1.3.1.
419 ID1112, p. 7 and 9.
420 See https://register.epo.org/espacenet/application?number=EP04737029.
421 ID3343, p. 5.
422 Cilag AG is a company operating in Switzerland, integrated in the Janssen pharmaceutical companies of the Johnson & Johnson group of companies.
423 ID3343, p. 7.
424 ID1112, p. 2. In its later reply to the RFI of 10 December 2010, Azad claimed that the contract manufacturer "*produced several pilot batches of Perindopril API for testing purposes only*". ID3343, p. 5.

Arrow and Teva suggest that the production of pilot batches started by November or December 2003.[425] Azad planned to sell commercial batches of perindopril API at USD [20,000-35,000] per kilogram.[426] Several companies, including Arrow, Teva and Sandoz, had expressed interest in purchasing perindopril API from Azad, signed secrecy agreements and received product samples by the time of the Azad Agreement (for further details, see below section 4.2.2.3).[427]

(311) An email of 2 September 2004 from Azad to Servier sent in the framework of Servier's due diligence of Azad's technology (see paragraphs (363) - (364)), recognises that pilot plant batches were produced to support MA applications of Azad's customers, and refers to pilot batches produced for Azad by its contract partners (CCSB and Laboratory for Process Research of the University of Zurich) in April and May 2004. Azad also explained that "*commercial manufacture will have a significantly larger batch size, 50kg"*.[428]

(312) According to Azad, scaling up for industrial quantities[429] and preparations of the DMF[430] were on-going in autumn 2004, but were apparently not completed as the API development was stopped altogether upon Servier's acquisition of Azad's technology as described below.

4.2.2.2 Azad's alleged difficulties in development

(313) Azad claimed that the company encountered many problems in the development of the perindopril API due to: "*a) the on going difficulties […] [with] the production of validated commercial batches of the active pharmaceutical ingredient of Perindopril, b) the uncertainty concerning the adequate stability data of the batches, c) the inability to secure purchasing orders from interested generic customers and last but not least d) its limited financial resources*".[431] These were also the alleged reasons why the company "*decided to exit the Perindopril project and offered its 2patents to Servier on June 28, 2004"*.[432]

(314) Azad's *ex post* claims concerning the alleged problems with its perindopril project must be set against Azad's contemporaneous statements. In an email provided by Azad's then cooperation partner, Teva, dated 10 August 2004 ([…]*), Azad explained that "*the last batch of intermediates caused an out-of-spec regarding an impurity […] we now know that the spec for isomeric purity for one of the key intermediates was set too wide by our development partners. […] So now we have had to order more intermediates from our supplier at the narrower spec. in order to replace the failed batches. […] This is a very unfortunate and unexpected occurrence and was out of Azads control. However, we have made sure that it won't happen again"*.[433]

425 See paragraphs (324) and (333).
426 ID1112, p. 2.
427 ID1112, p. 8.
428 ID0104, p. 237 - 238.
429 ID1112, p. 9.
430 ID0104, p. 241.
431 ID1112, p. 7.
432 ID1112, p. 7.
433 ID3454, p. 4.

(315) On 14 September 2004, after Teva further inquired about its open order,[434] Azad explained that the intermediates had been ordered in August 2004 and that they were hoping that they would reach CCSB by November, even if this involved paying a premium price to one of the two suppliers.[435]

(316) In the context of the aforementioned due diligence, Azad transmitted a study to Servier demonstrating that, "*the [Azad API] material is slightly hygroscopic and that the delta polymorph is s**table** under both ambient and dry (sealed) condition*".[436] Azad furthermore provided a further stability study on perindopril delta[437] which showed that the API was stable at 25°C and 80% relative humidity, but partial conversion to beta crystalline form was possible at 25°C and 90% relative humidity. On this basis, the following conclusion was reached: "These data indicate that commercial delta perindopril will be stable under routine shipping and storage conditions, and that commercial delta perindopril will not contain beta perindopril".

4.2.2.3 Azad's development discussions with generic companies

(317) Prior to the assignment of its patent application and related know-how to Servier in November 2004, and as already mentioned above, Azad discussed the possibility of entering into development partnerships with other generic companies. However, without providing further explanations or supporting documents, Azad claimed in reply to a RFI that these companies were not interested in committing themselves during these negotiations.[438]

(318) This appears to directly contradict the information provided by the generic companies. At least two of them, Teva and Arrow, have even received significant compensation payments from Azad following the disruption of the collaboration due to the agreement with Servier (as further explained below).

(319) Given the limited cooperation provided by Azad, the following overview of Azad's cooperation with generic companies will principally rely on more elaborate information provided by operators who themselves claimed that they had manifested interest in cooperation on perindopril with Azad.

4.2.2.3.1 Arrow's cooperation with Azad concerning perindopril

(320) In contrast to Azad's submissions, the reply by the Arrow Group,[439] a generic company who had cooperated with Azad concerning perindopril, to the Commission's RFI of 5 August 2009[440] provides more details and substantiation of the situation at the time.

(321) According to its reply, Arrow had been actively seeking to develop perindopril since 2002 and intended to launch products in numerous countries. Its commercial rationale for this was to "*secure the advantages of being the first generic product to market*".[441] Before the Azad Assignment Agreement was concluded, in 2003/2004 Arrow Group considered itself to "*likely be the first or an early entrant into several*

434 The email exchange between Teva and Azad also refers to an earlier order that was delivered and considered closed (ID3454, p.3 - 10).
435 ID3454, p. 3.
436 ID0104, p. 241.
437 ID0104, p. 254 - 277.
438 ID1112, p. 6 - 8.
439 ID1571.
440 ID0919.
441 ID1571, p. 7.

of the markets […]" on the basis of the Azad API,[442] which was seen as "*the most attractive option for development*".[443] According to Arrow, Azad supplied Arrow with perindopril API, and was preparing a DMF for perindopril API, which was necessary to obtain MAs for Arrow's finished generic perindopril based on Azad's API.[444]

(322) Arrow's endeavours to develop a product using Azad's perindopril API are described in the reply to question 17 of the said Commission request.[445] According to Arrow, initial discussions started as early as February and July 2002, during which Azad Fine Chemicals, Azad's marketing arm, indicated that it was developing perindopril API. In December 2002, Azad Fine Chemicals expressly inquired if Arrow would be interested in using Azad as a perindopril API supplier. Arrow expressed interest in such an arrangement and signed a confidentiality agreement with Azad on 5 May 2003.[446] While Arrow's subsequent analysis of the API showed traces of beta polymorphs among the delta polymorphs, which would contradict Azad's claims that its API did not infringe Servier's polymorph patents,[447] Arrow nonetheless considered Azad to be an attractive supplier of perindopril in delta polymorphic form given that other sources (e.g. Sochinaz SA/Cipla) involved a pure alpha polymorphic form, which Arrow considered to infringe the '947 patent.[448]

(323) In August 2003, Azad issued a declaration of non-infringement for its perindopril erbumine, which was joined to Arrow's reply to the RFI.[449] In a five page declaration, Azad listed the relevant patents and patent applications, and explained for each such patent/application why, to the best of Azad's knowledge, its API was not patent-infringing. In particular, Azad explained that it differed from the alpha polymorphic form.[450]

(324) In June 2003, Azad had already reportedly informed Arrow that the perindopril API production would start in autumn 2003. Hence, Arrow ordered [0-10] kg of API in approximately July 2003. Arrow pressed Azad for supplies, and the latter invoked difficulties producing a consistent polymorph (for example, the delta polymorph sometimes converted to the alpha polymorphic form[451]). In approximately December 2003, Arrow received a substantial sample. According to Arrow, "*the sample was not just a promotional one, i.e. it was large enough for development*".[452] Arrow then began extensive testing on this sample, including that of bioequivalence. As a result of its inquiries, Arrow became concerned that the water content exceeded the European Pharmacopoeia requirements and that residual solvents were also

442 ID1571, p. 12.
443 ID1571, p. 17.
444 ID1571, p. 16 -18.
445 ID1571, p. 16 - 20.
446 ID1570, p. 16 - 20.
447 ID1571, p. 17. Subsequent evidence shows that this concern was transitory because later analysis did not show traces of beta polymorphs, see paragraph (325).
448 ID1571, p. 17.
449 ID1570, p. 9 - 13.
450 The following patents/applications relevant for the EU are referred to in the Declaration: EP 0049658 B1, EP 0308339 B1, EP 0308340 B1, EP 0308341 B1, EP 0309324 B1, EP 1256590 A1, EP 1279665 A1, EP 1319668 A1, EP 1321471 A1, WO 96/33984 A1, WO 01/56353 A2, WO 01/56972 A1, WO 01/58868 A1, WO 01/83439 A1 (gamma polymorph), WO 01/87835 A1(alpha polymorph), WO 01/87836 A1 (beta polymorph).
451 ID5080, p. 1 and 5.
452 ID1571, p. 17.

present in the API. There were further extensive discussions between the companies.[453] It was unclear what the regulatory implications of not meeting the European Pharmacopoeia specifications would be.[454]

(325) In February 2004, Arrow selected a formulation method that avoided the conversion of the delta form into other forms.[455]

(326) In June 2004, Arrow ordered [5-15] kg of perindopril API from Azad. According to Arrow, Azad had difficulties in fully meeting this order, due, in particular, to delays in the supply of an intermediate compound for the production of perindopril API.[456] It is noteworthy that this order took place only days before Azad had reportedly decided to offer its perindopril API technology to Servier due to, amongst others, its alleged inability to secure purchasing orders from generics.

(327) Arrow successfully completed a US bioequivalence study in 2004 and was planning to launch the EU bioequialence study. According to Arrow, Azad was expected to provide a DMF to Arrow for the purpose of marketing authorisation procedures. In September 2004, an extensive discussion took place between these companies concerning the timing of the submission of the DMF to the UK and the Portuguese authorities. Arrow claims that it pressed for early filings and that Azad delayed the procedure.[457] Arrow expected that the European DMF could be filed by February 2005.[458]

(328) Azad did not provide any contemporary documents in this respect but explained that it had mostly oral contacts with Arrow concerning problems of deliveries, delays and the deficiencies of pilot batches produced by CCSB. It confirmed its awareness that Arrow (and others) was "*interested to prepare regulatory files for submission of dossiers, based on Azad API*", yet claimed it was not aware of the progress by the companies.[459]

(329) In November 2004, Azad informed Arrow that Azad would not supply its product or its DMF to Arrow for any territory (the Azad Assignment Agreement was entered into with Servier on 9 November 2004). In response to this, Arrow sent Mr Mike Baronian (CEO of Azad) the following email dated 29 November 2004:[460]

"Dear Mike

Following my conversation with Regina, it is now clear that you are refusing to supply us with a DMF and product for the whole world including the US.

You told me in our telephone conversation that you had done a deal with the brand[461] *to stay off the market in Europe, however I understood that you were going to supply us for the US.*

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453 The water content issue also emerged in Azad's discussions with Niche, in the context of which Azad reported that the problem would be addressed by sealing the material immediately after drying, and that the material was stable at < 0.1% of water. ID0025, p. 154.

454 ID5080, p. 6.

455 ID5080, p. 4.

456 ID1571, p. 17.

457 ID6602, p. 18.

458 ID5095.

459 Reply to the RFI of 10 December 2010, ID3343, p. 9.

460 ID1570, p. 15.

461 According to Arrow, the reference to "the brand" stands for Servier. See ID1571, p. 18.

I find this not just surprising but out of character. We have had a very good relationship with you. You have always supplied samples, development materials and DMFs on a number of other products and we thought we had built up a confidence with you. On this particular project we have worked even closer discussing patents, testing polymorphs etc.

It is especially shocking and disappointing after all the work we have put in and which you were aware of that you have pulled the rug. […]"

(330) According to Arrow, Azad never responded to this email.[462] However, Arrow and Azad had a meeting in this regard on 7 December 2004. Arrow submitted internal minutes of that meeting.[463] The minutes report that Azad initially indicated that the perindopril project was discontinued for financial reasons. Representatives of Arrow expressed their surprise about this explanation and referred to previous contacts with the CEO of Azad as set out in the above email. Arrow also requested Azad to provide it with the "*DMF which was almost ready*". According to the minutes, Azad representatives first denied a deal, but after further discussions admitted that a deal had been done. Arrow then expressed discontent and announced legal action.

(331) The termination of the cooperation, and the non-supply of the DMF and API by Azad to Arrow,[464] led the latter to start legal proceedings against Azad and Servier pursuant to which Arrow claimed damages of USD [low nine digit figure][465] which is described in more detail in section 4.2.2.7.

4.2.2.3.2 Teva's cooperation with Azad concerning perindopril

(332) According to Teva, its contacts with Azad began around April 2003.[466] Azad had novel delta and epsilon polymorphs for which Teva received from Azad two sets of technical documentation ("Technical Package") in June and November 2003. It also received an "*undated declaration of non-infringement from Azad*", which assumingly corresponds to the one referred to by Arrow. Azad's API contract manufacturer, CCSB,[467] provided Teva with various certificates of analysis during Teva's examination of the suitability of the product.

(333) Teva was developing a full dossier for perindopril,[468] and purchased [quantity]* of API in November 2003 and [quantity]* of API on 10 June 2004. Further orders amounting to [quantity]* were still outstanding in August 2004, when Azad reported that the batches failed and explained that the problem (out-of-spec impurity) was identified and addressed by narrowing the specifications for the intermediates used. To remedy this, Azad was willing to pay premium prices for those higher quality intermediates in order to ensure that the production of further batches could start in November 2004.[469]

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462 ID1570, p. 17.

463 ID1570, p. 17.

464 ID1571, p. 19.

465 ID0104, p. 172-176.

466 Reply to the RFI of 7 July 2010, ID2481, p. 4.

467 The company name does not fully correspond to the one provided by Azad, i.e. China Chemical Synthesis Industrial Co. Ltd, Taiwan, but matches the acronym used by Azad (CCSB).

468 According to Azad, Teva took a number of steps to develop a full administrative dossier required to obtain a MA for generic perindopril. Teva established an analytical method to test the API purchased from Azad, produced several lots of finished doses, run the stability analysis and started the bioequivalence studies (ID3343, p. 7-8).

469 ID3454, p. 3 - 6.

(334) Several, mainly oral, contacts were made regarding the upscaling of production, the quality and stability of Azad's perindopril API, purchases and possible purchase orders (Azad however provided no evidence of these contacts). Azad was also aware that Teva was undertaking bioequivalence studies for the EU and [non-EEA jurisdiction]* based on Azad's perindopril.[470]

(335) At the time Azad terminated its co-operation, Teva also completed a bioequivalence study for [non-EEA jurisdiction]* using Azad's API. Like Arrow, Teva did not report any major difficulties with the development of Azad's perindopril API.[471]

(336) Teva contacted [company name]* by email on 21 October 2004 announcing that it intended to submit Perindopril Tablets to […]* markets, [non-EEA jurisdiction]* and EU, and requested [company name]* to provide it with a […]* ([…]* for the purpose of [non-EEA jurisdiction]* regulatory proceedings before the [non-EEA administration]*).[472] Teva copied Azad on this email.

(337) In November 2004, Teva itself issued a signed Certificate of Analysis for "*Perindopril Tert-Butylamine (Ph.Eur.)*" based on API supplies from [company name]*.[473] The reference to European Pharmacopoeia suggests this certificate was prepared for the purpose of EU regulatory filings. The Certificate lists the tests carried out on the basis of Azad perindopril and demonstrates that the substance conformed to the required specifications of the European Pharmacopoeia, which was later explicitly confirmed by Teva.[474]

(338) More generally, Teva has explained, on the basis of contemporaneous documents and the recollection of its staff, that while there were potential technical issues that Azad's API confronted (solvent used, water content, product purity), "*Azad took all the necessary steps to overcome these issues. Teva's recollection is that none of the technical issues in question would have posed insurmountable problems relative to the project"*.[475]

(339) However, in October 2004, while Teva was preparing the regulatory filing for [non-EEA jurisdiction]*, "*Azad suddenly stopped cooperating with Teva and the relationship was terminated*". The termination of the relationship by Azad was not documented in writing beyond an email from Azad's [name of individual]* of 15 November 2004.

(340) This email contains an exchange concerning Teva's preparations to request regulatory approval [...]* with [non-EEA adminsitration]*. To this end, Teva requested a […]* on 15 November 2004 mentioning that the [non-EEA application]* would take place in a "*couple of weeks*". Azad's reply was ambiguous: "*[…] I just spoke to my boss, Mike Baronian about this. I'm sure you know the situation. All he told me is that he is looking into it. I'm sorry I cannot give you more information at this time. I think your boss(es) are in contact with Mike about this issue"*.[476]

(341) According to Teva, at the time Azad terminated its cooperation with Teva, " Teva had not started the EU bio-study since it was awaiting for completion of the [non-

470 ID3343, p. 7 - 9.
471 ID3624, p. 7.
472 ID3451, p. 1.
473 ID3452.
474 ID5055, p. 2.
475 Reply to the RFI of 10 December 2010, ID3624, p. 7.
476 ID2479, p. 1 - 2.

EEA jurisdiction]* study and in any event needed additional samples from Azad for the purposes of submission in the EU".[477] According to Teva, these additional samples were needed because EU regulatory standards require the provision of six months stability data of two batches from each strength, unlike the [non-EEA jurisdiction]* which only requires one. As a result of Servier's acquisition of Azad's patent application and the related know-how (the "*Azad Technology Acquisition*"), these additional batches were never provided.[478]

(342) Azad and Teva discussed the conditions of the termination of their cooperation.[479] Subsequently, Azad honoured Teva's request for reimbursement of cost of around USD [0.5 - 1.5] million due to Azad's late termination of the cooperation. This is further described in section 4.2.2.7. The following internal Teva communication dated 23 July 2008 sheds light on Teva's understanding of the situation:[480] "*they provided [u]s material, we performed biostudy then they faced financial difficulties due to Fosinopril price erosion they didn't expect in the USA so couldn't refuse the offer to have several good millions for their process/polymorph so stop[p]ed support us. they compensated us for all the expenses we had (I think more than $*[0.5 - 1.5 million]*)"*.

(343) According to Teva, it was "faced with a problem as it had no development or supply agreement in place with Azad".[481] Teva stated that, "if its collaboration with Azad had continued, it may have been able to make a regulatory submission in Europe in the first half of 2005" and the launch could be expected in 2007.[482] As with [company name]*, Teva explained that a broad range of issues (technical/regulatory/legal) may generally impact on the success of a project in the pharmaceutical sector.[483]

(344) In an internal communication from 3 October 2005, Teva recognised that sourcing independent APIs was increasingly problematic: "*The position with Perindopril is very complicated in terms of patents - particularly process patents which affect API manufacturers. This is partly why everyone is late (once an API manufacturer has got round the process patents Servier has bought the company, sourcing API has been very difficult)*".[484]

4.2.2.3.3 Other companies which had been cooperating with Azad

(345) Cimex Development of Switzerland (now part of Acino Pharma AG, Switzerland) was offering a perindopril formulation with API not covered by Servier's patents in the course of 2004. Acino Pharma AG's submissions to the Commission[485] confirmed that the development project was based on cooperation with Azad. In June 2004, Azad reportedly asked Cimex to develop a pharmaceutical formulation of perindopril erbumine in a new crystalline form but, according to Acino Pharma, "*[t]here was never even a contract between Azad and Cimex*". After the first contact with Azad, Cimex outsourced the pharmaceutical development to another company. In

477 Reply to the RFI of 10 December 2010, ID3624, p. 7.
478 ID3624, p. 7, ID3454, p. 3 - 9.
479 ID2480.
480 ID3459, p. 4.
481 Reply to the RFI of 7 July 2010, ID2481, p. 5.
482 ID5055, p. 2.
483 ID3624, p. 4 and 6.
484 ID0082, p. 70
485 ID3137, p. 2.

September 2004, Cimex Development offered the product via email to, amongst others, Ratiopharm and [company name]*.[486] According to Acino Pharma, [company name]* was amongst the companies which expressed an interest.

(346) In early December 2004, the development cooperation with Cimex was terminated by Azad before the report on the first results of the development was ready: "*The reason given by Azad was that there was new information on major price cuts of ACE inhibitors on the European market and that customers of Azad had indicated that the product is no longer of interest for them. Therefore Azad had decided to stop the development of the product".*

(347) Krka also had discussions with Azad as a promising cooperation partner with an independent process / polymorph which could have led to product launches in Krka's traditional markets.[487] The Azad synthesis was considered to be "**long and complex […], for which very pure intermediates were necessary […]*".[488] Azad proposed that, after stability had been confirmed and Krka had evaluated the sample, Krka would order the quantity of API needed to conduct certain pre-formulation studies. Krka evaluated that the epsilon perindopril crystalline form converted into the alpha form covered by the '947 patent[489] (the Commission recalls that Azad developed its API on the basis of the delta and not the epsilon form). Therefore, "*[i]n view of expected nullification of alpha patent the source has been declared not worthwhile to proceed*".

(348) As described in section 4.3.1.1, Niche was developing a finished dosage form perindopril based on the API developed by its cooperation partner Matrix. In the period May 2003 – November 2004, Niche considered Azad as a possible back up source of API for Niche and the preparation of a DMF was discussed between those two companies.[490]

(349) Although Niche flagged several possible problems to Azad, none of them was of such nature as to bring their cooperation to an end. On the contrary, Azad was a valid option for Niche until the deal between Servier and Azad occurred as will be shown below.

(350) The question of the water content in the API was raised by Niche in February 2004. The Azad material was claimed to be hygroscopic, and was more stable at 2% rather than 0.5% water content. It was recognised that such a product would not comply with the European Pharmacopoeia specifications (limit of 1%) and Azad was examining ways to have these specifications amended. This issue was however resolved. In July 2004, Azad's API was said to comply with the European Pharmacopoeia standards, as the water level would be below 1%. According to Azad, the material was still hygroscopic, but the sealing of the material would be carried out immediately after drying.[491]

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486 See, for example, ID1487, p. 63 - 66.

487 ID0045, p. 119.

488 Courtesy translation of the original text: "*gre za dolgo in kompleksno sintezo perindoprila, za katero potrebuješ zelo čiste intermediate*", ID0045, p. 118.

489 Reply to the RFI of 5 August 2009, ID1307, p. 101-102.

490 ID0025, p. 153-159.

491 ID0025, p. 158.

(351) In June 2004, Medalia, an agent for Azad, informed Niche that Azad already knew that its polymorph was stable for several months. Medalia explained that validated API would be available in August 2004.[492]

(352) It appears that, at the time, Niche was involved in a comprehensive examination of Azad's API to which the latter referred as "due diligence". Niche's scientists considered the option of keeping Azad as a back up/second API supply source but considered the possibility that the Azad API included a mixture of alpha and beta covered by the Servier patents. On the other hand, Niche's patent attorney confirmed it was "*highly unlikely*" that the Azad material would infringe any of Servier's patents. As Azad's API contained a different polymorph, Niche would possibly need to undertake another bioequivalence study. The DMF was expected by the beginning of 2005.[493]

(353) In an email of 2 November 2004 to Niche, Ratiopharm, which was discussing supply of finished perindopril formulation from Niche, insisted on including Azad API as a back-up to Matrix API in Niche's dossier.[494] Ratiopharm considered Azad API as potentially appropriate,[495] but both Matrix and Niche were rather reluctant for commercial reasons to include Azad, their competitor, as their second source of API.[496] Ratiopharm sought an update from Azad on 10 November 2004, a day after the conclusion of the Azad Assignment Agreement, and on 11 November 2004, started to look for new sources of API.[497]

(354) Specifar, a Greek company, initiated the development of perindopril using the delta form of perindopril erbumine API from Azad in 2004. By the end of October 2004, Specifar had two licensing partners in the EU for perindopril (Alternova and Ratiopharm).[498] According to Specifar, pilot batches (4.95 kg at a price of USD 40,000, or around EUR 31,400, per kg) were (successfully) manufactured and supplied to Specifar in September 2004.[499] However, in autumn 2004 Azad informed Specifar that it was no longer in a position to continue the supply of the active ingredient. Therefore, Specifar had to find another source of API and, in 2005, initiated development based on Glenmark's API in alpha form of perindopril erbumine (further facts on Glenmark and Arch Pharmalabs are presented below).[500]

(355) According to Specifar, it expected to apply for MAs in May 2005, and an average duration of these proceedings was estimated at 1.5 - 2 years, which would have allowed for market entry by the first half of 2007.[501]

(356) In reply to Question 16 of the RFI of 9 July 2010 inviting Specifar to identify operators who have developed a viable alternative technology in the period 2000 - 2009, Specifar stated the following: "*To the best of our knowledge, the only operator*

492 ID0025, p. 156.
493 ID0025, p. 155-156.
494 ID1709, p. 29.
495 ID1481, p. 30.
496 ID1709, p. 29.
497 ID1487, p. 106.
498 ID2428, p. 14.
499 ID4759, ID4760 and ID2428, p. 6. Reference to "successful" added in the main text as Specifar's reply distinguishes between successful pilot batches (Azad, Glenmark) and unsuccessful ones (Arch Pharmalabs).
500 ID2428, p. 2-3.
501 ID5004, p. 2.

that fits the described criteria (patent-free with regards to EP1296947, stable, industrially applicable, able to support a marketing authorization application, economically sustainable) is Azad".[502]

(357) PharOS, another Greek company, was also amongst the companies which were developing perindopril formulations based on Azad's API. According to PharOS's email to Ratiopharm dated 19 August 2004, their development was still at an early stage due to the delay of the needed API quantities from the supplier (Azad). PharOS added that, according to their knowledge:[503]

"the first commercial batches [from Azad were] supplied for the US development to one Israel company and one batch to one Canadian developer (Arrow). The third batch was delivered to Specifar. Anyhow we have already made [trials] on the API and we trust we have a stable formulation. As soon as we receive the two outstanding batches we will be able to [deliver] 6 months later […] the dossier".

4.2.2.4 Discussions between Servier and Azad leading to the Azad Assignment Agreement

(358) Notwithstanding its cooperation projects for the development of perindopril as described above, Azad claimed it had many problems and thus decided by 28 June 2004 to abandon the projects and pursue negotiations with Servier on the sale of its perindopril related IPR. On the same day, the companies signed a confidentiality agreement concerning the possible purchase by Servier of Azad's IP rights.[504]

(359) Negotiations between Azad and Servier started at the latest by August 2004. On 27 August 2004, a letter of intent between Azad and Servier[505] was signed by [employee name]* for Servier and Azad representatives. The document bears the marking "*041342/[employee name of Servier]*/[employee name of Servier]**" and appears to be prepared by Servier, as the acronym [employee name of Servier]* appears to refer to [employee name]* of Servier, who is also associated with other Azad drafts,[506] as described further below.

(360) The preamble to the letter of intent states that Servier was interested in analysing the synthesis process and delta and epsilon polymorphic forms developed by Azad for the manufacture of perindopril erbumine ("the Azad Process") "*in order to possibly purchase all AZAD intellectual property rights relating to that process*". The preamble also acknowledged that Azad was "*producing and selling kilo quantities [of perindopril erbumine] to third parties*".

(361) Clause I of the letter of intent envisages that Servier would carry out a due diligence process concerning the Azad Process. Against the payment of a non-refundable sum of USD 5 million, Azad committed to disclose its complete file (including for example an expert assessment, a letter of non-infringement, details of the preferred and alternative synthetic routes in the commercial production, and 50 g or more of perindopril containing the relevant polymorphic forms).

(362) Clause II of the letter of intent granted Servier an option to decide by 24 September 2004 whether or not it wanted to purchase all the IPR for the Azad

502 ID2428, p. 4.
503 ID1487, p. 233.
504 ID3343, p. 6.
505 ID0104, p. 298 - 302, ID3343, p. 6.
506 ID0104, p. 78.

Process. If so, a sale and purchase agreement would be signed and executed by 30 September 2004.

(363) Subsequently, Azad provided information to Servier on several occasions. On 1 September 2004, Azad submitted an information package[507] to Servier containing the information as specified in clause I of the letter of intent.[508]

(364) In addition, there were several subsequent contacts between Servier and Azad's experts. Servier's experts met the chemical experts of the University of Zurich and representatives of Azad on 22 September 2004 in Zurich "*to inspect the laboratory and verify the information submitted to Servier*".[509] The following day, on 23 September 2004, Azad submitted further clarifications to address Servier's concerns regarding Azad's perindopril stability study, essentially confirming that "*the apparent variations in the "time zero" and 3 months XRD data are the result in changes in the method of sample preparation protocol during the stability study, and are not an indication of instability of the δ polymorph*".[510] According to the Azad Assignment Agreement, the provision of information to Servier continued until 11 October 2004.[511]

(365) The review of Azad information took longer than expected for Servier,[512] and the preparations for the conclusion of one or more agreements between Servier and Azad were still on-going at the end of October 2004. An email dated 22 October 2004[513] from [employee name of Servier]* entitled "Azad" and addressed to, amongst others, [employee name of Servier]* and [employee name of Servier]*, contained two draft agreements, namely a "**patent application assignment agreement* " and a "**service agreement* ". In view of the content of the email and the initials marked on the two documents ([employee name of Servier]* and [employee name of Servier]* – the initials of two members of Servier's legal department), the drafts seem to be prepared by Servier.

(366) The draft assignment agreement of 22 October 2004[514] was similar to the final agreement concluded on 9 November 2004, as presented below.[515]

(367) The draft service agreement of 22 October 2004[516] does not bear the name of Servier's contract partner, but was included in the email entitled "Azad" as mentioned in paragraph (365). According to the draft, Servier would pay up to EUR 2.5 million for detailed reports on the (unspecified) EU generic market to Servier on an exclusive basis, in particular concerning: market characteristics, elements for deciding how to establish corporate presence on a market, competitor activity and arrival of new competitors, and products still under patent protection. In reply to the RFI of 7 February 2011, Servier stated that the draft was prepared in the context of

507 ID0104, p. 181.
508 ID0104, p. 299.
509 ID0104, p. 181.
510 ID0104, p. 92 - 95.
511 ID0104, p. 181. The exchanged information formed part of the transferred Know-How as per the agreement between Servier and Azad.
512 ID3842, p. 30.
513 ID0104, p. 78 - 91.
514 ID0104, p. 79 - 85.
515 According to Azad, the letter of intent set out an indicative valuation for the patent (USD 25 million) and a down payment (USD 2.375 million) for the review of Azad's information. After the evaluation of this information, the price was adjusted. (ID3343, p. 7).
516 ID0104, p. 86 - 91.

its "*technology monitoring*" but that no such agreements have been signed with Azad or any other third party (with the exception of Orifarm/Copyfarm).[517]

4.2.2.5 The Azad Agreement

(368) On 9 November 2004, Mr Mike Baronian, President of Azad's Board of Directors, on behalf of Azad Pharmaceutical Ingredients AG, and [employee name of Servier]*, [employee name of Servier]* and [employee name of Servier]*, proxy, on behalf of Les Laboratoires Servier, signed the Azad Agreement.[518]

(369) The preamble to the Azad Agreement contains, amongst others, the following statements:

- Non-infringing IPRs: "*Servier has conducted a thorough due diligence of the products and information received from AZAD, has independently and fully assessed the merits and particularities of the Patent Applications (including the patentability of it) and the associated know how and is of the opinion that the Patent Applications do not infringe the SERVIER Patents"*.
- Servier's rationale for the acquisition: "*SERVIER is interested to strengthen the defense mechanism for its own alpha, betha and gamma forms of Perindopril and has decided to purchase the Patent Applications and its know how"*.

(370) The key obligations arising from the Azad Agreement are as follows:

- Azad irrevocably assigned the patent applications for two new polymorphic forms delta and epsilon of perindopril (Swiss application No. 2003 1109/03 and PCT/CH 2004/000374, now under publication number EP1636185 – "Patent Application") and related know-how to Servier worldwide in return for the agreed payment (Article 1.1, 1.2);
- Azad committed "*that it shall not directly or indirectly use, transfer, assign or license rights related to the Patent Applications and the Know-How any more*" and to provide any necessary support for the assignment, maintenance, as well as defence in proceedings related to the Patent Application (Article 1.1, Article 1.3);
- In addition to the assignment of the Patent Application Azad disclosed and transferred the Know-How to Servier; Azad also undertook to describe four synthesis routes for the manufacture of perindopril[519] and to give all reasonable technical assistance to Servier at no further cost (including up to three days of assistance by an Azad chemist and answering all reasonable requests) (Article 3);
- Azad committed that it "*shall keep the transferred Know-How secret and shall not use it for any other purpose than covered by this Agreement*" for a period of ten years from its signature (Article 5.1);

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517 ID3842, p. 19.

518 ID0104, p. 180 - 190.

519 These 4 routes are: A) preferred non-infringing route for the synthesis of ZP3, B) alternate non-infringing route for the synthesis of ZP3, C) method for coupling ZP3 and ZP5, and D) process for direct crystallisation of delta perindopril.

- Azad warranted in particular that: (a) it had capacity to commit itself as stipulated in the agreement (Article 2.1, 2.2) and that it would "*hold harmless and indemnify Servier*" in case of any liability for Azad's breach of warranties in Article 2.1 and 2.2 (Article 2.3); (b) the Patent Applications and Know-How did not infringe any third party's IPRs (explicit reference is made to the statements in the preamble, i.e. the letter of non-infringement, and Servier's statement that the Patent Applications do not infringe Servier's patents) (Article 2.4); and (c) the agreement was not inconsistent with its contractual or other legal obligations, be they existing or prospective (Article 2.5);

(371) Servier committed to pay EUR 13,374,243[520] to Azad for the assignment. The first instalment of EUR 1,868,460 (USD 2,375,000) had already been paid on 1 September 2004 with the commencement of the due diligence process.[521] The second instalment of EUR7,572,182 was due on 9 November 2004, i.e. the date of signing, in the form of a bank cheque. And the third instalment of EUR 3,933,601 was due on 9 November 2005 (Article 4).

(372) According to Azad, the company stopped all activities relating to perindopril in December 2004,[522] i.e. immediately upon the conclusion of the agreement with Servier.

4.2.2.6 Azad's and Servier's explanations for the Azad Agreement

(373) With the exception of the agreement itself, the Commission received no contemporaneous Servier documents explaining the objectives of the acquisition or assessing the commercial value of Azad's patent application for Servier.[523] Thus, only the agreement itself can be relied on, as well as the subsequent explanations of the companies in the present investigation.

(374) On a general note, Servier explained that the rationale for its acquisitions of patents and patent applications was to improve the production processes and increase the production capacities while optimising production costs.[524] The three types of improvements were (i) the reduction of the process cycle time, (ii) optimising the synthesis and purification of perindopril, and (iii) improving the production of tablets.

(375) It is noteworthy that in the same reply Servier claims the following specifically in relation to the Azad Agreement:

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520 Following the exchange rate applied to the 1st instalment paid on 1 September 2004 (USD/EUR 1.2711), this sum amounts to roughly USD 17 million as stipulated in the draft Agreement of 22 October 2004 (see above).

521 Reference is made to the provisions of clause I, 2nd paragraph, point (a) of the letter of intent of 27 August 2004, ID0104, p. 300.

522 ID1112, p. 7.

523 As an annex (Annex 13-04, ID9066) to its reply to the Statement of Objections, Servier provided a short study from 6 September to 24 September 2004 on the Azad technology. However, this study – done in a very short period of time in the first stages of the due diligence, and after months of discussions had passed since the process began on 28 June 2004 (see paragraph (358)) – is of limited scope. It merely confirms the technical feasibility of the Azad process, without comparing its efficacy to that of the Servier production process, or assessing the possibility of incorporating it into that process or of a return on investment for Servier. Furthermore, the study is dated from 14 September 2004, that is to say apparently a week after its beginning and ten days before its purported end. [confidential]

524 Reply to the Commission's RFI of 6 August 2009, ID1151, p. 24.

"[…] (does not concern arginine salt)*

Objective sought: Potential reduction of the crystallisation time of perindopril terbutylamine".

(376) Servier claims that at the time of the Azad Agreement, the switch to arginine salt had not yet been decided and, therefore, any improvement to the production process for perindopril erbumine was welcome.[525] It also claims that eventually the Azad technology was not applied because of Servier's shift of focus from the *erbumine to the arginine salt*:[526]

*"*The acquisition of knowledge provided by the patents of AZAD and Lupin has not yet been implemented for the production processes.*

The AZAD Technology aimed at isolating another crystalline form of tert-butylamine salt which, were it easier to isolate, could allow significant time savings. However, SERVIER subsequently decided to focus on the production of arginine salt […] and to eventually abandon the production of tertbutylamine salt".

(377) However, potential cost savings were not explicitly referred to as a rationale for the Azad Agreement. On the contrary, the preamble to the Azad Agreement[527] which stated that "*Servier* [was] *interested to strengthen the defense mechanism for its own alpha, betha and gamma forms of Perindopril and has decided to purchase the Patent Applications and* [Azad's] *know how*". In addition the agreement also explicitly states that Azad's IPRs are not infringing Servier's IPRs.

(378) In its reply to the RFI of 6 August 2009, Servier explained that the terms "*'*strengthen the defense mechanism' refer to the strengthening of the industrial protection of the perindopril tertbutylamine crystalline forms which Servier had already studied in the context of the industrial development of perindopril*".[528]

(379) The agreement does not set out Azad's considerations for the sale and transfer of its perindopril-related IPR to Servier. Azad's *ex post* explanations for the Azad Agreement essentially relate to alleged development problems[529] and have been presented above in more detail.

4.2.2.7 Developments after the conclusion of the Azad Assignment Agreement

(380) The IPRs acquired from Azad were not further developed by Servier. Out of the six acquired patents/patent applications enumerated in Servier's answer to question 33 of the Commission's RFI of 6 August 2009, only one patent application assigned from Krka in 2007 is claimed to have led to some improvement of production processes (in addition to [company name]* as described above). [530]

(381) Azad terminated its perindopril project shortly after the conclusion of the Azad Agreement,[531] and disrupted the abovementioned cooperation projects with generic companies. According to Azad, following the agreement with Servier, Azad had no other intellectual property rights or significant know-how relating to the production

525 ID3842, p. 24.
526 Reply to the RFI of 7 February 2011, ID3842, p. 24.
527 ID0104, p. 182.
528 ID1151, p. 36. For Servier's other considerations see ID5068 and ID3842, p. 30.
529 ID1112, p. 7.
530 ID1151, p. 25.
531 See paragraph (372).

of perindopril, and did not initiaite a new perindopril development project.[532] This is in line with Servier's explanations which confirmed that, apart from the know-how transferred to Servier,[533] Azad did not make Servier aware of any know-how that would not be covered by the Azad Agreement.[534]

4.2.2.7.1 Compensation paid by Azad to generic companies

(382) Evidence on the Commission's file shows that two of Azad's generic partners, Teva and Arrow, claimed, and eventually received, significant compensation for Azad's termination of their respective cooperation.

Arrow

(383) Following the meeting of 7 December 2004 in which Azad confirmed the deal with Servier, Arrow decided to claim compensation from Azad for its failure to supply the API and continue with the cooperation as previously agreed. Arrow also decided to pursue a case against Servier for breach of contract.[535]

(384) This led to an exchange of correspondence between Arrow and Servier as summarised below.

(385) In a letter of 11 August 2005 sent by its lawyers,[536] Arrow claimed that it had entered into a supply agreement with Azad regarding perindopril API and the respective DMF, and that Servier was aware of this supply agreement. Due to the termination of API supplies and failure to supply the DMF, both Azad and Servier were in breach of Swiss law and as a result of such actions, Arrow claimed to have suffered a loss.

(386) An exchange of correspondence between Servier and Arrow subsequently ensued in which Servier denied any liability.[537] A letter by Servier[538] dated 6 October 2005 contained the following statement:

"[Servier have] *no legal duty to help Arrow developing its activities: as a matter of principle, antitrust laws impose no duty upon companies to deal with their rivals.*

However, [Servier] *are ready to meet [Arrow] should they be ready to negotiate on a fair and reasonable basis, and in strict accordance with the applicable laws, a sub-license of the intellectual property rights that* [Servier] *have duly acquired from AZAD".*

(387) With respect to Servier's offer to discuss a sub-licence, Arrow replied (via its lawyers SJ Berwin) on 26 October 2005.[539] In this reply, Arrow indicated that, while it "*question[ed] in itself the commercial value of a sub-licence of the delta-polymorph developed by AZAD at this time, it believe[d] it would be helpful to meet Servier to discuss the position generally to determine whether there can be a mutually*

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532 ID3343, p. 5.

533 According to Servier, this know-how consisted of: detailed operational modalities, including for the preparation of intermediary carbanine, coupling method, crystallisation of the delta form, delta stability studies (ID3842, p. 30).

534 ID3842, p. 31.

535 Reply to the RFI of 5 August 2009, ID1571, p. 18.

536 ID1570, p. 20 - 21.

537 See Servier letter of 26 August 2005 signed by [employee name of Servier]* (ID1570, p. 22 - 23) and reply by SJ Berwin on behalf of Arrow dated 15 September 2005 (ID1570, p. 24 - 26).

538 ID1570, p. 27 - 28.

539 ID1570, p. 29.

satisfactory resolution of the disputes". In February 2006,[540] Arrow advised Servier that it was interested in proceeding with a sub-licence of the assigned Azad IPRs, and considered that "*the sub-licence [would] be on a royalty-free basis*".

(388) In its letter dated 28 February 2006,[541] Servier dismissed Arrow's royalty-free sub-licence claim as unreasonable and reiterated its proposal to negotiate the sub-licence on "*a fair and reasonable basis*" specifying that this would imply a fair remuneration for the licensor. This avenue was not discarded by Arrow, which had on 24 March 2006, via SJ Berwin, proposed a meeting to negotiate the terms.[542]

(389) In the end, no licence agreement was concluded. According to Arrow, this was because of concerns that, in addition to risks inherent to the development of the delta polymorph API, a sub-licence on the patent application Servier purchased from Azad would no longer be an effective option. It would require the reactivation of capacities of CCSB, and the attached costs and delays were unknown. Moreover, the DMF would need to be finalised and filed, and possibly another bioequivalence study would be necessary. In addition to the discontinuation and the ensuing delays, Arrow had already lost all its commercial advantage compared to other companies, and thus relied on other sources of API (e.g. Lupin[543]), apparently covered by the '947 patent, and the patent challenges to the '947 patent.[544]

(390) Moreover, although the exact wording of the Azad Agreement was likely unknown to Arrow, the provisions of the Azad Agreement banned Azad from sharing any know-how related to the agreement with any third party for a ten year period (Article 5.1).[545]

(391) In parallel to the exchanges concerning the possible sub-licence, on 11 October 2005 Arrow filed a court action in Switzerland against Azad and Servier.[546] In its action, Arrow alleged that: (i) Azad breached the contract for the supply of perindopril API to Arrow; and (ii) Servier induced that breach by agreeing that Azad would not supply any third parties with its perindopril API.[547] Arrow claimed USD [low nine digit figure] in damages plus interest from Azad and Servier.[548] The direct costs for the development of the perindopril products (perindopril plain and perindopril/indapamide combination product) based on Azad API allegedly amounted to around EUR [500,000-1,000,000].

(392) Other considerations underlying its claim for damages were:[549]

"(a) if Azad had supplied [Arrow] with perindopril API as originally agreed, then: CCSB (the API manufacturer in Taiwan under contract to AZAD) would have filed the DMF in the EC in February 2005; [Arrow] *would have filed its Product Licence applications by 1 March 2005 for those Member States in which it wished to sell*[550]

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540 ID1570, p. 57.

541 ID1570, p. 59.

542 ID1570, p. 60.

543 ID1571, p. 18 - 37.

544 Reply to the RFI of 4 July 2011, ID5080, p. 5 - 6.

545 ID0104, p. 184.

546 ID1571, p. 19.

547 ID1571, p. 19.

548 ID0104, p. 173.

549 ID1571, p. 19-20.

550 Arrow later received marketing authorisations based both on Lupin and Glenmark API (which, as will be shown below, contained the alpha polymorph) as of April 2008 for the following countries: BE, CZ,

and regulatory procedures would have been completed and [Arrow] *would have been ready to market in the EEA by 1 April 2007;*

(b) [Arrow] would have been likely to have achieved a market share in perindopril markets in the EEA of at least 20 per cent, by setting its prices at a significant discount to Servier's Coversyl; and

(c) the delay to [Arrow]'s *development of perindopril products to launch in the EEA, arising from a need to find a new supplier of API, was around one and a half years".*

(393) A tri-partite settlement between, on the one side, Azad and Servier, and, on the other side, Arrow, was concluded on 4 October 2006 at Servier's headquarters.[551] Azad committed to pay a total sum of USD [seven digit figure] to Arrow in instalments. All three parties essentially agreed to a "*general release*" pursuant to which the settled claims were withdrawn and could no longer be invoked under any circumstances. The settlement also states that is not to be understood as an admission of any liability.[552]

(394) Arrow reportedly decided to settle its claim due to the strict conditions that must be met in order to establish the existence of a legally enforceable supply contract under Swiss law ("*there was no written agreement and Arrow essentially relied on Azad's good faith*"). Reflecting the prospects of Arrow's claims in Swiss courts, the sum agreed on was allegedly much lower than the loss incurred by Arrow.[553]

(395) Servier explained that "[a]s per the terms of the Settlement agreement Servier neither paid nor received any money from the other parties as it was clearly a commercial dispute between AZAD and Arrow. Servier Patents were not challenged in any way".[554]

Teva

(396) Teva also sought compensation from Azad because of the termination of their cooperation, which came at an advanced stage of the cooperation. However, Teva considered that it was *"faced with a problem as it had no development or supply agreement in place with Azad. Nevertheless, since Azad terminated the cooperation very late, literally before filing for US approval, Teva demanded full reimbursment for its development costs…"* These expenses amounted to around USD [0.5–1.5]* million. Teva actually quantified the development costs to amount to around USD [< 1 million]* for the US and USD [< 500,000]* for Europe, totalling around USD [0.5–1.5 million]*.[555]

(397) On 13 January 2005, an invoice was sent for this amount from Teva to Azad in relation to "*return of development cost for development of perindopril erbumine finished dosage forms for the European and USA markets*".[556] Azad agreed to such reimbursement, and settled Teva's invoice in February 2005.[557]

DK, ES, FR, HU, IE, IT, MT, NL, PL, PT, SK, UK. By September 2009 (date of reply) it had only launched in France on 3 July 2009 (i.e. after the annulment of Servier '947 patent).

551 ID1571, p. 19, ID2075, p. 2.

552 ID0104, p. 172-176.

553 Reply to the Commission's RFI of 5 August 2009, ID1571, p. 19.

554 Reply to the Commission's RFI of 6 February 2009, ID2075, p. 2.

555 ID2480.

556 ID2476.

557 ID3624, p. 9.

4.2.2.7.2 Continued business relationship between Azad and Servier

(398) Less than a year after the conclusion of the settlement agreement, Servier and Azad Pharma AG concluded a further agreement for the acquisition of non-perindopril compounds from Azad. Servier refused to provide more information concerning this transaction, claiming it was unrelated to perindopril.[558]

4.2.2.8 Actual or attempted transfers of technology from possible sources of perindopril API to Servier

4.2.2.8.1 Niche

(399) The Draft Heads of Agreement ("HoA") between Niche/Unichem and Servier dated 31 January 2005[559] contained a clause whereby Niche and Unichem would agree to assign to Servier "*all right title and interest in patent applications [insert numbers of Niche's formulation patents] and any foreign equivalents*". However, the clause was not retained in the settlement finally concluded between Niche and Servier on 8 February 2005[560] (Niche/Matrix had no pending patent applications concerning perindopril).

4.2.2.8.2 Krka

(400) In the framework of the Assignment and Licence Agreement[561] signed on 5 January 2007, Krka assigned to Servier two patent applications, WO 2005/113500 (API production process), and WO 2005/094793 (preparation of perindopril formulations), and received a back-licence with no right for Krka to sub-license it. Servier reportedly paid Krka EUR 30 million for these patent applications.[562] As to the reasons for Servier's acquisition, Krka stated the following: [563]

"We assumed that Servier feared that patents could have been assigned or licensed to any third competitor who could have developed a product with required Phar.Eu. purity, even i[f] alpha form had been revoked – Krka's patents solved "purity problem".

4.2.2.8.3 Lupin

(401) In the framework of the settlement agreement between Servier and Lupin concluded on 30 January 2007, Lupin assigned to Servier three patent applications for production processes relevant for the API. Servier paid EUR 40 million to Lupin in the context of the Settlement Agreement, reportedly as consideration for the patent applications.[564]

4.2.2.8.4 Sandoz / Lek perindopril development and attempted acquisition of technology by Servier

(402) Sandoz' API development started at the end of June 2004, after it had acquired, through its Slovenian subsidiary Lek, patent rights over perindopril API (synthesis,

558 ID5064, p. 6.
559 ID3764, p. 1.
560 For more detail, see section 4.3.1.
561 ID0119, p. 42 - 45.
562 For more detail, see section 4.3.3.
563 ID1307, p. 97 - 98.
564 For more detail, see section 4.3.4.

crystal form, complexes) from Diagen, another Slovenian company, in April/May 2004.[565]

(403) Sandoz' patent applications for CD complex perindopril API (non-crystalline form of perindopril erbumine) were filed in January 2004, and for perindopril formulations (tablets) in February 2006. These patent applications, which became public from November 2004, concerned the preparation and purification of crude perindopril, preparation of perindopril erbumine API (cyclodextrin inclusion complexes of perindopril and its salts, or "CD complex"), and perindopril formulation.[566]

(404) The first pilot API batch was manufactured in July 2005, and the first API batches, used for completion of the CMC (information on chemistry, manufacturing and controls, equivalent to the DMF) were manufactured in July/August 2005 and November/December 2005. The information was prepared in July/August 2006 as CMC documentation and was included as part of the final dossier. The bioequivalence study was initiated in November 2005 and completed in August 2006. The first commercial API batches were manufactured in March 2008.[567] Sandoz applied for marketing authorisations for plain perindopril in September 2006.[568]

(405) Information provided by Krka indicates that Sandoz's API development was aimed at Sandoz' own development and marketing of perindopril formulation: "*There was one competitor (Sandoz), which developed stable and non-infringing crystalline form in formulation, but they were not offering the product for cooperation*".[569] According to Krka, "*Sandoz's technology is much less competitive in terms of production cost (cost of goods) – it's too expensive and it is our estimation that on highly competitive markets, economics of their product would be negative"*.[570]

(406) According to Sandoz's reply to the RFI of 5 August 2009, in the period 2006-2007, several informal negotiations between Servier and Sandoz took place. On 18 May 2006, the companies discussed, amongst others, "*the possibility of some form of commercial cooperation*" relating to perindopril.[571] In 2007, "*Sandoz discussed the possibility of a distribution agreement with Servier for perindopril, using Servier's perindopril technology. Ultimately, these discussions did not result in any agreement*

565 ID4778, p. 2 - 3.

566 ID1467, p. 1 - 2. Source: EPO:

Patent	Priority filing date	Publication date
WO2004099236	08.05.2003	18.11.2004
WO2004101515	16.05.2003	25.11.2004
WO2007017087	25.07.2005	15.02.2007
WO2007020009	12.08.2005	22.02.2007
WO2007020012	12.08.2005	22.02.2007
WO2005068490	14.01.2004	28.07.2005
WO2007088035	02.02.2006	09.08.2007
WO2005068425	14.01.2004	28.07.2005

567 ID4778, p. 2-3.

568 ID1470, p. 4-9.

569 ID1307, p. 97.

570 ID2301, p. 10.

571 ID7834, p. 15.

or arrangement".[572] Later in the year, the contacts between the companies focused on a possible technology transfer from Sandoz to Servier.[573] Those negotiations led to signing of the Heads of Agreements by [employee name]* on behalf of Servier, and Messrs R. Saynor and W. Volk on behalf of Sandoz, on 15 October 2007.[574]

(407) According to the Heads of Agreement, Servier would proceed with the acquisition only if Sandoz' technology proved to be a patent-free and industrially viable source of competition to Servier. Under clause 1, Sandoz was to allow Servier to assess whether the Sandoz perindopril product fulfilled the conditions identified above. In consideration for the sale, Servier would pay an amount possibly exceeding USD [40–55]* million upon the signature of the sale agreement.

(408) An analysis of Sandoz's perindopril corresponding to clause 1 of the Heads of Agreements was carried out by Servier. They confirm that the perindopril was amorphous and stable (although long term stability studies were not carried out). This report also suggests that the route of synthesis is different from that of Servier. The report prepared by Servier contains nothing to suggest that Sandoz's product would not meet any of the three conditions for Servier to purchase the IPRs.[575]

(409) According to Sandoz, the "*[n]egotiations continued until mid-2008*". However, ultimately they did not lead to the conclusion of an agreement, as "*Sandoz determined it was not in its commercial interests to enter into an arrangement with Servier. Therefore, no final agreement or arrangement was concluded or executed. Indeed, during the negotiations, in early 2008, Sandoz launched its own formulation generic product*".[576]

(410) Sandoz launched 2 mg and/or 4 mg perindopril tablets in a number of Member States: the Netherlands and the UK in May 2008, Ireland in June 2008, Belgium in July 2008, France in September 2008, Hungary in December 2008, the Czech Republic in January 2009 and Italy in June 2010.[577]

4.2.3 Importance of the assigned IPRs and perceptions of Servier's practices concerning independent API sources

(411) Servier explained that patent acquisitions were an attractive option from its perspective for various reasons. First, acquiring IPRs allows the holder to better control the grant process. Second, in view of the investment in the industrial applications, an acquisition affords more security to the rights holder than a licence, in particular if obtained from a competitor. Third, an acquisition is of a definitive nature and allows the holder to freely decide on licensing.[578]

(412) However, generic companies took a different view of these acquisitions and considered that they negatively impacted their market entry.

(413) In an email of 7 February 2005, Teva stated that Niche had agreed on the supply of perindopril to certain Teva affiliates and complained that "*Teva development [was]*

572 ID7834, p. 19.
573 ID1480, p. 20.
574 ID0113, p. 114 - 116.
575 ID0108, p. 182 - 183.
576 Reply to the RFI of 5 August 2009, ID1480, p. 20.
577 ID1468.
578 Reply to the RFI of 6 August 2009, ID1151, p. 25 - 26.

delayed as cannot acquire any API (Servier keep buying up API companies)".[579] This remark was made around three years after Servier's acquisition of [company name]*'s IPR, three months after Servier's acquisition of IPRs from Azad, and on the eve of the conclusion of the settlement agreements between Servier, and Matrix or Niche, respectively.

(414) Discussions between Krka and Ivax during 2005 in relation to perindopril also demonstrate concerns about Servier attempting to buy out all API producers. An email from Ivax's personnel of 17 June 2005 states that:

"KRKA feel there is a strong likelihood that Servier will attempt to buyout all API manufacturers, (I have not advised them of our source except to say it is not Matrix, who were bought out with Niche)".[580]

(415) Another internal Teva email states (10 August 2005): *"In any conversations with Servier, it is important that they are not given the name of our APIs supplier. The general industry consensus is that Servier will attempt to take out API sources"*.[581]

(416) An internal Teva communication from 3 October 2005 reports on problems regarding the development of perindopril: "*The position with Perindopril is very complicated in terms of patents - particularly process patents which affect API manufacturers. This is partly why everyone is late (once an API manufacturer has got round the process patents Servier has bought the company, sourcing API has been very difficult)*".[582]

(417) In an email of 6 November 2006 from Nomura Code,[583] a financial consulting company, received by Teva concerning stock investment recommendations for Krka, the settlement between Krka and Servier of 27 October 2006 was considered "*a positive result for Krka, which is one of relatively few companies developing the API for generic perindopril*".[584]

(418) Krka's reply to the RFI of 5 August 2009 confirms that there were very limited sources of perindopril API of sufficient quality (e.g. in view of the European Pharmacopoeia standards): *"The companies which have developed API and were willing to enter into cooperation agreements were non existing"*.[585]

(419) This was echoed by an article published on 18 April 2007 in the Economic Times, an Indian newspaper, which reported on the acquisition of Lupin's IP rights by Servier. The press article reads:[586] "*In yet another attempt by big pharma to delay the entrance of generic players in the market, France's Servier Laboratories has acquired IP-related rights on Perindopril, better known in Europe under its brand name Coversyl, from domestic pharma company, Lupin. […] Although Servier's original patent on Perindopril has expired in most European countries, this move*

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579 ID0078, p. 62.

580 ID0346, p. 39.

581 ID0358, p. 545.

582 ID0082, p. 70.

583 According to its website, Nomura Code is a European investment banking team focused, amongst others, on healthcare and provides a full range of advisory, fundraising and broking services. http://www.nomura.com/. Nomura Code closed in August 2013 (See http://investing.businessweek.com/research/stocks/private/snapshot.asp?privcapId=8122024).

584 ID0087, p. 41.

585 ID1307, p. 97.

586 ID5007.

will allow the French company to prevent generic players from entering the market and continue to enjoy exclusivity".[587]

(420) On the same note, Sandoz, from which Servier attempted to purchase IPRs (as described in section 4.2.2.8.4), internally reported on the content of perindopril related contacts with a generic company, which " *informed about the fact that Servier is closing deals with developers to cancel their development*".[588]

4.3 Patent settlements

4.3.1 Niche/Unichem and Matrix

(421) This section describes two separate patent settlement agreements entered into by Servier and Matrix,[589] and Servier and Niche[590] together with its parent company Unichem (although the latter denied, at first, having entered into any settlement agreement with Servier).[591] Both settlement agreements were signed on 8 February 2005. They are considered together in this section as Niche/Unichem and Matrix were contractually linked cooperation partners for perindopril and, as such, there is a strong interdependence between the events leading to the conclusion of both agreements.

(422) Under the terms of the settlement agreements, Niche/Unichem and Matrix each agreed: (i) not to enter the market for perindopril before September 2008 at the earliest (and only then provided their product did not infringe the '947 patent); and (ii) not to challenge any of Servier's main patents (or seek a declaration of non-infringement). In addition, Niche and Matrix agreed to cancel, terminate or suspend all customer relations associated with perindopril until the expiry of the process patents and refrain from applying for regulatory approval. In return for the above commitments, Servier paid Niche and Matrix GBP 11.8 million each. Servier also transferred GBP 2.5 million to Niche in the framework of the Biogaran deal (for details of this agreement see section 4.3.1.4.1.3).

4.3.1.1 First contacts between Niche (Bioglan) and Matrix (Medicorp) for their common project

(423) The suggestion that Niche (Bioglan) and Matrix (Medicorp) become active in the development of a generic version of perindopril seems to have emerged in the late 1990s, leading to steps being taken for its development from 2000. A meeting between Niche (Bioglan) and Matrix (Medicorp) took place at the factory of Matrix (Medicorp) in Hyderabad on 11 January 2000. It is noted in the minutes of this meeting that a cooperation agreement between Niche (Bioglan) and Matrix (Medicorp) was envisaged and, further, that perindopril involves a *"difficult synthesis"* and is *"difficult to manufacture and probably will not be copied by to* [sic]

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587 Lupin has claimed this quote was incorrect. See section 4.3.4.9.3.

588 ID7162.

589 When referring to the activities of Medicorp prior to May 2003 "Matrix (Medicorp)" will be used. For activities after May 2003 reference is only made to "Matrix" as Matrix is the only remaining entity and the legal successor of Medicorp (see section 1.2.3 for more details on the company structure of Matrix (Medicorp)).

590 When referring to the activities of Bioglan prior to April 2002 "Niche (Bioglan)" will be used. For activities after April 2002 reference is only made to "Niche" as Niche is the only remaining entity and the legal successor of Bioglan (see section 1.2.4 for more details on the company structure).

591 See ID5494 where Unichem stated not to have entered "*into any agreement with Les Laboratoirs Servier for any matter whatsoever*". In a later submission, Unichem did not deny this fact any longer, ID7168.

many companies". Matrix's (Medicorp's) process chemist had already looked at the formulation and was confident that the molecule could be copied.[592]

(424) Following a letter of intent,[593] on 29 June 2000 [employee name and function]* of Niche (Bioglan), requested from Matrix (Medicorp) that the cooperation agreement be concluded as soon as possible.[594] On 19 September 2000 the first draft contract was handed over to Matrix (Medicorp).[595]

4.3.1.1.1 The development and licensing agreement between Niche (Bioglan) and Matrix (Medicorp) relating to perindopril

4.3.1.1.1.1 Summary of the agreement

(425) On 20 March 2001 Matrix (Medicorp) and Niche (Bioglan) signed a development and licensing agreement concerning perindopril 2 and 4 mg tablets.[596] In line with previous discussions, the agreement proposed that the parties would jointly develop and promote generic versions of perindopril in a number of EU, and certain non-EU, countries. The agreement covered: *"[tests]*, manufacturing process, one […]*study and all other relevant documents for submission […]. The promotion and sale of this dossier and the corresponding finished products"*.[597]

(426) The agreement stated that both Niche (Bioglan) and Matrix (Medicorp) would market their generic perindopril dossier and product in the EU.[598] The development and licensing agreement also permitted Matrix (Medicorp) to sell the product directly in the EU [and to pay a proportion of profits on the sale of the product to Bioglan]*.[599]

(427) According to the development partnership the parties would establish a joint project team to take all necessary decisions. […]*.[600]

(428) The agreement further indicates that *"Bioglan [Niche] will purchase the finished dose from Medicorp [Matrix] at an agreed cost price plus [5-50%]"* and then sell the product in the agreed territory.[601] Moreover, it was agreed that the profits from the sales would be […]* between the two companies.

(429) Clause 9 of the agreement stated that the parties must inform each other in writing should their product infringe the property rights of any third parties: *"[…]*"*[602]

(430) Paragraph 3 of clause 4 allows the parties to terminate the agreement: "*In case the delays in some phases are likely to delay the project to such an extent, so as to make the launch of the product non-viable, then both parties agree to cancel the project with immediate effect. Termination of the agreement must be in writing"*.[603]

592 ID0028, p. 93.
593 ID0028, p. 88 - 92.
594 ID0027, p. 15.
595 ID0027, p. 15.
596 This agreement and all subsequent amendments: ID1709, p. 32 - 45, ID0659 and ID0665, p. 11.
597 ID1709, p. 36.
598 ID1709, p. 40. Countries other than the Member States of the EU are also cited.
599 ID0659, p. 7.
600 ID0659, p. 2 - 7.
601 ID0659, p. 7.
602 ID1709, p. 41.
603 ID1709, p. 39.

4.3.1.1.1.2 Summary of amendments

(431) Following the acquisition of Bioglan by Niche in April 2002 the development and licensing agreement was amended (amendment No. 1) on 4 May 2002 to confirm that Niche was to take over all responsibilities and obligations of Bioglan as set out in the agreement.[604]

(432) A second amendment to the development and licensing agreement was signed on 20 January 2003, adding the 8mg strength of perindopril to the development programme.[605]

(433) Following the merger of Matrix and Medicorp on 20 May 2003,[606] a third amendment to the development and licensing agreement was signed on 30 March 2004, confirming that Matrix was to take over all responsibilities and obligations of Medicorp as set out in the agreement. [607]

(434) In a fourth amendment, also signed on 30 March 2004, details with respect to cost-sharing were agreed. [Details of cost sharing arrangement between Matrix and regarding various categories of costs related to patent issues]*.[608] […]* [609]

4.3.1.1.1.3 *Ex post* interpretations of the development and licensing agreement by the parties

(435) According to the submissions of Matrix, its agreement with Niche (specifically in relation to distribution and marketing) was implemented in a slightly different way than set out above. Matrix characterises its role as that of a mere API supplier. Accordingly, Matrix (Medicorp) claims that it was responsible for developing the perindopril API in India as the basis of the DMF while Niche (Bioglan) was responsible for obtaining MA's, customers and distribution.[610] Matrix also specified that "*all of the contracts with customers were entered into by Niche"*.

4.3.1.1.2 R&D activities on the basis of the development and licensing agreement

(436) Following the conclusion of the development and licensing agreement, a meeting between Niche (Bioglan) and Matrix (Medicorp) took place on 2 April 2001. The minutes of the meeting indicate that the perindopril project was delayed and confirm that perindopril was Niche's (Bioglan's) priority project.[611]

(437) Contemporaneous documents show that both Niche (Bioglan) and Matrix (Medicorp) were aware of potential patent issues and were aiming at a generic version of perindopril that would not infringe any patents. An extract from a monthly patent report dated 15 June 2001 confirms that Niche (Bioglan) asked Matrix (Medicorp) to develop a non-infringing perindopril formulation.[612]

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604 ID1709, p. 35.

605 ID1709, p. 34.

606 According to Niche's Memorandum of 23 March 2009, Matrix acquired already one year earlier, in May 2002, a majority interest in Medicorp. ID0463, p. 2.

607 ID1709, p. 33.

608 ID1709, p. 32.

609 ID1709, p. 32.

610 ID1452, p. 10, 13, and 20 (Matrix's reply to questions 14, 22 and 40 of the Commission's RFI of 5 August 2009).

611 ID0028, p. 76 - 80.

612 ID0028, p. 16.

(438) On 15 August 2001 another meeting was held between the companies, the minutes of which state that Matrix (Medicorp) successfully produced perindopril at laboratory scale.[613]

(439) As early as January 2002, Niche assumed that it would be able to launch perindopril in the UK in January 2004.[614]

(440) On 8 and 9 April 2002 another meeting between Niche (Bioglan) and Matrix (Medicorp) took place. With respect to the route of synthesis, it was agreed that [name of Niche counsel]* (European patent attorneys) would review the current route of synthesis to identify areas where there could be a risk of patent infringement. With regards to Servier's three polymorph patent applications published only months before, the minutes state that one of the forms was possibly covered by prior art. According to this information, the proposed final purification stage does not use the solvents claimed in the patent applications, although it is acknowledged that there may be a claim for infringement if one of the polymorphs were present.[615]

(441) According to the minutes of a teleconference between Niche and Matrix (Medicorp) held on 29 August 2002, the latter indicated that it had significantly progressed with the development of perindopril API. It is stated in the minutes that: *"Perindopril tablets are made and very good. We believe we have a stable formulation"*.[616] A final DMF containing a full data set on the API was expected to be ready by mid-December 2002.[617]

(442) Further to a meeting between Niche and Lupin on 2 July 2003, Niche noted: *"They [Lupin] know we have it and acknowledge they are behind us"*[618] which confirms that Niche and Matrix considered themselves to be at a more advanced stage with their perindopril project compared to Lupin, one of their competitors.

4.3.1.1.3 Agreement for development and manufacture of perindopril tablets between Matrix (Medicorp) and Unichem

(443) On 27 March 2003, Matrix (Medicorp) concluded an agreement for the development and manufacture of perindopril tablets with Unichem.

(444) According to clause 1.1 of the agreement Matrix (Medicorp) would develop the perindopril API and provide it to Unichem. Using the Matrix (Medicorp) API, Unichem would develop the formulations and manufacture bio-batches (the details of Unichem's services provided to Matrix are outlined in clause 1.2).[619]

(445) As explained by Matrix (Medicorp) in response to question 15 of the Commission's RFI of 13 August 2010, Unichem was responsible for the production of perindopril in final dosage form (finished formulations).[620] In return, Matrix (Medicorp) agreed that [25-50%] of the licensing fees for the dossiers would be shared with Unichem (clause 1.4) and [25-50%] of Matrix's (Medicorp's) share of profits to be derived

613 ID0028, p. 73. See also ID3268, p.1 and ID0027, p.16.
614 ID0025, p. 23 - 24.
615 ID0028, p. 65.
616 ID0028, p. 61.
617 ID0028, p. 60 - 63.
618 ID0027, p. 21.
619 ID2613, p. 3 - 11.
620 ID2579, p. 11.

from the sale of commercial consignments would be shared by Matrix (Medicorp) and Unichem (clause 2.5).[621]

(446) Clause 12.2.b. of the agreement reproduced the termination clause (clause 4, paragraph 3) of the Development and Licensing agreement concluded between Niche (Bioglan) and Matrix (Medircorp), i.e. that termination of the agreement would be triggered in case the development failed or encountered insurmountable difficulties.[622]

(447) On 12 April 2004 the agreement was amended in order to confirm that Matrix would take over all responsibilities and obligations of Medicorp as set out in the development and manufacture agreement with Unichem.[623]

4.3.1.1.4 Acquisition of customers

(448) Shortly after the conclusion of the development and licensing agreement with Matrix, Niche (Bioglan) started meeting potential customers in order to conclude supply agreements for perindopril. These customers were companies willing to obtain the licence concerning the product dossier for perindopril that was co-developed by Niche and Matrix and/or to obtain the final product for supply on the relevant market(s). The creation of a distribution network through such contracts was considered necessary since Niche would not have the in-house distribution capability to market the product throughout the whole EU.[624] Niche signed a total of 14 customer contracts (licence and supply agreements) covering the EU territory between August 2001 and August 2004, as follows from Table 8 below.[625]

621 ID2613, p. 3 - 11.
622 ID2613, p. 11.
623 ID2613, p. 2.
624 ID0463, p. 3.
625 ID0463, p. 3, ID3268, p. 17.

Table 8: Overview of Niche's customers for perindopril formulations

Customer *(in chronological order)*	**Date of contract**	**Territory covered**
1. Alpharma Ltd.	1 August 2001	[…]*
2. [generic company]	29 April 2002	[…]*
3. Leciva (now Zentiva)	12 June 2002	[…]*
4. Pabianickie Zaklady Farmaceutyczne Polfa	31 December 2002	[…]*
5. Pannonpharma Kft	3 February 2003	[…]*
6. Keri Pharma Ltd.	28 May 2003	[…]*
7. Laboratorio Medinfar S.A.	9 June 2003	[…]*
8. Galex d.d.	18 June 2003	[…]*
9. DuraScan Medical Products AS	4 August 2003 (Heads of Agreement)	[…]*
10. Ratiopharm GmbH	28 October 2003 (Heads of Agreement)	[…]*
11. Stada	3 December 2003	[…]*
12. GENERIS farmaceutica, S.A.	15 March 2004	[…]*
13. Docpharma NV (DAA)	7 June 2004	[…]*
14. Winthrop Pharmaceuticals (formerly Sterwin Medicines)	9 August 2004	[…]*

Source: ID3268, p. 17.

(449) Most of these contracts were licence and supply agreements for perindopril 2 mg and 4 mg tablets.[626] Some of the contracts involved sale of the dossier, supply and distribution and some also related to perindopril 8 mg tablets. These contracts were generally concluded for a five-year term, included a termination clause and a minimum quantity requirement. The geographic scope varied depending on the regional activities of the generic operators.

(450) Despite some alleged technical difficulties with the product development in 2004, Niche did not terminate any of these customer contracts - not even in autumn 2004 - the period for which Niche *ex post* claimed that *"the obstacles"* to product launch were *"becoming insurmountable"*.[627] Niche had, on the contrary, continued its efforts to find additional customers for its product in 2004 and 2005. In particular, Niche met Teva on 25 May 2004[628] and 25 November 2004[629] to discuss, amongst other issues, the licensing and supplies of perindopril.

626 ID1173, p. 4 – 14.

627 ID1577, p. 8. Niche claims in its reply to the Statement of Objections that the conclusion of the customer contracts reflects an aspiration from Niche to be the first generic entrant but it was not a foregone conclusion that Niche would or could be the first. Also Niche indicates that it was not totally certain whether Matrix would fail and had not completely lost hope that the project would succeed therefore it did not terminate the customer contracts (reply to Statement of Objections, ID8524, p. 95-96).

628 ID0025, p. 160.

629 ID0025, p. 161.

(451) Only four days before settling with Servier (i.e. 4 February 2005), Niche met Teva again. The minutes of this meeting provide evidence of preparations of a licence and supply agreement for several Member States.[630] An upfront payment from Teva to Niche of EUR [200,000 – 700,000]* was foreseen. Details relating to prices and logistics were also discussed during the meeting.[631]

(452) On the day before signing the settlement agreement with Servier, Niche worked on a draft letter of intent with Teva, according to which Niche would agree to apply for a parallel marketing authorisation in the Netherlands for perindopril 2 and 4 mg on behalf of Teva. It was foreseen in this draft letter of intent that Teva used the *"resultant Dutch MA as their Reference Member State (RMS) MA to make Mutual Recognition Procedure/s (MRP) to all the other countries of the Territory"*.[632] The draft letter of intent refers to a Licence and Supply Agreement, indicating that the respective Heads of Agreement are *"currently being formalized"*.[633]

(453) The fact that Niche was meeting potential customers in order to broaden its distribution network for perindopril shows Niche's determination to prepare for the commercialization of generic perindopril.

4.3.1.1.5 Marketing authorisation procedure

4.3.1.1.5.1 Applications and subsequent procedure

(454) In April 2003, Matrix provided to Niche the DMF necessary for the marketing authorisations[634] discussed above. In October 2003 Niche applied for marketing authorisations in the UK under its own name.[635] Moreover, Niche had contracted with customers (see paragraph (450)) which were applying for marketing authorisations in several other countries in 2003 and 2004, namely in Denmark, the Netherlands, the UK, Portugal, the Czech Republic, Slovenia, Hungary, France and Sweden.[636]

(455) Niche initially expected regulatory approval by October 2004.[637] As will be explained in the following section, however, the expected date of approval was later altered due to certain delays in the regulatory approval process. A new DMF was completed in December 2004 as Matrix needed to refine the route of synthesis in order to avoid infringement. From minutes of a meeting between Niche and Matrix on 10 December 2004, it appears that *"Servier have conceded that the process does work"*.[638] Niche had received deficiency letters from the MHRA during 2004.[639] It can be assumed that these had been answered since Niche also received a deficiency letter after the conclusion of the settlement agreement. Some of Niche's customers also received deficiency letters from the national regulatory authorities where they had applied for a MA and the majority of these letters had been answered.[640]

630 The Netherlands, Belgium, France, Germany, Italy and Spain.
631 ID0025, p. 162.
632 ID0025, p. 185.
633 ID0025, p. 185.
634 ID1577, p. 4.
635 ID4718, p. 106 and ID4898, p. 1.
636 ID1032, p. 5 and ID4718, p. 106.
637 ID1577, p. 5.
638 ID4718, p. 6.
639 ID382, p.82, p.144.
640 Annex A to Niche's reply to the Statement of Objections, ID8525, p.2-3.

(456) Despite delays and difficulties, Niche was expecting a MA in the course of 2005 as can be seen from one of the regular updates distributed to Niche's customers on 30 November 2004: *"There have been some delays in obtaining regulatory approval in the UK and this is now not expected until early in the New Year"*. The update also stated that *"there should still be Judgment in the English proceedings* [the infringement proceedings between Servier and Niche] *at or about the same time as regulatory approval"*.[641] Judgments in the UK patent court "*are normally produced within a few weeks of the end of the trial"*.[642] Given that the judge of the *High Court* hearing the case between Servier and Niche had set the trial for February 2005, such judgment could have been rendered around April 2005.

(457) A similar timeline for approval applied to licences that could have been granted to customers in different Member States on the basis of the DMF provided to them by Niche. According to an internal document from October 2004, these were expected by the end of the first quarter of 2005 with variations in the second quarter (for the updated DMF).[643]

(458) In reply to the Commission's RFI of 13 August 2010, Matrix explained that at the time of the settlement, it *"anticipated that marketing authorisation for the EEA may have been six months away"*.[644] According to the information available to Matrix, Niche had made a MA application to the MHRA in 2004, which had triggered questions to Niche and follow-up discussions with that agency, with support from Matrix.[645]

(459) Niche itself stated in September 2004 that, together with Unichem and Matrix, it had a *"limited lead over other generic competition which should not be squandered"*.[646] A report from a meeting between Niche and Krka dating from 11 November 2004 indicated that *"[Krka] admitted that we are ahead of Krka"*.[647]

(460) One day before the conclusion of the patent settlements, it appeared as though Niche thought all outstanding API issues could be resolved. In an email from [employee name and function with Ratiopharm]* of 7 February 2005, Niche was asked to explain why it did not want Ratiopharm to submit a variation of the DMF for regulatory submission in the Netherlands. The reason, stated in an internal communication was "*To put it simply: we are not yet fully ready for a submission application"*.[648] The internal email does not, however, express concern that the MA would not be granted in the coming months.

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641 ID0025, p. 136. It is noted that these updates also called "newsletters" were drafted by Mc Dermott Will & Emery, Niche's external counsel. Although Niche claims in its reply to the Statement of Objections that the newsletters were not genuine representations of the material facts but words of encouragement and motivation and best case scenarios (ID8524, p. 12-13 and 24), they being drafted by external counsel is a sign of their fair representation of the situation.

642 ID4945, viewed on 31/05/2011.

643 ID1709, p.61.

644 ID2579, p. 6.

645 ID2579, p. 6.

646 ID0027, p. 228. In its reply to the Statement of Objections, Niche explains that the *"limited lead"* was mentioned to maintain pressure on Matrix and that a limited competitive edge can easily be lost (ID8524, p. 100). This statement confirms that Niche had a head start over other generics, a fact that it itself acknowledges in its reply to the Statement of Objections (ID8524, p. 33).

647 ID0028, p. 107.

648 ID2450, p. 35.

(461) DAA Pharma, one of Niche's customers for perindopril, applied for MA to the Dutch Medicines Evaluation Board and obtained MA based on the Niche dossier in May 2005, i.e. three months after the settlement.[649] In reply to the Commission's RFI of 22 December 2010, Matrix (who had meanwhile acquired Apothecon and DocPharma) explains that this MA was unusable following the settlement agreement between Niche and Servier.[650]

(462) In the light of the foregoing, it seems fair to conclude that MAs were within reach, but not yet granted, at the time when the settlements were concluded. A number of technical issues still needed to be resolved[651] but the parties were actively and constructively working on them.

4.3.1.1.5.2 Manufacturing and other difficulties relating to the complexity of the perindopril molecule

(463) In its reply to the Commission's RFI of 5 August 2009, Niche explains that it had encountered "insurmountable" manufacturing difficulties in obtaining a commercially viable perindopril when it decided to settle with Servier: *"[…] discussions regarding a settlement commenced some time after the 2nd phase due diligence which took place 21st January 2005. At this point in time it was apparent that the manufacturing difficulties that had been encountered over the previous few months were becoming insurmountable. When Servier made an offer to settle Niche had no financial alternative but to negotiate for as high a figure as possible whilst at the same time ensuring that Servier remained unaware of the insurmountable manufacturing problems"*.[652] In stark contrast to this, Matrix stated explicitly in reply to question 5 of the Commission's RFI of 13 August 2010 that: *"Matrix did not consider abandoning its research and development efforts for perindopril erbumine API prior to the settlement with Servier"*.[653] In addition, and as mentioned above, Matrix explained *ex post* that, at the time of the settlement, *"marketing authorisation for the EEA may have been six months away"*.[654]

(464) While it is uncontested that, since the beginning of their common development project, Matrix and Niche were faced with difficulties due to the complexity of synthetisation of the perindopril molecule, Niche's statement of "insurmountable" difficulties is in conflict with contemporaneous facts and events as set out below.

(465) One of Niche and Matrix's concerns was to avoid infringement of Servier's patents. According to Niche's *ex post* explanations in reply to question 13 of the Commission's RFI of 5 August 2009, Niche was advised by its legal adviser in early 2004 that its perindopril API *"could be found to infringe Servier's process patents ('341 in particular)"*.[655] Niche therefore asked Matrix to refine the process to

649 ID3319, p. 1 - 2.

650 ID3319, p. 2.

651 Niche claims in its reply to the Statement of Objections that the difficulties it faced seemed insurmountable but also that it was seeking to find solutions to these difficulties which could not be resolved in the immediate future, within the next 2-3 years (ID8524, p. 110). However, Niche submits no evidence in relation to the time period suggested, i.e. why 2-3 years would be necessary to overcome these issues.

652 ID1577, p. 8.

653 ID2579, p. 7.

654 ID2579, p. 6.

655 ID1577, p. 2.

produce an API which would not infringe any of the three Servier process patents.[656] Before any such modification of the process took place, a client of Niche, Sandoz, ceased its commercial relationship with Niche (January 2004), due to a fear of infringement and because of extremely restrictive ethical recommendations in terms of patents.[657] In its response to the Statement of Objections, Servier claims that it is not surprising that Niche decided to conclude a settlement agreement since it believed its product infringed the '340 and '341 patents.[658] However, the document cited by Servier, just like the termination of commercial relations between Niche and Sandoz, predates the decision of Niche and Matrix to amend their process.

(466) Another customer, Ratiopharm, also had concerns about possible infringement with different risks assessed for different countries.[659] The launch with Niche's product in Denmark, France, Spain and Portugal was not possible, according to Ratiopharm's evaluation.[660] For the UK, there was a risk of running into difficult infringement suits but Ratiopharm was advised by its patent attorney that launching with Niche's product was recommended with a chance of winning the infringement case and a bearable risk to launching the product as described in the dossier.[661]

(467) According to their development contract, Matrix and Niche aimed to produce a non-infringing API and consequently Matrix refined the process in 2004 by amending the route of synthesis, which required a new DMF.[662] In an email dated 21 June 2004 from [employee name and function with Niche]*, addressed to one of Niche's clients, [employee name of Niche]* expressed his confidence that the final product of the synthesis would consist of *"90 % alpha with 10 % beta but this cannot be guaranteed until scale-up and validation"*[663], i.e. that the final product would not infringe the '947 patent (Alpha patent) but that this cannot be guaranteed. Niche's patent situation was positively assessed in the email of 21 June 2004, reflecting the legal and patent advisers' opinion: *"The patent position is that on the basis of advice from our legal and patent advisers we show enough differences to make our route different from the relevant patents"*.[664] Another internal document from June 2004 mentions that Servier believed that Niche infringes the three process patents and adds that *"advice [*from top barristers in UK, patent attorneys and solicitors*] is we do not infringe any process patent of Servier […]"*.[665] In addition, an email from Niche to Matrix sent in August 2004 concludes that *"we can confirm that we do not believe that it [the process] can validly infringe any patent rights owned by Servier. The*

656 ID1577, p. 2.

657 ID0027, p.193. Servier cites this document in its reply to the Statement of Objections (paragraphs 24 and 290, ID10114, p. 25 and 145) and quotes the following excerpt in reply to Sandoz's decision not to sign a contract with Niche: *"not sure how they know whether we infringe or otherwise as they have not had any detailed information on our product process […] even though they do not really know it, we currently do infringe - oh poo and double poo trible* [sic] *and quadrouple poos bang goes my bonus!"*. It is reiterated that this document dates from January 2004, i.e. before any amendment to the process had been made.

658 Reply to the Statement of Objections, paragraph 308, ID10114, p. 151 citing ID0027, p. 28.

659 ID3635.

660 ID1709, p. 29 and 75

661 ID1709, p. 29 and ID0028, p.150-151.

662 ID1577, p. 4.

663 ID1709, p. 56

664 ID1709, p. 56.

665 ID0027, p. 34.

latest version of the process description is consistent with the strategy we have recommended".[666]

(468) Despite some hurdles and delays in obtaining regulatory approval, Niche expected to be ready to launch perindopril in early 2005. This was also the expectation of Servier based on Niche's submissions during the patent litigation before the English courts. On 30 September 2004 [name and function of Servier counsel]*, in his second witness statement on behalf of Servier in the English proceedings (further details on these proceedings in section 4.3.1.2.2) between Servier and Niche explained that Niche was confident of having a product on the UK market shortly after December 2004.[667]

(469) According to the minutes of a meeting held between Matrix and Niche in Hyderabad on 14 October 2004, Matrix reported that it had sent an update of the original DMF, including an update of the original route of synthesis, to Niche.[668] Matrix aimed to produce a product with an alpha polymorph not exceeding 80% in order not to infringe Servier's '947 patent which claims 90% or more of the alpha structure. In October 2004 the trial batch was under analysis and the initial data showed that the material contained approximately 95% alpha. It was discussed that optimisation trials should be conducted in order to determine the conditions necessary to obtain a lower alpha ratio of approximately 85%[669] and thus avoid any possible infringement of Servier's '947 patent. In the context of the regulatory issues that were discussed during the said meeting, it was agreed that *"API manufacture can start in December [2004]"*.[670]

(470) In keeping with the above, in an email dated 21 October 2004 Niche asked its customer Ratiopharm about its perindopril launch supply requirements for 2005, which indicated Niche's confidence of soon having a viable product: *"[C]an you let me know if there are any markets other than the UK where you expect registration and launch in 2005? If so, what markets and when would you require initial launch quantities and what volumes will you want for the first launch order/s. We require this for our production planning of 2005 and would appreciate an indication by mid November latest if possible"*.[671]

(471) Another difficulty in the development of perindopril concerned changes in the particle size and the related issues of hardness of the tablets and the dissolution profile. Changes in particle size potentially alter the bioavailability of a medicine (i.e. the speed at which it gets into the blood) and can ultimately undermine the bioequivalence required for marketing authorisation.

(472) In November 2004, perindopril particle size issues were discussed in correspondence between Niche and Matrix. Difficulties were encountered during the optimization trial of perindopril, namely the sieving did not work as planned, probably due to the particle size.[672] After having checked the revised DMF, Niche was worried about whether Matrix would be able to explain and justify the change in the particle size distribution: *"Although it is accepted that the API is soluble, we will need to*

666 ID0027, p. 233.
667 ID2634, p. 5.
668 ID1709, p. 60.
669 ID1709, p. 60.
670 ID1709, p. 61.
671 ID0028, p. 151.
672 ID466, p. 17.

demonstrate that all other physico-chemical properties remain the same […] and that content uniformity and dissolution profiles of the resulting tablets are consistent with those used in the bioequivalence study".[673]

(473) In order to overcome those technical difficulties, a further tableting trial was suggested by Niche to [name of individual]*, a former Niche consultant,[674] on 13 December 2004.[675] The parties were therefore constructively thinking of different solutions to the difficulties in order to be able to launch the final product.

(474) In January 2005, Niche and Matrix discussed a newly detected impurity in Matrix's API. Niche considered that the problem may be linked to a specific raw material Matrix was using. Niche suggested that production be stopped until the problem is remedied, "*the worst case scenario being that we have to start production afresh*".[676] Unichem also mentioned difficulties related to the impurity which was out of specification limits in the three batches that were analysed in February 2005 (post-settlement) and the issue was drawn to Matrix to investigate the issue.[677] In its supplementary reply to the Commission's RFI of 5 August 2009, Niche contended that this newly detected impurity was the main reason for the delay in receiving regulatory approval.[678]

(475) Matrix, on the other hand, appeared to be more confident that any difficulties relating to the API's purity and stability could be overcome within a reasonable period of time. In his fourth witness statement in the English patent litigation dated 27 January 2005, [employee name of Matrix]* explained: *"[…]*".[679] It was therefore foreseen in the Quality Overall Summary that manufacturing would be restricted to [3-10kg] batches. This was the size of the small scale batches Matrix successfully produced in October 2004, which were of sufficient quantity for a commercial launch according to Matrix's reply to the Commission' RFI of 13 August 2010.[680]

(476) In addition, a contemporaneous document dated 29 November 2004 prepared by [employee name of Niche]* (report on the hearing of November 2004 in the English patent litigation) clearly states that Niche did not believe that there would be insufficient quantities of perindopril for launch: *"(…) Servier's assertion, which Niche refute, that the process being used by Matrix will produce insufficient quantities for Niche to launch and therefore the process will be scaled up and as a consequence will infringe".*[681]

(477) It is noteworthy that neither Niche nor Matrix were minded to make use of clause 4, paragraph 3 of their Development and Licensing agreement which allowed the parties to cancel the project if delays made the launch of the product non-viable (i.e. in the face of insurmountable difficulties): *"In case the delays in some phases are likely to delay the project to such an extent, so as to make the launch of the product non-viable, then both parties agree to cancel the project with immediate effect.*

673 ID1709, p. 64.
674 ID3268, p. 1.
675 ID1709, p. 76 – 78.
676 ID1709, p. 68 - 74.
677 ID7168, p. 3.
678 ID1577, p. 5.
679 ID2638, p. 6 - 7.
680 ID2579, p. 6.
681 ID4718, p. 4.

Termination of the agreement must be in writing".[682] Niche explained, in reply to question 4 of the Commission's RFI of 22 December 2010, that it did not consider invoking the termination clause because […]*.[683]

(478) On the contrary, as will be detailed in section 4.3.1.5, in the post-settlement period (i.e. post 8 February 2005), Niche and Matrix continued to discuss their common perindopril project in order to finalise the marketing authorisation process.

(479) It thus seems fair to conclude that despite some technical hitches, the parties were actively trying to find solutions and there is no evidence of any "insurmountable" barriers. As indicated above, the parties expected to launch the product during the course of 2005, which would have been by far the earliest product launch for an independent generic perindopril.

4.3.1.1.5.3 The marketing authorisation process was followed closely by Servier

(480) Contemporaneous documents found during the inspection of November 2008 at the premises of Servier UK illustrate that Servier closely monitored the UK market during 2003 and 2004,[684] in particular the MA applications for perindopril, in order to be in a position to react to the expected threat of a competing generic perindopril.

(481) On 7 January 2004, an agreement concluded between Servier and the consultancy firm [company name]* reveal research commissioned by Servier about different generic companies including, amongst others *"Profile Unichem Laboratories Limited"* and *"Research into Niche Generics Limited […]".*[685]

(482) A further research report by [company name]* dated 17 December 2004 stated that: *"Research shows that recent applications by Niche Generic and Matrix Laboratories Limited, Neolab limited and Cipla Limited have one thing in common: an Indian background with links to Ranbaxy, Cipla and Matrix, which would suggest that there could be a strategy behind these attempts to produce and market the generic Perindopril. It would appear that these companies are converging to attack Servier's Perindopril. It is our belief that, despite their claims, they do not ignore the fact that by producing generics of Perindopril that could breach the process patent and if so will be legally challenged. We therefore think this could be a strategic ploy to make the Niche/Matrix offer more attractive"* (emphasis added).[686]

4.3.1.2 Patent dispute between Niche and Servier

4.3.1.2.1 Warning letters and early patent issues

(483) On 16 July 2003, Niche received a warning letter from Servier explaining that Servier was *"determinated to oppose any attempt to launch a generic of our drug* [Servier's perindopril] *by all legal means"*. Servier contacted Niche as it became aware of Niche's intention to market generic perindopril in Europe.[687] This letter also stated: *"We inform you that we have different patent protection for our drug [perindopril] until at least 2008 especially in European countries".*[688]

682 ID1709, p. 39.
683 ID3268, p. 1.
684 ID0034, p. 451 and 455.
685 ID0034, p. 444.
686 ID0034, p. 453.
687 ID2634, p. 4 - 5.
688 ID0466, p. 58.

(484) The following day, on 17 July 2003, Niche replied to Servier, stating that it did not intend to breach any patents when launching generic products: *"We are aware that Servier have certain process patents in place until 2008. It is not our intention to launch any product in the future, which could infringe the rights of a patent holder. Niche Generics Limited intend to take steps to prove that our source of Perindopril does not infringe the patents of Servier (...)"*.[689]

(485) As illustrated above, Niche and Matrix paid particular attention to develop a product which would not infringe the process patents, those of Servier in particular, and were confident they would overcome the patent hurdles.

(486) On 19 January 2004, [name and function of Niche counsel]*, reported in an email to Niche's top management the content of his conversation with Ratiopharm's patent department. He reports that he had explained to Ratiopharm that Niche believed it would not infringe any of the process patents ('339, '340 and '341) or any other valid patent in Europe with its generic perindopril: *"I explained that [name of Niche counsel]* had been advising Niche at every step of the way and that Niche was confident that it had a product that would not infringe any valid patents in Europe"*.[690]

(487) On 13 February 2004, Servier again warned Niche about its existing patent protection for perindopril. This letter drew attention to the process patents '339, '340, '341 and to patent '324 (the latter was not included in the subsequent patent litigation by Servier). It also contained a list of 24 other patents and patent applications.[691] Servier threatened to bring proceedings against Niche if the latter did not provide evidence (e.g. samples of the product, details of manufacturing process) of non-infringement.[692]

(488) In March 2004, Niche informed Matrix of Servier's intention to start patent infringement proceedings against Niche if Niche did not reassure Servier of the non-infringement of its patents.[693]

(489) Niche's legal strategy towards Servier is set out in an internally prepared presentation for a board meeting held on 26 April 2004.[694] It states that Niche decided to (i) send a signal to Servier that it was not infringing any of the main process patents; and (ii) argue that the '947 patent is, in any event, invalid. If Servier did not reply to the letter within 21 days, Niche was prepared to go to court to obtain a declaration of non-infringement.[695] This document stated that *"Both Niche's lawyers and patent attorneys believe that we are setting out very strong arguments of non-infringement"*. Against this background it is concluded: *"The aim is through the weight of evidence to persuade Servier to conclude that we do not infringe and this will allow a commercial arrangement that will suit Niche and to an extent Servier by keeping other generic versions of perindopril off the market for as long as possible"*.[696]

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689 ID3855, p. 1.

690 ID0027, p. 179.

691 ID0027, p. 167 - 169. This included two patents that Servier had internally classified as patents "**zero inventive step*" and fifteen patents which it had internally classified as "**blocking patents*" (ID9972, p. 78-119).

692 ID0027, p. 168.

693 ID3308, p. 4.

694 ID2450, p. 2.

695 ID0027, p. 224 - 225.

696 ID0027, p. 226.

(490) The letter from Niche's to Servier's lawyers was sent on 27 April 2004. It contained a brief confidential process description and a claims chart.[697] Moreover, the letter argued that Niche did not infringe any of Servier's patents.[698] With respect to the process patents Niche invited Servier: *"1. to accept that none of the process claims is infringed; 2. if your client is unable to give our client that comfort, please let us know which specific claims are alleged to be infringed and of which of the process patents; 3. in the event that your client's assertion is not one of literal infringement (and we do not see how it can be) the basis under the Protocol to Article 69 EPC on which your client intends to maintain infringement"*.[699] In addition, Niche's lawyers indicate that *"[given the above analysis] there is no infringement based on the processes used by Niche*".[700]

(491) In the same letter Niche argued that the patentability of the '947 patent was based on the purity of the alpha polymorphic form. Since Niche's product is a mixture of the alpha and beta polymorphic forms of perindopril erbumine, it cannot infringe the '947 patent. Niche explained that if infringement were to be asserted, it would seek revocation of the '947 patent on several grounds. In particular, Niche would argue a lack of inventive step: *"Neither the '947 nor the '948 Patent discloses any surprising, unusual or non-routine chemistry and the '947 Patent is so obviously invalid for lack of inventive step, we invite your clients to surrender it now"*.[701] Moreover, Niche announced that it would argue that claim 1 of the '947 patent was not novel due to Servier's own prior art. According to Niche, Servier had produced tablets containing perindopril erbumine in the alpha polymorph form since around June 1999.[702]

(492) Shortly thereafter Niche's lawyer contacted Servier's lawyer to explore the possibility of a settlement. On 12 May 2004, [name of Servier counsel]* reported this initiative to Servier's patent department.[703] According to [name of Servier counsel]*, Niche, *"first proposed that the matters in issue could be referred for expert determination in confidence, rather than litigated in open court. Second, he enquired whether Servier would be open to discussing ways of achieving a negotiated settlement. This could be for example by Servier agreeing a licence in favour of Niche or alternatively entering into a supply agreement whereby Niche could become an approved second source of supply of perindopril"*.[704]

(493) [Name of Servier counsel]* further reported Niche's reasoning to Servier, which presented the option of appointing an expert or of settling with a licence or with the conclusion of a supply agreement as a win-win situation for Servier and Niche: *"In the view of Niche, it was in the interests of neither party to engage in litigation on the validity and infringement of Servier's patents in open court. If Niche were successful in revoking Servier's patents, this would obviously be damaging for Servier. However, it would also not be particularly advantageous for Niche, given that it*

697 ID2634, p. 4.
698 ID2450, p. 13 - 17.
699 ID2450, p. 15.
700 ID0025, p. 123.
701 ID2450, p. 15.
702 ID2450, p. 15 - 16.
703 ID3842, p. 6 - 7.
704 ID3853, p. 1.

would open the way for other generic entrants into the market. Niche did not want to 'win the battle, but lose the war'".[705]

(494) On 25 May 2004, [name of Servier counsel]* reported to Servier's patent department that he had communicated to Niche Servier's readiness to enter into discussions but made clear that *"any discussions would be on the basis that Servier considered the Niche process to infringe Servier's '339, '334*[706] *and '341 patents"*.[707] [Name of Servier counsel]* also mentioned that Niche's lawyer was interested in knowing Servier's position on the polymorph patents.[708]

(495) On 1 June 2004, Niche's lawyer [name of Niche counsel]* sent a without prejudice letter to Servier's lawyer referring to their telephone conversation of 25 May 2004. He stressed the *"diametrically opposed views"* of Servier and Niche on the infringement of the process patents.[709] Niche's lawyer also pointed to the fact that, with respect to the '947 patent, Servier *"is caught between the rock of non-infringement and the hard place of invalidity"*.[710] In this letter, Niche's lawyer suggests that they could explore other ideas and proposed a meeting between Servier and Niche.

(496) A report dated 4 June 2004 sent to a Niche customer indicated Servier's arguments, which were considered by Niche's lawyers as *"very weak"* according to British juridical standards. In addition, it was stated that *"Servier have not come back with anything substantial beyond a mere assertion of infringement"*.[711]

(497) The initial settlement discussions between Servier and Niche were not successful and, ultimately, Servier decided to bring a patent suit against Niche before the High Court (for details see next section).[712] The infringement action was limited to Niche despite the fact that Servier already knew that Matrix was Niche's API supplier.[713] Servier only threatened Matrix with infringement proceedings on 7 February 2005, one day before the conclusion of the patent settlement.

4.3.1.2.2 The patent litigation between Servier and Niche before the High Court

(498) On 25 June 2004 Servier started infringement proceedings against Niche in the High Court relating to the process used in the development of Niche's perindopril. Servier also requested that Niche consent to an interim injunction restraining Niche from infringing Servier's '339, '340 and '341 process patents.[714] A draft application notice for an interim injunction and a draft order for an interim injunction were served on Niche on the same day.[715]

(499) The subject matter of the litigation with Niche only concerned Servier's process patents ('339, '340 and '341).[716] Niche served on Servier a counterclaim for invalidity

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705 ID3853, p. 1.
706 This seems to be a mistake, it is assumed that the '340 patent is meant.
707 ID3852, p. 1.
708 ID3852, p. 1.
709 ID3854, p. 1.
710 ID3854, p. 1.
711 ID0025, p. 128.
712 ID2626, p. 1.
713 ID3842, p. 6.
714 ID0465, p. 50 - 51 and ID2634, p. 4 - 5.
715 ID0463, p. 7.
716 ID465, p. 50.

of the '947 patent on 9 July 2004.[717] Niche argued that the claim in the '947 patent was anticipated by the '341 patent and was therefore not novel.[718] This counterclaim appears however to have been refused by Servier given that it was served before the defence of Niche in the infringement proceedings[719] and it was also not filed later by Niche together with its defence in the infringement case.[720] Servier's position was that *"it would be sensible for the court to hear both of these actions* [infringement and revocation] *together since [they] relate to the same chemical compound"*[721] whereas Niche considered it inappropriate that *"the revocation of the '947 patent runs on the same track as the infringement proceedings"*.[722] No separate revocation action was filed thereafter by Niche, nor was there any action initiated by Servier about infringement of the '947 patent.

(500) A hearing in the High Court took place on 28 July 2004, at which Niche applied for an order requiring Servier to set out the basis of the alleged infringement.[723] Servier lodged a counter application asking for: (i) a sample of Niche's product; (ii) disclosure of the names of Niche's suppliers; (iii) a hearing date for an interim injunction; and (iv) a lengthier timetable to hear the infringement allegations.[724] The judge ordered, *inter alia*, a speedy trial and, therefore, denied Servier a hearing for an interim injunction for the time being.[725]

(501) In a note dated 5 July 2004 from Niche's lawyers to Niche's customers,[726] it is stated that the reluctance of Servier to claim an infringement of the '947 patent can only be explained by a perceived weakness of this patent: *"The position on the alpha polymorph patent, 947 is that Servier are still asserting insufficient information. They seemed remarkably reluctant to risk suit on the 947 patent"*.[727]

(502) Servier, on the other hand, blamed Niche for not being forthcoming as it did not provide enough information about its product for Servier to be able to determine whether the '947 patent is infringed.[728]

(503) In relation to the process patents, the note indicates that Servier had requested Niche to consent to an interim injunction to which Niche's reply was that *"the case on infringement on the process patents is hopeless […]"*.[729]

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717 ID0465, p. 59-60.

718 Later revocation of the '947 patent by the EPO and in the UK essentially relied on the same argument (see section 4.1.2.4.2.2.1.).

719 Annex 06-07 of Servier's reply to the Statement of Objections, ID9060, p. 9.

720 Annex 06-05 of Servier's reply to the Statement of Objections, ID9060.

721 Annex 06-07 of Servier's reply to the Statement of Objections, ID9060, p. 10.

722 Annex 06-05 of Servier's reply to the Statement of Objections, ID9060.

723 ID3740, p. 7.

724 ID3740, p. 7.

725 ID0463, p. 4 and Annex 06-06 to Servier's reply to the Statement of Objections ID9060, p. 17.

726 Servier claims in its reply to the Statement of Objections that Niche's notes to customers or "newsletters" are pure marketing material and that they are far from describing the litigation in an objective manner (paragraphs 312-313, ID10114, p. 152-153). A similar argument has been made by Niche and was addressed in footnote 641 of this decision. Servier goes as far as to mention in paragraph 312 (footnote 226) of its reply that one of the examiners of the second newsletter was concerned about the ethics of this document (ID10114, p. 153) – this is however a misinterpreted fact since the examiner of the newsletter was commenting on whether correspondence exchanged with Servier could be shown to customers and whether this could be considered as "contempt of court" (for reference, see ID0025, p.128). The newsletters signed by Niche's legal counsel made Niche aware that legal consequences may ensue from the information or misinformation of the customers.

727 ID0025, p. 131.

728 Annex 06-07 to Servier's reply to the Statement of Objections, ID9060, p. 13.

(504) Niche's note to customers dated 10 August 2004 stated that: *"The longer Servier waits before attempting to assert the '947 patent against Niche, the less likely the Court will be to grant Servier an interim injunction against Niche. There seems little point in Niche provoking a patent action under a patent that Servier appears to be too scared to enforce"*.[730] This position is confirmed in a subsequent note from Niche's lawyers, presumably dated September 2004.[731]

(505) Servier's statement of case setting out the grounds upon which Servier alleged infringement was served after the July hearing.[732] Both parties then started with the preparation of the expert evidence upon which their cases would be based. Matrix, in its supporting role as API manufacturer, provided witness statements which will be described in section 4.3.1.2.3.2.

(506) A further hearing took place on 18 October 2004 at which Servier sought a court order for inspection of the process being carried out by Matrix. In addition, in a note presumably dated from the end of October 2004[733] updating customers about the patent litigation, Niche's lawyer explained that Servier *"appear to be withdrawing from their allegation that Niche and its suppliers are not carrying out the process as described. Servier instead sought to raise a new allegation that Niche's process would be impossible to perform at a larger scale. […] Niche see this new allegation as a tactic to delay the trial which is unlikely to succeed. Niche and its supplier have no intention to scale the process up but plan to produce sufficient quantities of perindopril erbumine to satisfy the market requirements of their customers by increasing throughput of batches"*.[734]

(507) On 26 November 2004, a further court hearing took place and regarding which Niche's legal team was *"buoyant […] as they believe that many of the arguments put forward by Servier and the judges' comments in response to them have strengthened [Niche's] case"*.[735] Servier made an application to the court to adjourn the hearing of the trial claiming not to be ready. This was, according to Niche's lawyers, reluctantly accepted by the Court[736] which however accepted to postpone the hearing from December 2004 to February 2005. In a note dated 30 November 2004 updating Niche's customers, the lawyers stated that *"there should still be Judgment in the English proceedings at or about the same time as regulatory approval"*.[737] As stated in section 4.3.1.1.5.1., this judgment could have been rendered around April 2005. In addition, two of the three grounds on which Servier was relying to assert infringement were described by the Court as *"very thin"*. According to Niche's lawyers, the Court had the impression that Servier's case was, in relation to the

729 ID0025, p. 131. To support its argument that the newsletters to customers were not an objective description of the litigation, Servier notes in its reply to the Statement of Objections that Niche was quick in saying that the case of infringement was hopeless whereas there had been no evidence exchanged at the time (paragraph 313, ID10114, p.153). The parties had exchanged information on the issue of infringement of the process patents in the previous months (see warning letters) and this conclusion may have been made on this basis.

730 ID0025, p. 133.

731 ID0025, p. 134.

732 ID3741, p. 18.

733 The presumption regarding the date of this document is based on the information included in Newsletter n°6.

734 ID0025, p. 135.

735 ID4718, p. 4.

736 ID0025, p. 136.

737 ID0025, p. 136.

remaining ground, *"in some disarray"*. Niche's lawyers expressed their satisfaction *"as the trial Judge is now well aware of the weaknesses in Servier's case"*.[738]

(508) The trial in the High Court was scheduled for 7 – 8 February 2005 and around that time the preparations for the trial were intensifying.[739] In the end, the hearing only lasted half a day as on that day the case was settled out of court thereby discontinuing the litigation between Niche and Servier.

(509) Servier claims in its reply to the Statement of Objections that the Commission wrongly portrayed the litigation according to Niche's lawyers' very optimistic view of it.[740] First, it is noted that the Commission has used the documents on the file which describe the parties' perceptions of the litigation's possible outcome. As set out in Servier's reply to the Statement of Objections, it believed that it had chances to win the litigation against Niche and the witness statements of Professor Motherwell identify that there are no material differences between Niche's process description and the process patents[741] – except these witness statements, Servier has submitted no internal documents on this issue. Second, there was a genuine dispute between the parties which is acknowledged by the Commission and uncertainty on the outcome of that litigation. In any event, Niche believed that there was a realistic chance that it would be successful in the litigation against Servier.

4.3.1.2.3 Matrix's involvement in the patent litigation before the High Court

4.3.1.2.3.1 Revelation of Matrix's identity as the API supplier of Niche

(510) As confirmed in the second witness statement of Servier's lawyer [name of Servier counsel]* of 30 September 2004, Servier discovered that Matrix was Niche's API supplier in June 2004 through an article entitled "The Matrix Evolution" from the publication "Business World" dated 29 December 2003.[742] The article contains details of the development agreement between Niche and Matrix and Servier had inferred from it that Matrix was more than a *"simple supplier of the API"*.[743]

(511) Servier received explicit confirmation of Matrix's identity as Niche's perindopril API supplier through [employee name of Matrix]*'s witness statement dated October 2004, in which Matrix's role was further described.[744] Despite this knowledge, Servier did not launch any infringement proceedings against Matrix in the UK or elsewhere but only contacted Matrix formally on the eve of the settlement itself, on 7 February 2005.[745]

738 ID0025, p. 136 - 137.

739 ID2579, p. 12 (reply by Matrix to RFI 13/08/2010) and ID0025, p.136.

740 Servier's reply to the Statement of Objections, paragraph 330, ID10114, p.159.

741 Servier's reply to the Statement of Objections, paragraph 325-326, ID10114, p.157.

742 ID3847, p. 1 - 6 and ID3842, p. 6. Servier claims in its reply to the Statement of Objections that Niche refused to inform Servier of the name of its API supplier in order to make the proceedings for Servier more complicated. At the same time Servier explains that one of the means available to a High Court judge in patent proceedings is to order an inspection of the API manufacturer's site and that in this case it seemed that Niche and Matrix wanted to avoid such inspection (paragraphs 524-526, ID10114, p. 221). The Commission stresses that the judge can order an inspection if considered necessary. The fact that Niche refrained from mentioning the name of its API supplier is irrelevant given that the judge had powers to ask for such information and order an inspection.

743 ID3847, p. 2 - 6 and ID2634, p. 9.

744 ID2579, p. 12 and ID2636.

745 ID2639, p. 1 - 2.

(512) During the investigation, Matrix explained its non-participatory role in the patent infringement proceedings between Servier and Niche: *"Matrix understands that Servier became aware of Niche's intentions to obtain marketing authorisations for Perindopril in 2003 - 2004 and Matrix was informed (…) that Servier had sued Niche before the Patents Court in England & Wales for infringement of a number of its patents, in particular, European Patent numbers EP (UK) 0 308 339, (UK) 0 308 340 and (UK) 0 308 341 ('the Patents in Suit')[…]. Matrix received updates from Niche in relation to the patent infringement proceedings during 2004 and early 2005. Matrix provided assistance to Niche, in particular by providing details of its production process for the Perindopril API".*[746]

(513) According to Matrix's explanations, [employee name and function with Niche]* periodically forwarded copies of pertinent correspondence between Niche and Servier to Matrix.[747] In addition Matrix explained: *"[P]eriodic telephone conferences would have taken place between Niche ([employee name of Niche]*) and the development team at Matrix. At certain points during the litigation, such as in late 2004 and early 2005 during the preparation of [employee name and function with Matrix]*'s witness statements, Matrix understands that these telephone calls occurred on a regular basis. […] On a number of occasions, Matrix was requested to provide input and/or comments on draft correspondence to Servier. Matrix was also requested to provide technical detail on the process for the manufacture of perindopril API in order to assist Niche's legal advisers prepare pleadings and submissions for the Court proceedings".*[748]

(514) Thus Matrix was duly informed throughout the on-going litigation between Niche and Servier and even actively participated through the witness statements provided by [employee name of Matrix]*.

4.3.1.2.3.2 Matrix's witness statements in the proceedings before the High Court

(515) The witness statements on behalf of Niche by [employee name and function with Matrix]*, in the English patent infringement proceedings between Niche and Servier constitute key evidence because they provide detailed contemporaneous evidence on the state of the API development prior to the conclusion of the settlement. [Employee name of Matrix]*'s witness statements were made between 13 October 2004 and 27 January 2005.[749]

(516) According to [employee name of Matrix]*'s witness statements, Matrix had undertaken the first commercial run of API batches during October 2004. Dr Mohan also stated that a number of batches were under way in November 2004 in preparation for the planned commercial launch.[750] The subsequent quotations demonstrate that the level of production and capacity of the process used by Matrix was expected to be sufficient to satisfy API orders from Niche for the launch of perindopril.

(517) [Employee name of Matrix]*'s second witness statement of 25 November 2004 reads: *"[…]*".*[751]

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746 ID1452, p. 13, reply to question 22 of the Commission's RFI of 5 August 2009.

747 ID2579, p. 12, reply to question 15 of the Commission's RFI of 13 August 2010.

748 ID2579, p. 12, reply to question 15 of the Commission's RFI of 13 August 2010.

749 ID2579, p. 12.

750 ID2579, p. 3.

751 ID2637, p. 1 - 4.

(518) The approximate capacity of Matrix's production is outlined in an annex to [employee name of Matrix]*'s second witness statement. It was calculated that under the then current equipment and scale, and based on Matrix's experience in running the initial batches in October 2004 *"Matrix expects to produce up to [confidential] kg of finished Perindopril erbumine per month which is more than adequate for Niche's current requirements"*.[752]

(519) The fourth witness statement of [employee name of Matrix]* dated 27 January 2005 reads: *"[…]*"*.[753]

(520) Furthermore, in [employee name of Matrix]*'s fourth witness statement it is explained that Matrix always made sure that when developing API it did not infringe the IPRs of third parties: *"[…]*"*.[754]

(521) In summary, [employee name of Matrix]*'s witness statements clarify that Matrix's capacity was sufficient to satisfy Niche's API orders and thereby commercial demand. Further up-scaling was neither considered necessary nor appropriate, as throughput could be increased.

4.3.1.2.4 Opposition procedures before the EPO

(522) Besides the English infringement proceedings, Niche was as of November 2004 party to the opposition procedure launched before the EPO against the '947 patent (see section 4.1.2.4.2.1).

(523) Niche had also filed around 11 August 2004 an opposition against the gamma patent before the EPO.[755]

4.3.1.3 Servier's attempt to acquire Niche

(524) As described above in section 4.3.1.1.5.2, Servier closely monitored generic companies and API producers by, in particular, commissioning market intelligence reports from [company name]* in the period leading to the settlement with Niche/Unichem and Matrix (2003 - 2005).[756] In the light of the on-going litigation and market research conducted by [company name]*, Servier acquired significant intelligence on Niche. In addition, Niche's largest customer at the time was Biogaran (for the product [product name]*)[757], a wholly-owned subsidiary of Servier active on the French generics market.

(525) In autumn 2004, Servier started considering whether or not to acquire Niche.

(526) According to Niche's reply to question 22 of the Commission's RFI of 5 August 2009, Niche received an indicative offer from Servier in October 2004 to purchase 100% of Niche's share capital for GBP [10–35]* million.[758] On

752 ID2637, p. 6.
753 ID2638, p. 6 - 7.
754 ID2638, p. 2 - 3.
755 ID0028, p. 189.
756 ID3842, p. 7.
757 ID3268, p. 3.
758 Niche is however unable to confirm the precise date of this offer, since it has not been able to locate a copy of this offer letter, ID1577, p. 7. Apparently, this offer was made significantly later, namely on 10 January 2005 as explained in paragraph (532).

28 October 2004, Servier sent Niche a draft non-disclosure agreement, which was ultimately signed on 15 November 2004.[759]

(527) On 3 November 2004, the first details of the information required for due diligence were set out in a letter from [name of bank]*, Servier's advisers, to Niche. The due diligence was structured as a two-step process. The letter included a list of items for phase 1 due diligence which *"should represent all information required by Servier to submit an indicative and non-binding offer for Niche"*.[760] According to this letter, Servier would not receive all available information relating to Niche's perindopril project during this phase of the due diligence, which *"may notably exclude information which regards perindopril and is deemed sensitive within the scope of the pending litigation between Servier and Niche. However, in order to assess a fair value for Niche, it would be important that your financial forecasts / business-plan would include your assumptions for perindopril (at least for the next three years)"*.[761]

(528) On 16 November 2004, the first phase of the due diligence commenced. Among the information provided in a data room was Niche's business plan as projected until 2009, but excluding references to perindopril:[762] *"As agreed no information relating to perindopril will be available at this stage and this has resulted in some financial information being summarised"*.[763]

(529) In the [name of bank]* report on the first phase of the due diligence (entitled *"[…]*"*),[764] it was stated that Niche increasingly relied upon profit sharing contracts with API suppliers in order to keep exclusive access to a particular API for a longer time period (five years renewable). Disregarding perindopril, for the end of 2006/start of 2007, Niche was expected to have had four new products ready for launch on the basis of the profit sharing contracts with API suppliers.[765] It was also stated that the financial structure of Niche was not positive.

(530) The report also contains a section, which is obviously but not explicitly, dedicated to perindopril ("**Product P*")[766]. The relevant extracts read:

*"*2. Product P*

As agreed between us, the subject was not directly discussed at this stage. However, the information shared and collected can be summarised as follows:

Matrix (active ingredient supplier): The company refers to product P in its communication and this is reflected in a report by Morgan Stanley dated July 2004 and following an interview with the company. Among the major products expected the main one mentioned is product P (by 2006, amount of revenue expected is $[0–30 million] on the active ingredient and the formulation). Income under a dossier*

759 ID1709, p. 13 - 14.
760 ID1709, p. 15.
761 ID1709, p. 15.
762 ID1709, p. 19 - 25.
763 ID1709, p. 25.
764 ID0108, p. 216 - 224.
765 ID0108, p. 216 - 217.
766 Servier confirmed in reply to question 67 of the Commission's RFI of 6 August 2009 that *"*Product P"* refers to perindopril in this document. ID1151, p. 38.

for Europe intended for Niche (i.e. : DMF of product P and/or MA) by the end of March 2005 (financial year of Matrix)".[767]

(531) On the basis of this report, Servier could conclude that Niche's development partner Matrix was expecting to have its first revenues from the sale of perindopril in Europe in March 2005. Moreover, Servier knew that Matrix was anticipating USD [0–30]* million of revenues from perindopril.

(532) Against this background, [name of bank]* submitted a preliminary, non-binding offer on 10 January 2005 on behalf of its client Servier[768] to *"all shareholders of Niche Generics Limited c/o [employee name and function with Niche]*"*[769] to acquire Niche for a price in the range of GBP [15–45]* million. The offer stated: *"Following our Phase 1 Due Diligence on 16 and 17 November, 2004, we are pleased to submit Servier Group's preliminary and non-binding offer (hereafter the 'Preliminary Offer') for Niche Generics Limited (hereafter 'Niche'). Based upon the information contained in the Phase 1 Due Diligence, we confirm Servier Group's interest in acquiring Niche on and subject to the general terms and conditions outlined below".* The offer was conditional on "*the satisfactory completion of Phase 2 Due Diligence".*[770]

(533) It appears as though Servier considered settling with a payment to Niche as an alternative to the acquisition. Correspondence between Niche and Unichem of 13 January 2005 comments on Servier's preliminary offer to acquire Niche's shares as follows:[771] *"In phone call last week they [Servier] expressed preference to pay a 'patent settlement' rather than acquire shares. They have suggested they are reviewing this and will be in a position to send in the coming days. I think they are struggling to devise a method that is acceptable".*[772]

(534) In a letter from [name of bank]* to Niche of 19 January 2005, Servier nonetheless confirmed its interest in starting phase 2 of the due diligence.[773] This letter suggested that *"in the [sic] case Servier Group decides to purchase Niche or to conclude an alternative transaction structure, this payment [the deposit of EUR 2 million] will be deducted from the final price".*[774]

(535) On 21 January 2005 the second phase of the due diligence took place following the payment of a non-refundable deposit of EUR [0–5]* million[775] (in return for the exclusive disclosure of information and the exclusivity of the negotiations reserved to Servier until 28 February 2005). Niche stated in its reply to the Commission's RFI of 27 July 2010, that *"Servier reviewed the Niche Generics Limited Perindopril dossier together with details of Niche's customers for the product."*[776]

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767 ID0108, p. 217.

768 Niche explained in reply to the Commission's RFI of 27 July 2010 that they have not been able to locate a copy of this letter sent by fax from Servier to Niche. ID2450, p. 1.

769 ID0108, p. 213.

770 ID0108, p. 213 - 215.

771 ID2450, p. 1.

772 ID2450, p. 5.

773 ID1709, p. 26.

774 ID1709, p. 26.

775 According to Niche, this sum allowed it to continue to trade, ID4718, p. 2.

776 ID2450, p. 1.

(536) According to Niche's explanations, Servier advised verbally Niche on 31 January 2005 that it no longer wished to proceed with acquiring Niche.[777] Instead the discussions on the patent settlement began in earnest.

(537) During the investigation, Servier explained that Niche was not acquired for several reasons, including its financial situation and the uncertain future evolution. Servier confirmed that in the second due diligence phase, Niche's external partnerships were analysed, including those relating to perindopril.[778] As to Niche, it indicated *ex post* that Servier's offer to acquire Niche *"was driven by their desire to prevent generic perindopril being launched"*.[779]

(538) In summary, prior to the conclusion of the settlement, Servier considered the options that would allow it to gain control over Niche's perindopril project. The first option was to acquire Niche's shares. The second option was – as explained in the email of [employee name of Niche]* of 13 January 2005 - *"to pay a patent settlement"*. Ultimately, after having carried out a fully-fledged due diligence and in full knowledge of the pending court proceedings, Servier decided in favour of the second option.

4.3.1.4 The settlement agreements and related agreements

(539) On 8 February 2005, Servier concluded two settlement agreements, one with Niche/Unichem and the other with Matrix. This section describes the history of the negotiations and the content of the settlements as well as the related agreements. It also summarises the explanations relating to these agreements provided by the parties.

4.3.1.4.1 Servier and Niche/Unichem

4.3.1.4.1.1 Negotiations prior to the settlement

(540) According to Niche's explanations, the patent settlement discussions began in late January 2005 and were conducted via the parties' legal representatives.[780]

(541) Draft heads of agreement dating from 31 January 2005 identify the main settlement provisions, some of them similar to the final settlement agreement signed on 8 February 2005.[781] By contrast, other obligations on the part of Niche were only present in the heads of agreement and were not taken up in the settlement agreement (e.g. withdrawal of any applications for regulatory approval and the acknowledgement by Niche that the process was infringing Servier's process patents).

(542) According to the draft, Niche and Unichem would also agree to assign Servier *"all right title and interest in patent applications"*[782]. In addition, it can be noted that the five payments foreseen in this draft are linked to the expiry date of the process patents and subject to the termination of all contracts relating to perindopril and the withdrawal of marketing authorisation applications.

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777 ID1577, p. 7 and ID2450, p. 1. Replies to question 22 of the Commission's RFI dated 5 August 2009 and question 7 of the Commission's RFI dated 27 July 2010.

778 ID1151, p. 38. Reply to question 66 of the Commission's RFI of 6 August 2009 Servier also provided a brief overview concerning Niche and Unichem. ID1124, p. 1 - 20.

779 ID4898, p. 2.

780 ID1577, p. 7, reply to questions 23-24 of the Commission's RFI dated 5 August 2009.

781 ID3764.

782 ID3764, p. 1.

(543) Judging by the Heads of Agreement dated from 31 January 2005, Servier did not intend to conclude a separate settlement agreement with Matrix at the time but intended to make some of the payments to Niche conditional on Matrix's acknowledgment of an infringement of the process patents and on Matrix's agreement not to manufacture any perindopril erbumine based products. A draft settlement agreement between Servier and Niche/Unichem dated 4 February 2005, however, suggests that a parallel settlement agreement with Matrix was also envisaged.[783]

(544) In its reply to question 29[784] of the Commission's RFI of 5 August 2009, Niche submitted a contemporaneous email from its external counsel of 5 February 2005 explaining *"Niche's views and the views of Niche's legal advisor"*[785] at the time of the settlement negotiations. Niche's external legal advisor strongly recommended a settlement with Servier. He explained that Niche was compensated for being bought out of the perindopril market and advised to obtain the best possible conditions. The email reads:

"[…]".[786]

(545) The discussions between Niche and Servier ultimately led to the conclusion of a settlement on 8 February 2005.

4.3.1.4.1.2 Terms of the Niche/Unichem Settlement Agreement[787]

(546) The main clauses of the settlement agreement signed on 8 February 2005 can be summarized according to the obligations imposed on the parties.

1. Obligations on Servier

(547) Servier agreed not to introduce any infringement actions based on '339, '340, '341 patents (defined in the agreement as "Patent Rights") and the '947 patent (defined in the agreement as "Alpha Patent Rights") anywhere in the world against Niche, Unichem or Niche customers[788] in respect of an alleged infringement occurring before 8 February 2005 (clause 5).[789]

(548) According to clause 13, Servier agreed to pay Niche GBP 11.8 million in return for the acceptance by Niche/Unichem of their obligations:

"In consideration for the undertakings set out above, and the substantial costs[790] *and potential liabilities*[791] *that may be incurred by Niche and Unichem as a consequence*

783 ID3779, p. 1 and p. 5.

784 *"29. Please describe your perception of the chances of prevailing in the perindopril* related litigation which eventually led to the patent* settlement, including potential litigation on patent*s not litigated but to which the settlement agreement relates. Please provide contemporaneous evidence".*

785 ID1577, p. 9.

786 ID1709, p. 53.

787 The term "Niche/Unichem Settlement Agreement" or "Niche/Unichem settlement" refers to the settlement agreement concluded between Servier and Niche/Unichem.

788 A customer of Niche refers to *"any third party with which Niche and/or its Affiliates have an agreement in force in connection with: (a) the supply by Niche to such Niche customer of perindopril made using the process; and/or (b) an application for regulatory approval by such Niche customer".*

789 ID0119, p. 138.

790 According to Niche, the notion of "substantial costs" essentially covered the "*costs of development and legal costs"*, ID3827, p. 1. Niche also submitted that its actual costs until 31/12/2004 amounted to GBP 875,911, see ID1577, p. 6.

791 According to Niche, the notion of "potential liabilities" covered *"compensation payments to be made to customers for breach of contract"*, ID3827, p. 1.

of ceasing their programme to develop Perindopril made using the Process, Servier shall pay Niche in free funds the sum of £ 11,800,000.00".[792]

(549) The settlement agreement foresaw that the payment would be made in two instalments. The first payment of GBP [5–15 million]* was scheduled for 14 February 2005 or before to the McDermott Will & Emery's Client Account.[793] The second payment of GBP [0–5 million]* was expected to be made before 5 October 2005.[794] The file shows that these payments were in fact made as planned.[795]

2. Obligations on Niche/Unichem

(550) On the basis of clause 3 "*Niche and Unichem shall not, and shall procure that its Affiliates shall not, carry out in relation to Perindopril [perindopril erbumine] made using the Process*[796] *any Restricted Act in any country of the world where Patent Rights [the '339, '340, and '341 patents] and/or Alpha Patent Rights ['the 947 patent] exist".*[797]

(551) The definition of "Restricted Act" refers to: (i) the act of making, keeping, importing, supplying, offering to supply, disposing of or carrying out any act that could constitute an infringement; and/or (ii) assisting, procuring or entering into any common design with a third party to carry out any of the acts referred to in (i).

(552) Clause 6 reads: *"Servier recognises that Niche shall be free to deal in Perindopril made in accordance with the Process without infringing the Patent Rights in such a country after the Local Expiry Date in that country".*[798]

(553) Clauses 3 and 6 refer to the local expiry date (i.e. date on which the last of '339, '340 and '341 would expire in a given country).[799] Clause 3 in conjunction with clause 6 therefore allowed Niche to launch perindopril [made using the process] after 2008 when Servier's process patents expired.

(554) Servier stressed that, according to clause 3, upon the expiry of the process patents in 2008 Niche was not allowed to manufacture or sell perindopril in a way that would infringe the '947 patent.[800]

(555) According to clause 10 of the settlement agreement, *"Niche and Unichem shall not, and shall procure that their Affiliates shall not, make any further or new application for Regulatory Approval in any country of the world where Servier Patent Rights exist, nor assist any third party to obtain such Regulatory approval. […] This undertaking shall apply in respect of a country until the Local Expiry Date in that country".*[801]

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792 ID0119, p. 140.
793 ID0119, p. 140.
794 ID0119, p. 140.
795 ID0025, p. 78 - 79.
796 The term "Process" is defined in the settlement agreement as *"the Process in Suit* [=the Matrix process], *any process that is substantially similar to the Process in Suit, and any process that if carried out in a country of the world where a Patent Right exists would fall within the scope of such Patent Right"*.
797 ID0119, p. 138.
798 ID0119, p. 138.
799 ID0119, p. 138. See clauses 4 and 6.
800 ID3842, p. 8, reply to question 19 of the Commission's RFI dated 7 February 2011.
801 ID0119, p. 139.

(556) Moreover, in clause 11 of the settlement agreement, Niche agreed to suspend or cancel its existing customer contracts: *"Niche shall cancel, terminate or suspend until the relevant Local Expiry Date at the option of Niche, each and every one of the Niche Contracts"*.[802]

(557) With regards to litigation issues, Niche agreed to withdraw its oppositions against the Alpha and Gamma patents at the EPO (clause 7).[803]

(558) Furthermore, Niche/Unichem agreed to abstain from any invalidity and non-infringement actions, either directly or through a third party, against any of the "Servier Patent Rights", namely '339, '340, '341, '947 patent (Alpha), '689 (Beta) and '948 (Gamma), except as a defence to a patent infringement action (clause 8). This meant that Niche not only agreed not to challenge the process patents which were valid until 2008, but also the '947 valid at the time until 2021, and the '689 and the '948 patents.[804] Clauses 7 and 8 will subsequently be referred to as the "non-challenge obligation".

(559) In summary, Niche/Unichem thus agreed: (i) not to carry out any "restricted act" with their generic perindopril until at least 2008 and (ii) not to challenge Servier's main patents. In addition Niche committed to terminate, cancel or suspend existing customer relationships concerning its product and to abstain from applying for any new marketing authorisations.

4.3.1.4.1.3 Terms of the Biogaran agreement

(560) On the same day that the Niche/Unichem Settlement Agreement was signed (i.e. 8 February 2005) a licence and supply agreement was concluded between Niche[805] and Biogaran concerning the transfer of three product dossiers and an existing marketing authorisation in return for a payment of GBP 2.5 million ("Biogaran agreement").[806] According to Niche, the Biogaran agreement was proposed by Servier "*to provide Niche Generics Limited with the total overall consideration agreed for entering into the Global Settlement Agreement*".[807]

(561) The Biogaran agreement[808] concerned [product names]*.[809] It foresaw that Niche would transfer the product dossiers (i.e. *"any and all information and/or data in*

802 ID0119, p. 139.

803 ID0119, p. 139 and 144.

804 ID0119, p. 139.

805 Unichem is not a party to this agreement.

806 ID2450, p. 21 - 37.

807 ID3268, p. 3. In its reply to the Statement of Objections, Niche claims that the Biogaran agreement was a genuine commercial agreement which only made sense once litigation was discontinued (ID8524, p. 54 and 141). However, Niche itself admitted that the magnitude of the payment (GBP 2.5 million) formed part of the settlement agreement and that the Biogaran agreement provided the total overall consideration for entering into the settlement agreement (see paragraphs (560) and (562)). Therefore, a contradiction exists between these statements prior to the Statement of Objections and the reply to the Statement of Objections. Moreover, it is noted that the Biogaran agreement negotiations which were allegedly blocked because of the litigation between Servier and Niche had begun before the settlement agreement's conclusion on 8 February 2005 (see paragraph (566) referring to a document from 4 February 2005).

808 ID2450, p. 21 - 22.

809 In relation to [product name]*, Biogaran and Niche had contacts back in 2002 with respect to licensing for France (ID0025, p.119). No agreement was reached prior to 8 February 2005 even if there were again contacts with respect to this molecule in 2004 (see Annex 1c), p. 2, and Annex 3 to Biogaran's reply to the Statement of Objections, ID9244).

possession of Niche related to the products and necessary for the obtention of marketing authorisations") for [product name]* to Biogaran for exclusive use by Biogaran in order to obtain MAs in France, the UK and [non-EEA jurisdiction]* and non-exclusively for the rest of the world. With respect to [product name]* and [product name]*, the transfer of the dossiers was made on a non-exclusive basis worldwide. As to [product name]* in particular, Niche agreed to transfer its marketing authorisation for France to Biogaran (clause 2.1).

(562) In consideration for the dossiers, schedule 3 foresaw a payment of GBP 2.5 million and payment terms that obliged Biogaran to pay Niche GBP [0–2]* million on or before 14 February 2005 and GBP [0–2]* million on or before 5 October 2005 (this is the same payment schedule as foreseen for the GBP 11.8 million transfer). According to Niche, *"the nature of the Biogaran Agreement is not normal commercial practice and in Niche's opinion the magnitude of the payment formed part of the Settlement Agreement"*.[810] Niche adds that this kind of agreements may happen on occasions where the agreements cover multiple products at the same time.[811] Schedule 3 also foresaw supply prices for different dosages of the three products to be supplied by Niche and Biogaran's responsibility for all registration fees in France.[812]

(563) Furthermore, clause 2.2 of the Biogaran agreement stated that: *"Biogaran will inform Niche of the obtention of the Marketing Authorisations from the use of the Product Dossiers"*.[813]

(564) Clause 14.4 of the Biogaran agreement stipulated that the possibility of obtaining MAs through this agreement was limited in time: *"In the event that the Marketing Authorisations are not obtained within 18 months from the date of coming into force of this Agreement at the latest, this agreement shall be automatically terminated"*. In addition, clause 14.5 provided that *"neither party shall be entitled to any compensation in the event of termination of this Agreement by the other party pursuant to clauses […] and 14.4"*[814] implying that the consideration of GBP 2.5 million would not need to be repaid in case MAs were not obtained.[815]

(565) Moreover clause 2.2 of the Biogaran agreement foresaw that once Biogaran had obtained its MAs, it should order product supplies from Niche. According to clause 4.2, the product orders had to be placed in writing in line with Niche's minimum batch sizes as set out in Schedule 2.[816]

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810 ID4898, p. 2. In addition, Niche has submitted that the price was fixed *"as part of the total overall consideration Niche required"*, ID4718, p. 1.

811 ID4898, p. 1.

812 ID2450, p. 33.

813 ID2450, p. 22.

814 ID2450, p. 28.

815 On this point, Niche claims in its reply to the Statement of Objections that the consideration under the Biogaran agreement was intended to act as a guarantee that regulatory approval will be sought by Biogaran (ID8524, p. 144). However, a comparison can be made with the two agreements concluded between Biogaran and [company name]*/[company name]* on [product name]* tablets and capsules where such guarantee was absent (Annex 5 to Biogaran's reply to the Statement of Objections, ID9244, p. 23, as further disclosed in ID10093, and ID5411, p. 4 as further disclosed in ID10094). Quite to the contrary, the agreements featured a clause whereby any payments made by Biogaran to [company name]*/[company name]* would be refunded in case MAs were not obtained within 18 or 12 months respectively.

816 ID2450, p. 23.

(566) An email dated 4 February 2005 sent by Biogaran's counsel to Niche mentions further rights requested by Biogaran *"in consideration of the amount at stake"*.[817]

(567) According to Niche (reply to question 9 of the Commission's RFI of 7 March 2011), Biogaran did not inform Niche that it had obtained any MAs nor did it request supplies of any products from Niche under the Biogaran agreement.[818] Assuming Biogaran complied with the provisions contained in clause 2.2, this would indicate that Biogaran had not obtained the MAs and that, therefore, the Biogaran agreement was automatically terminated in accordance with clause 14.4. Niche claimed in this respect that there was a tacit agreement that the contract would continue and that this can be inferred from the correspondence between Niche and Biogaran from 2007 to 2011.[819]

(568) Niche has provided evidence that Biogaran received the [product name]* dossiers from Niche on 10 March 2005 and on 15 April 2005 in accordance with the agreement.[820] In relation to [product name]*, the dossiers were transferred on 15 January 2007.[821] In an email sent to Biogaran on 18 September 2007, [employee name]* (of Niche) suggested that the [product name]* dossier would constitute a duplicate for Biogaran: *"I note from IMS data that you already supply [product name]* to the market under another licence. If this is correct, what is your strategy and plan to accommodate two separate products of the same?"*[822] In December 2009, in response to Niche's inquiry concerning the [product name]* dossier, Biogaran's Registration Manager responded that *"it was decided internally not to submit it for the moment"*.[823] Niche was advised by Biogaran in January 2011 that no decision had been made regarding submission for MA using this dossier.[824] As to [product name]*, the French MA was transferred to Biogaran and a Biogaran customer has been marketing the 10 mg product since 2008 – notwithstanding the amount generated by the Niche dossier with respect to [product name]* [EUR 100,000-200,000], Biogaran explains that it ensured the loyalty of an important customer which belongs to one of the main wholesalers in France.[825]

(569) Finally, Servier/Biogaran informed the Commission (after two refusals to provide information on the Biogaran Agreement) that it had achieved a total turnover of EUR [100,000-200,000] for a deal following which it transferred GBP 2.5 million to Niche.[826]

4.3.1.4.2 Servier and Matrix

4.3.1.4.2.1 Negotiations prior to the settlement

(570) As explained in section 4.3.1.2, Servier only brought infringement proceedings against Niche. However, Matrix followed the litigation very closely and provided essential input (e.g. witness statements). On or around 6 February 2005, Matrix

817 ID3779, p. 16.
818 ID3827, p. 1 and ID5405, p. 6 and 7.
819 Reply to Statement of Objections, ID8524, p.145.
820 ID3830, p. 1 - 2.
821 ID4898, p. 1.
822 ID3829, p. 6.
823 ID3829, p. 2.
824 ID3827, p. 1 and ID3829, p. 1 - 7.
825 Biogaran's reply to the Statement of Objections, ID9243, p.17. See also Annex 1c) to Biogaran's reply to the Statement of Objections, ID9244, p.11.
826 ID5405, p. 6.

claims to have received a phone call from Niche asking Matrix to come to London urgently as they had reached an advanced stage of negotiations with Servier relating to a possible settlement.[827] Matrix accepted Niche's request and Matrix's COO and CFO travelled to London.[828]

(571) On 7 February 2005, i.e. only one day before the conclusion of the settlement agreement with Servier, the latter sent a formal warning letter to Matrix. In this letter Servier claimed that Matrix was infringing Servier's process patents ('339, '340 and '341) and threatened to commence infringement proceedings. The letter also mentioned that Servier held the '947 patent.[829] It is unclear when this letter was received by Matrix. Certainly, Matrix never responded to this letter (indeed it seems to have had no time to do so given that the settlement was concluded the following day).

(572) According to the explanations given by Matrix in reply to the Commission's RFI of 16 January 2009, due to its supporting role in the litigation between Servier and Niche, *"Matrix was aware of the claims asserted by Servier against Niche at the time Servier sent a letter to Matrix threatening suit against Matrix on 7 February 2005"*.[830]

(573) Neither Servier nor Matrix submitted detailed contemporaneous information on the negotiation history of their settlement agreement. From a draft of the Niche/Unichem Settlement Agreement dated 4 February 2005, it can be inferred that a separate settlement agreement between Servier and Matrix was envisaged.[831]

(574) According to Matrix's reply to the Commission's RFI of 5 August 2009, the first meeting in relation to the settlement discussions took place between Niche and Matrix on or around 7 February 2005 on which Niche gave a brief, general update on the status of the settlement negotiations with Servier.[832]

(575) According to Matrix, Niche and Matrix together with Niche's legal advisors (McDermott Will & Emery) went to the offices of Servier's legal advisors (Bristows). Matrix claims that it did not have any role in drafting the Matrix settlement agreement and only a non-participatory role in the negotiations with Servier during which Niche was taking the lead.[833]

(576) According to Matrix, the draft settlement agreement with Servier had been drawn up by Servier's legal advisors. Matrix's representatives were allegedly presented with a final settlement agreement and were given a very short period to review the document and confirm whether they were prepared to enter into the agreement. Specifically, Matrix explained that it had less than an hour to review the agreement and that it did not have its own legal counsel with it.

(577) Matrix considered in its reply to question 28 of the Commission's RFI of 5 August 2009 that: *"Matrix understood that there had been some earlier discussions relating to a settlement between Servier and Niche during which the amount of the*

827 This is contested by Niche in its reply to the Statement of Objections (ID8524, p.146) but the way Matrix came to London (having been invited by Niche or not) is in any case irrelevant.

828 ID2579, p. 8.

829 ID2639, p. 1 - 2.

830 ID0665, p. 11.

831 ID3779.

832 ID1452, p. 14 - 15.

833 ID1452, p. 14 - 15.

settlement had been raised. Matrix was led to believe by Niche that any settlement sum was intended to cover both Matrix and Niche.[…]" [834] A post-settlement document relating to the settlement sums for Niche and Matrix clearly sets out the negotiations regarding the amount of money split between them. An internal Matrix email dated 9 September 2005, states that *"the settlement for Matrix should have been higher than Niche but 50% each. In fact we were at 75% to Matrix and then later to 60% (…) and eventually settled for 50% each with no legal expenses to our account"*.[835]

4.3.1.4.2.2 Terms of the Matrix Settlement Agreement

(578) On 8 February 2005, Matrix signed an agreement for the settlement of a patent dispute with Servier (the "Matrix settlement").[836] With a few exceptions, the main clauses of the Matrix settlement correspond to the agreement concluded between Servier and Niche/Unichem. The settlement can be summarised according to the obligations imposed on the parties.

1. Servier's obligations

(579) In clause 3 Servier agreed not to introduce any infringement actions based on '339, '340, '341 patents (defined in the agreement as "Patent Rights") and the '947 patent (defined in the agreement as "Alpha Patent Rights") against Matrix in any country in which these patent rights exist with the exception of the USA (defined in the agreement as "the Territory"): *"Servier shall not commence proceedings under the Patent Rights or the Alpha Patent Rights against Matrix in respect of any act of alleged infringement by Matrix in the Territory occurring before the date of this Agreement"*.[837]

(580) According to clause 9, Servier agreed to pay Matrix the sum of GBP 11.8 million in return for Matrix's commitment to accept the terms of the settlement: *"In consideration for the undertakings set out above, and the substantial costs and potential liabilities that may be incurred by Matrix as a consequence of ceasing its programme to develop and manufacture Perindopril made using the Process, Servier shall pay Matrix in free funds the sum of £ 11,800,000.00"*.[838]

(581) Like in the Niche/Unichem Settlement Agreement, the Matrix settlement foresaw that the payment would be made in two instalments.

2. Matrix's obligations

(582) Further to clause 1, Matrix agreed not to take any commercial actions based on the "Process", i.e. (i) the process in suit, or (ii) any process substantially similar to the one developed with Niche or (iii) any process that would infringe '339, '340 and '341 in the territories of '339, '340, '341 and/or '947:

"Matrix shall not, and shall procure that its Affiliates shall not:

(i) carry out in relation to Perindopril made using the Process any Restricted Act in any country of the Territory; and/or

834 ID1452, p. 16.
835 ID0655, p. 1.
836 ID0660, p. 1 - 6.
837 ID0660, p. 3.
838 ID0660, p. 4.

(ii) manufacture and/or supply Perindopril made using the Process, for use anywhere in the Territory".[839]

(583) The definition of "Restricted Act" refers to: (i) the act of making, keeping, importing, supplying, offering to supply, disposing of or carrying out any act that could constitute an infringement; and/or (ii) assisting, procuring or entering into any common design with a third party to carry out any of the acts referred to in (i).

(584) The obligation not to carry out any Restricted Act holds until the expiry of the '339, '340 and '341 process patents, i.e. until 2008, and only then provided that the '947 patent is not infringed (clause 2): *"The obligations set out in clause [1]*[840] *shall expire in each country of the Territory upon the Local Expiry Date in that country".*[841]

(585) As Matrix indicated in reply to question 11 of the Commission's RFI of 13 August 2010,[842] clause 4 of the Matrix settlement allowed Matrix to market the product after the expiry of the '339, '340 and '341 patents: *"Servier recognises that Matrix shall be free to deal in Perindopril made in accordance with the Process without infringing the Patent Rights in a country of the Territory after the Local Expiry Date in that country".*[843] Similarly, Servier indicated in its reply to the Commission's RFI of 1 July 2011 that clauses 1 and 4 give Matrix the right to launch perindopril after 2008 so long as it does not infringe the '947 patent.[844]

(586) According to clause 6 of the settlement agreement, *"Matrix shall not, and shall procure that its Affiliates shall not, make any application for Regulatory Approval in any country of the Territory, nor assist any third party to obtain any such Regulatory Approval. This undertaking shall apply in respect of a country until the Local Expiry Date in that country of the Territory".*[845]

(587) Moreover, in clause 7 of the Matrix settlement, Matrix agreed to cancel existing customer contracts:

"Matrix shall cancel, terminate or suspend until the relevant Local Expiry Date at the option of Matrix, each and every one of the Matrix Contracts".[846]

(588) In addition, clause 8 of the settlement agreement states that Matrix *"(...) shall cancel, terminate or suspend each Matrix Contract before 30th June 2005".*[847] The product development agreement with Niche was, according to Matrix, *"likely covered by clauses 7 and 8".*[848]

(589) Matrix agreed to abstain from any invalidity and non-infringement action against any of the "*Servier Patent Rights*", namely '339, '340, '341, '947 (Alpha), '689 (Beta) and '948 (Gamma), except as a defence to a patent infringement action (clause 5). This

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839 ID0660, p. 3.

840 ID2579, p. 9. As explained by Matrix in reply to question 10 of the Commission's RFI of 13 August 2010 there is a typographical error in clause 2 and the reference should be to clause 1 instead of clause 3.

841 ID0660, p. 3.

842 ID2579, p. 10.

843 ID0660, p. 3.

844 ID5064, p.1.

845 ID0660, p. 4.

846 ID0119, p. 149.

847 ID0119, p. 149.

848 ID5044, p. 4.

means that Matrix not only agreed not to challenge in any form the process patents valid until 2008, but also the '947 patent valid at the time until 2021 as well as the '689 and the '948 patents.[849] This clause will be subsequently referred to as the "non-challenge obligation".

(590) In summary, Matrix thus agreed not to enter the market with its generic perindopril until at least 2008 and not to challenge Servier's main patents.

4.3.1.4.3 Views and explanations of the settlement agreements

4.3.1.4.3.1 Niche/Unichem Settlement Agreement (including Biogaran agreement)

(591) In order to better understand the factors taken into account by the parties when deciding whether or not to settle, contemporaneous evidence is of crucial importance. However, *ex post* explanations provided by Niche and Servier are also of interest and are reported in this section.

Contemporaneous evidence

(592) According to clause 20 of the Niche/Unichem settlement, Niche and Servier had to agree on how the conclusion of the settlement would be communicated, both within their companies and to the outside world.

(593) Niche's internal[850] draft communication explains the discontinuation of the perindopril project to its employees as follows:

"The agreement with Servier is that we cannot launch the product until the process patents have expired towards the second half of 2008. The court case was started (a half day only) […] It was the intention of Servier to complete the arrangement before the case started. We felt confident that we would have won the case against the three patents in suit but we were aware that under European law we would have to fight the case in many of the jurisdictions across Europe not knowing what the outcome would be. For instance the case in the UK will have cost over £1,100,000 […]. In any case the cost to Niche if it won the case would be over £400,000 as it can only claim between 60-70% back from the originator.[…]"*[851]

(594) An excerpt from another draft document from the same time period as the previous one describes the agreement as follows: *"we have agreed with Servier that the launch of perindopril will not take place until such time as the process patents have expired"*. [852]

(595) The final wording of the communication to staff was agreed upon between Servier and Niche's lawyers on or around the day of the settlement and signed by the same people that signed the Niche/Unichem settlement.[853] The version of the communication posted on the intranet of Niche on 9 February 2005 reads:[854]

"[…] Although Niche denies the allegation of infringement we recognise that there is considerable commercial uncertainty on a global or even a European scale. Accordingly Niche have concluded that it is better to suspend the project rather than face the possibility of a launch which is later stopped and we get a claim for price

849 ID0660, p. 3 - 4.
850 ID2450, p. 2 and p. 20.
851 ID0027, p. 210.
852 ID0027, p.215.
853 ID3268, p. 1.
854 ID3268, p. 1 and p. 4. A similar draft appears to have been prepared for customers, see ID0028, p.274.

depression from Servier. We have therefore agreed that we will delay our launch of Perindopril until the process patents have expired, but not until after the polymorph patents have expired.

We took these steps in the best interests of the Company having regard to the commercial uncertainty in the legal position once it became clear for the first time in November 2004 that the Niche sourced Perindopril consists of about 98% on the alpha polymorph".

(596) Both quotes explicitly refer to the obligation not to carry out "any Restricted Act" as defined in the Niche/Unichem Settlement Agreement and explain that the envisaged delay will last until Servier's process patents have expired. They also show that although Niche was confident that it would win the litigation on the process patents in the UK, it was concerned about the litigation risks regarding the process patents outside the UK and those regarding the '947.

(597) Niche also considered the antitrust liabilities associated with the conclusion of the patent settlement. In a letter to Niche's financial auditor on or around 31 March 2005 it is stated that the Board of Directors *"has considered the implications of Article 81 EC Treaty on the company in connection with the Servier Agreement and have studied carefully the legal opinion received. […] in their opinion there is no need for any note in the accounts regarding any potential contingent liability"*.[855]

(598) Niche also assessed what the settlement would mean from a financial perspective. According to Niche's overview of the financial year 2004/2005 found during the inspection of November 2008, the *"Settlement arrangement on Perindopril boosted licence income to GBP 15.4m"*.[856] This led to a gross profit margin of 77%, which is an exceptional increase compared to the expected 38% and the ratios achieved in the preceding years (the actual profit ratio in the financial year 2003/2004 was 37%).[857] The attractiveness of the settlement with Servier is further explained in Niche's monthly report dated some time after March 2005, also found during the abovementioned inspection: *"The settlement on perindopril has put the Company on a sound footing to look forward to the future and with increasing demand from our European customers we can look forward to a brighter future […]"*[858]

(599) In another internal document concerning Niche's financial situation, probably dated 28 February 2005, Niche celebrates the settlement with Servier: *"Following the recent patent settlement with Les Laboratories Servier, Niche Generics Limited ('Niche') now finds itself in a significantly improved financial position. With approximately [GBP] [0–20 million]* cash available"*.[859]

(600) Similarly in a gross profit analysis, probably dated 2006 or 2007, Niche explained what the settlement meant in comparison with its expected sales from perindopril: *"Perindopril sales sacrificed in settlement. Settlement was equivalent to over 10 year planned sales and 20 years planned gross profit"*.[860] In its reply to the Statement of Objections, Niche indicates that this quote merely compares the quantum of the

855 ID0025, p. 46.
856 ID0027, p. 79.
857 ID0027, p. 79.
858 ID0027, p. 91.
859 ID0028, p. 207.
860 ID0025, p. 57.

payment with perindopril sales, if Niche were in a position to launch which it claims was not the case.[861]

(601) According to contemporaneous documents found during the inspection at Niche's premises, the development costs between 30 June 2000 and 19 December 2003 amounted to around GBP [0–500,000]*.[862] In the subsequent period the costs rose due to, in particular, legal advice as can be seen from a document submitted *ex post*. The total product development costs including legal advice for the period 30 June 2000 to 18 March 2005 amounted to around GBP [0–5]* million.[863]

(602) In a draft discussion document dated 2 October 2007 relating to Niche and Unichem it is mentioned that perindopril *"was forecast to produce substantial revenues in the business plan from 2004/05 onwards. This product was never launched. It was indeed the agreement to postpone the development/launch which gave rise to the windfall mentioned above"*[864] (emphasis added).

(603) In June 2008 an email exchange between Niche and [bank name]* took place. In this exchange the bank asked Niche to explain *"Detail of extra ordinary income of £ [5–20]* million in 2005 & why there was delay in launch of the product"*.[865] On 4 June 2008 Niche explained, amongst other things, that:

"As there was uncertainty on both sides as to who would win in a court case and neither party could really afford to lose a commercial settlement was entered into with Niche receiving a payment in agreement not to launch perindopril until the 3 process patents expired in September 2008".[866]

(604) In summary, Niche's contemporaneous evidence (including documents *in tempore non suspectu*) confirms that Niche discontinued its generic challenge (including product development/launch) in return for the payment received from Servier. The payment amounted to more than ten years of planned sales and 20 years of planned gross profit.

(605) Contemporaneous evidence found during the inspection at Servier's premises provides elements of its anti-generics strategy.[867] An internal Servier presentation dated June 2006 entitled "*Coversyl: defense against generics*"[868] provides a comprehensive overview of Servier's measures devised to combat generic entry and the effects of their implementation. The subtitle *"Did it work?"* points to four aspects which suggest that its strategy was so far successful, one of which being the *"UK court case patent settlement NICHE/MATRIX"*.

Ex post explanations by Niche and Servier

(606) As mentioned in paragraph (463), Niche explained the circumstances in which it decided to settle with Servier:

"[…] discussions regarding a settlement commenced some time after the 2nd phase due diligence which took place 21st January 2005. At this point in time it was

861 ID8524, p.153.
862 ID0027, p. 181.
863 ID2450, p. 34.
864 ID0024, p. 9.
865 ID0026, p. 31.
866 ID0026, p. 30.
867 ID0105, p. 159 - 186.
868 ID0105, p. 172.

apparent that the manufacturing difficulties that had been encountered over the previous few months were becoming insurmountable. When Servier made an offer to settle Niche had no financial alternative[869] *but to negotiate for as high a figure as possible whilst at the same time ensuring that Servier remained unaware of the insurmountable manufacturing problems".*[870]

(607) Niche also explained the factors it took into account when deciding to enter into the settlement agreement with Servier, pointing to: (i) the confidence that it would win the English patent litigation; (ii) the uncertainty surrounding the validity of the '947 patent and Niche's inability to pay damages in the event that the patent was found to be valid; and (iii) the API manufacturing problems.[871] Niche reiterated certain of these factors and explained in its reply to the Statement of Objections that these factors (untenable financial situation, rising litigation costs, serious and recurring setbacks in producing non-infringing perindopril, issues with the '947 patent and the end of litigation in all jurisdictions) made it commercially rational for it to settle with Servier.[872]

(608) In its reply to the Commission's RFI of 6 August 2009, Servier mentioned the general factors in favour of entering into the settlement agreements:[873]

*"*In general, Servier devotes an unusually large part of its resources and its energy to research, to the development of innovative products, to the development of its existing products to extend their indications and meet the needs of medical professionals and patients. A quarter of the turnover of the group is thus reinvested in Research and Development. The settlement agreements allow us to achieve these objectives by taking advantage of legal certainty without which a laboratory such as Servier cannot invest significantly.*

The conclusion of these agreements allows us to quickly close disputes that otherwise could take years.

The conclusion of such amicable agreements, including with regard to patents, is also generally encouraged by the British courts and the public authorities, in particular for reasons of speed and cost.

It is in this sense that Servier is also in favour of amicable settlement of disputes when that appears reasonable.

When our company is thinking of concluding settlement agreements, it takes into consideration, with the assistance of its counsel/lawyers and based on their recommendations and evaluations, a certain number of factors which vary from case to case. We generally take into account, in particular, the duration of the remaining protection of our product, the risk associated with judicial decisions regarding the challenging of our patents and its impact on other litigation, the costs of defence (which could have amounted for instance to more than EUR 2 850 000 for the litigation against Apotex in the United Kingdom, which amount only takes into account the external costs, and in another litigation - Generics UK v. Daiichi – could even exceed EUR 4.25 million), the length of these proceedings, the size of the

869 Niche has submitted that it had entered into a discounting/factoring arrangement with GMAC in December 2004 which provided it with additional working capital, see ID4718, p. 2.

870 ID1577, p. 8, reply to question 25 of the Commission's RFI of 5 August 2009.

871 ID1577, p. 7 - 8, reply to questions 23 and 24 of the Commission's RFI of 5 August 2009.

872 See reply to the Statement of Objections, ID8524, p.25.

873 ID1151, p. 15 - 16.

relevant market, the consequences of the arrival of a generic on our turnover (a quarter of which is reinvested in R&D), the impact of any negative judgment on our activity and our image, etc. Besides, entering into an amicable settlement agreement can in some cases give Servier, a medium-sized company, the opportunity to access expertise, technical information and/or (improvements) manufacturing processes other than those developed by our company. Agreements can in certain cases allow us to act as a supplier of generics and thus achieve economies, of scale in particular. All these gains in efficiency, such as we calculate at the time of the agreements, are naturally taken into account".

(609) In the same reply, Servier identified the cost of the proceedings before the EPO and before the English courts.[874] As only the aggregate sums are indicated for each set of proceedings, it is not possible to establish whether these calculations include possible duplications of costs (e.g. for certain studies, experiments etc.). According to Servier, the total external cost of litigation with Apotex amounted to EUR [0–5 million]*. The proceedings with Ivax/Teva, which were stayed at an early stage and then settled, cost EUR [100,000–200,000]*. The proceedings against Niche/Matrix (settled in the oral hearing stage) cost EUR [0–5 million]*. The proceedings against Krka (interim injunction proceedings, settled before the hearing in the main proceeding) cost around EUR [300,000–400,000]* and the proceedings with Lupin (settled before the hearing in the main proceeding) cost EUR [200,000–300,000]*. The aggregate cost of Servier's perindopril litigation in the UK thus reportedly amounted to EUR [0–5 million]*. The costs of the EPO opposition procedure amounted to EUR [50,000–60,000]* and of the procedure before the EPO Technical Board of Appeal to an additional EUR [40,000–50,000]*.[875]

(610) In its reply to question 34 of the Commission's RFI of 9 April 2010,[876] inviting Servier to present its arguments for exemption under Article 101(3) should the settlement agreements be found to be restrictive, Servier claims that these agreements do not restrict competition within the meaning of Article 101(1) of the Treaty.[877] The following argument, albeit raised by Servier in the context of efficiencies, also relates to the question of the restrictive nature of the settlement agreements under Article 101(1) of the Treaty:[878]

*"*It is settled case-law that to assess the compatibility of an agreement with the common market under the prohibition in Article 81(1) EC, one should examine "the economic and legal conditions" under which the agreement operates, [reference to C-22/71, Béguelin Import, ECR p. 949, paragraph 13]. The Commission must take into account of the competition situation that would exist in the absence of the agreement [reference to T-328/03, O2 Germany vs. Commission, ECR 2006, p.II-1231, paragraphs 68-69]. Thus, when the settlements do not restrict the freedom of generic manufacturers beyond the scope of intellectual property rights subject to litigation, settlement agreements cannot be regarded as restrictive of competition, given that intellectual property rights de jure exclude competition. To hold otherwise would be to deny the fundamental right of a company to which rights have been legally granted to defend these rights or seek to maintain them".*

874 ID1144, ID1151.
875 ID1151, p. 23.
876 ID2051, p. 14.
877 ID2365, p. 29.
878 ID2365, p. 30.

(611) Furthermore, Servier considered, before the adoption of the Statement of Objections, the Commission's request to provide justification under Article 101(3) of the Treaty as immaterial:[879]

*"*In the absence of evidence from the Commission that the agreements in question restrain competition, it would be meaningless to analyse whether these agreements "could be exempted" according to the criteria of Article 101(3)".*

(612) Notwithstanding the response provided in the previous paragraph, Servier explained why the settlement agreements did not restrict competition, but provided a source of efficiencies:[880]

"[…] Far from restricting competition, the settlement agreements have generated efficiencies: they have allowed SERVIER and the opposing party to quickly terminate litigations allowing them to obtain the necessary legal certainty to make investments and/or to avoid wasting resources.*

In this regard, we note that the conclusion of settlements to disputes, including in matters of patents, is generally encouraged by the courts (especially British ones) and the public authorities. […] With regard to SERVIER, the settlements led to savings in costs and processing times, so that it was able to devote all its resources and energy to research, the development of innovative products and the development of its existing products, in the interest of prescribers and patients.

Moreover, the conclusion of certain settlement agreements gave SERVIER the opportunity to access know-how, technical information, improvements and/or manufacturing processes. These agreements also offered potentially interesting perspectives in terms of cost savings in production and of technical progress.

These agreements, particularly when they were subject to a licence, allowed us to benefit from commercial support from the partner in the countries in which they are well established in order to promote the market penetration of our products, which stimulates competition (for example, the licence agreement with Teva in the UK, or the licence agreement with Krka in some central European countries).

Finally, the settlement agreements have in no case prevented other generic manufacturers, not parties to the litigations, from challenging the intellectual property rights covered by the settlement agreements or from entering into the market. Other generic manufacturers have entered the market without violating the intellectual property rights held by Servier".

4.3.1.4.3.2 Matrix Settlement Agreement

(613) No contemporaneous evidence was submitted by Matrix to explain its reasons for entering into the settlement agreement. One document, a draft due diligence report of July 2006 prepared by Mylan's advisers before the acquisition of the shares in Matrix, indicated *in tempore non suspecto* that Matrix received "*compensation*" for a "*favourable*" settlement agreement and that *"it [was] not allowed to manufacture and sell the specific product over the remaining term of the contract"*.[881]

(614) *Ex post*, Matrix submitted the main reasons for settling with Servier.

879 ID2365, p. 30. See section 5.7 for the assessment under Article 101(3) of the Treaty.
880 ID2365, p. 30 - 31.
881 ID5383.

(615) In reply to question 22 of the Commission's RFI of 5 August 2009, Matrix argued that Niche forced Matrix into a situation where it had no option but to settle because without Niche, Matrix would have lost the only customer for its perindopril API:

"If Niche were to enter into a settlement agreement with Servier, Matrix would no longer have a development partner in the EEA with which to take forward the Perindopril project. Niche had developed the dossier to obtain marketing authorisations in the EEA and Niche had all of the relationships and contracts with customers in the EEA. Accordingly, Matrix recognised that were Niche to enter into any form of settlement arrangement with Servier, all of Matrix's efforts and all of its associated costs would be wasted and it would lose all of the sales of Perindopril API that it would have expected to achieve through the Niche partnership.

Whilst Matrix may have hypothetically been able to supply the Perindopril API to other third party customers, Matrix would have had to try and find another development partner to produce a marketing authorisation dossier which would require significant time and investment for both Matrix and any new partner it may have been able to find. Such a delay would have meant that Matrix was unlikely to generate any revenue from a Perindopril API for a further period of at least 2 – 3 years, i.e. the time taken for a new partner to develop a dossier and go through the application process. Moreover, in Matrix's view it would have been very difficult to find a partner, particularly given that in the patent infringement proceedings against Niche, Servier claimed Matrix's Perindopril API infringed a number of Servier's patents. […]".[882]

(616) In addition, Matrix points to the "**fait accompli*" created by Niche that made it settle with Servier: *"Matrix was presented with a 'fait accompli'. As a result of this expedited timeline, and due to the fact that Matrix was confined to a non-participatory role during the negotiations, Matrix had no opportunity to undertake any detailed analysis of the settlement. Matrix was however mindful of the significant amount of time and resources that it had expended on the Perindopril API project. Accordingly, in view of Niche's position, Matrix felt that it had no option but to settle".*[883]

(617) Moreover, Matrix submitted *ex post* that *"the only commercially rational option [at the time of the settlement] was to mitigate the exposure [Matrix] face by recouping its investment in the project by means of the settlement".*[884]

(618) According to Matrix's reply to question 5 of the Commission's RFI of 13 August 2010, Matrix did not, at any time prior to the settlement with Servier, consider abandoning its research and development efforts for perindopril API.[885] The allegedly insurmountable manufacturing difficulties in producing perindopril API – as reported by Niche - were not relevant as far as Matrix was concerned, even though Matrix was responsible for the development of the API and was therefore best placed to assess such difficulties. On the contrary, Matrix felt that the remaining obstacles were being addressed constructively.[886]

882 ID1452, p. 14.
883 ID1452, p. 15.
884 ID3141, p. 6.
885 ID2579, p. 7.
886 ID2579, p. 6.

(619) In Matrix's reply to question 28 of the said RFI, Matrix seemed to consider that Niche had negotiated the settlement sum for both companies to adequately reflect their foregone profits and years of development costs:[887]

"Matrix wanted the figure for which it settled to reflect the fact that this was a project on which it had been working for a number of years involving a number of employees and moreover that Matrix had hoped that its cooperation with Niche on perindopril would ultimately generate significant or important profits for Matrix and in this regard Matrix understood that Niche had managed to obtain significant up-front payments from its customers. Matrix did not undertake however any stepwise assessment by reference to each individual matter referred to in the question but rather it was a combination of all of these factors that were relevant in its own assessment of the adequacy of the settlement sum".[888]

(620) According to Matrix's reply to question 26 of the Commission's RFI of 5 August 2009, the settlement agreement with Servier had the following effects for Matrix:

"[The '339, '340, and '341] patents all expired in September 2008 and accordingly, Matrix was prevented from manufacturing, marketing or selling perindopril erbumine or assisting a third party to do the same for a period of approximately three and a half years, from February 2005 until September 2008. […]

Matrix was also prevented from challenging certain of Servier's other patents, in particular, the erbumine alpha patent, EP 1 296 947, the beta patent EP 1 294 689 and the gamma patent EP 1 296 948. The only exception to this was if Servier asserted these patents against Matrix in which case Matrix could claim they were invalid in its defence".[889]

(621) In its reply to question 31 of the Commission's RFI of 8 December 2009,[890] Servier described the Niche/Unichem Settlement Agreement and the Matrix Settlement Agreement as having been prepared separately but in parallel.

(622) Servier also explained that its interest in negotiating with Matrix stemmed from the fact that it could prevent Matrix's DMF being licensed to third parties as this could have led to new violations of Servier's patent rights.[891]

4.3.1.4.3.3 Reaction of generic companies in relation to the Niche/Unichem and the Matrix settlements

(623) From an internal Teva communication dated 4 January 2006, it becomes clear that generic companies viewed the settlement agreements between Servier and Niche/Unichem and Matrix as a compensation given to the generic companies in exchange for an obligation not to enter the market. The communication stated: *"We know that in the past Servier has been quite aggressive (for example they convinced*

887 ID1452, p. 16-17. Niche denies to have negotiated a settlement sum for Matrix (reply to the Statement of Objections, ID8524, p. 159). In any event, the final settlement sum that Matrix received was equal to the one received by Niche pursuant to clause 13 of the agreement, i.e. GBP 11.8 million, and Niche had begun negotiating with Servier before Matrix.

888 ID1452, p. 16 - 17.

889 ID1452, p. 16.

890 ID1723, p. 16 - 17.

891 ID1723, p. 17.

Matrix/Niche not to commercialize their product - they basically paid them not to enter the market)".[892]

(624) Several references to Servier's attempts to buy out all API producers can be found in the discussions between Krka and Ivax during 2005 related to perindopril. For example, in an email from Ivax of 17 June 2005 it is stated: *"KRKA feel there is a strong likelihood that Servier will attempt to buyout all API manufacturers, (I have not advised them of our source except to say it is not Matrix, who were bought out with Niche)".*[893]

4.3.1.5 Developments post settlement

4.3.1.5.1 Discontinuation of the perindopril project between Niche and Matrix

(625) Both Niche and Matrix were initially interested in continuing their joint perindopril project to the extent permissible under the settlement agreements. In an email from [employee name and function with Niche]*, to [employee name and function with Matrix]* at the time, dated 7 March 2005, Niche asked Matrix to provide the API material for manufacturing some tablets in Goa to complete the registration of MA licences for the UK.[894] This complied with the respective settlements because these agreements did not oblige the companies to withdraw from pending MA procedures.

(626) In that email of 7 March 2005, Niche explained that the main restriction they had to face came from the settlement agreements rather than from technical difficulties: *"we understand the* [production] *process was stopped after the agreements were signed*".[895]

(627) In addition, the email concludes that Niche would like *"to complete the development of the product and G. and I were pleased to hear that Matrix still wishes to work with Niche to complete the project".*[896]

(628) Furthermore in an internal email of 27 April 2005 from [employee name and function with Niche]* to [employee name and function with Niche]*, the key areas for an upcoming meeting with Matrix were explained. According to this email, Niche planned to launch perindopril in 2008:[897]

"Are Matrix going to continue with developing perindopril to support our UK applications through to grant. This would then allow us to launch in 2008".[898]

(629) On 5 May 2005, [employee name and function with Niche]*, sent an email to [employee name]* of Matrix indicating that the latest meeting with Matrix seemed

892 ID0082, p. 72 - 73.

893 ID0346, p. 39.

894 ID0027, p. 212.

895 ID0027, p. 212.

896 ID0027, p. 212.

897 Niche explains in its reply to the Statement of Objections that it hoped to develop non-infringing perindopril but due to the absence of a third party API supplier with non-infringing API post-settlement, the project was continued with Matrix for launch in 2008. Niche expected the potential launch of perindopril in the UK could take place in 2008 because of litigation issues and its inability to produce non-infringing perindopril (ID8524, p.13-14). However, Niche was bound by an exclusive partnership with Matrix at the time of the settlement agreement and could not have developed perindopril with another company without violating the 2001 development agreement. Also, the delay in launch until 2008 was foreseeable already at the time of signing the settlement agreement (see paragraphs (593), (594) and (602) of this Decision).

898 ID0028, p. 27.

inconclusive regarding the question of how to proceed with perindopril and therefore suggested a further meeting.[899] The minutes from this meeting indicate that its purpose was to *"discuss with Matrix the current status of the perindopril project"*.[900]

(630) On 13 May 2005 Niche sent a letter to Matrix informing it about a deficiency letter received from the UK MHRA relating to Niche's request for MA. Niche asked Matrix to supply some API materials necessary to answer some of the UK MHRA questions. In particular, Niche asked whether Matrix could make available to Unichem *"new API within the impurity specification"*[901] in order for them to manufacture batches.

(631) However, in a letter from Matrix to Niche dated 22 June 2005, Matrix declared with immediate effect the suspension of the Development and Licensing Agreement with Niche dated 26 March 2001 until the three process patents expired in 2008.[902] A letter from Matrix to Servier of the same day entitled *"compliance status"* in relation to the Matrix settlement suggests that Matrix was obliged, pursuant to clause 7 and 8 of the settlement with Servier, to suspend its cooperation agreement with Niche which was part of the "Matrix contracts" as defined in the settlement agreement.[903]

(632) Matrix explained in reply to questions 3 and 7 of the Commission's RFI dated 22 December 2010, that the possibility of explicitly invoking the termination clause of the Development and Manufacture Agreement between Matrix and Unichem was not considered. As the Development and Licensing Agreement between Matrix and Niche was suspended, there was no "*business or commercial need for any further steps to be taken in respect of the Development and Manufacture Agreement*".[904] In any event neither Matrix nor Unichem seem to have considered it necessary to terminate their cooperation.

4.3.1.5.2 Customer relationships

(633) Niche was obliged to cancel, terminate or suspend all of its customer contracts relating to "Perindopril" as per the settlement agreement (Niche had concluded 14 contracts with customers relating to perindopril).[905] The same obligation applied to Matrix (clause 7 of the Matrix Settlement Agreement) which was however not contractually bound by any customer relationships.

4.3.1.5.2.1 Customers of Niche

(634) On 14 February 2005, Niche sent a letter to its customers informing them of the conclusion of the settlement agreement with Servier: *"[…] have settled the UK infringement suit in relation to perindopril on a worldwide basis given the uncertainties in multi-jurisdictional litigation"*.[906] Niche also indicated the consequences that the settlement had on their contractual relationships: *"this settlement will have an impact on the agreement between our two companies for this product which may result in you wishing to terminate or cancel the agreement"*.[907]

899 ID3268, p. 21.
900 ID0028, p. 25.
901 ID1709, p. 49.
902 ID0027, p. 207.
903 ID0601, p. 1.
904 ID3308, p. 2 and 5.
905 ID0119, p. 140.
906 ID1173, p. 65 (this letter provides an example of the standard letter sent to customers on this date).
907 ID1173, p. 65.

(635) In a letter to its auditor drafted on or around 31 March 2005, Niche explained the level of provision relating to the suspension of the customer contracts as foreseen in the settlement. An overall provision of GBP [0–3]* million was made, which was GBP [0–1 million]* over the total amount that Niche had received as advances from customers.[908]

(636) According to a document found during the inspection dated around April 2005, it can be understood that Niche considered its obligation to terminate its customer relationships as very narrow: *"The Board has taken the view that, having entered into negotiations and/or having notified the licencees that the company is terminating/suspending the agreements, unilaterally if necessary, they will have fulfilled their part of the obligation under the Servier agreement"*.[909]

(637) The Commission understands that there were discussions between Niche and Matrix concerning the refund of Niche's customers.[910] In its reply to the Commission's RFI of 5 August 2009 Matrix confirmed that "*all refunds made by Niche were for its account"*.[911]

(638) On 20 June 2005 Niche informed Servier that it had already fulfilled its contractual obligation to cancel, terminate or suspend all contracts with customers before 30 June 2005: *"we have satisfied our contractual obligation to you to suspend, cancel or terminate all of the agreements with Niche customers"*.[912]

(639) Although by June 2005 the discussions with a number of customers regarding damages had not yet been concluded, most relationships were terminated by 2006.[913] Niche attempted to limit refunds to its customers to fees received upfront and paid back a total of around GBP [0–5]* million.[914] In its dealings with customers, Niche expressly attributed responsibility to Matrix for not being able to fulfil its contractual obligations. For example, Niche told a customer that Matrix was *"not keen on pursuing the project because of the difficulties and ultimately wanted to negotiate with Servier"*.[915]

(640) This line of reasoning, i.e. putting the blame on Matrix as the reason for its inability to supply customers, can also be found in other negotiations regarding damages claims. For example, on 10 May 2005 Niche was advised by its lawyer to argue vis-à-vis a customer that Niche did not have a supplier of perindopril API anymore:

"[…]".[916]

4.3.1.5.2.2 Customers of Matrix

(641) As explained in paragraph (631), Matrix suspended its contract with Niche in relation to perindopril in June 2005 as it had agreed to comply with this obligation in the Matrix settlement.[917] Although section 4 of the Matrix settlement reads *"Customers of Matrix"*, the Matrix contracts mentioned in clause 7 and 8 of the

908 ID0025, p. 46 - 48.
909 ID0025, p. 46.
910 ID1709, p. 49.
911 ID1452, p. 20.
912 ID0027, p. 205.
913 ID1173.
914 ID1032, p. 6.
915 ID0027, p. 223.
916 ID3268, p. 18-19.
917 ID0601, p. 1

agreement included only the Development and Licensing Agreement between Niche and Matrix. Matrix had not concluded any direct customer contract[918] so there was no need to terminate or suspend any contract pursuant to clause 7 of the Matrix settlement.

(642) However, on 25 October 2005, [employee name]* of Servier sent an email to Matrix asking it to contact various MA bodies in the EU (including France, the UK and the Netherlands) to inform them that the DMF developed at the time by Matrix was null and void and that, due to the patent settlement with Servier, *"Matrix has stopped the development and commercialization of perindopril and therefore cannot provide to anybody the active substance manufactured according to the process in dispute and therefore the DMF developed at the time by Matrix, cannot be used and should be considered as null and void. The reason is that we have heard that, in some countries, some companies are still making reference to your DMF and to Matrix as a supplier of active substance in their application for product license. Some product licenses have even been granted on this basis (it is the case in Holland, in Hungary and Slovenia although the drug is not commercialised). We do not doubt that you are respecting fully the agreement as laid down in the agreement signed on 8th February 2005 and we thank you for that"*[919](emphasis added).

(643) A day later, on 26 October 2005, [employee name of Servier]* sent an additional email to Matrix insisting that a letter be sent to the relevant regulatory authorities stating that Matrix wishes to withdraw its DMF: *"[…] it would be greatly appreciated if you could send a letter informing Regulatory Authorities of all countries where your DMF might have been submitted, that you no longer manufacture perindopril due to technical difficulties and therefore you withdraw your DMF"*.[920]

(644) Matrix discussed internally the issue raised by Servier and, as expressed in an internal communication on 29 October 2005, came to the conclusion that: *"we have not supported any of the customers with the process of regulatory approval of their application. Further, even if they get regulatory approval, we will not offer API for them to launch the product in the market. As per this agreement [with Servier], we are not required to write to the regulatory agencies and withdraw the DMFs already filed. Therefore, in view of maintaining customer relationships, we also recommend that this should not be done"*.[921]

(645) This position was communicated in Matrix's reply to Servier on 24 November 2005. In this letter Matrix confirmed that, since the date of execution of its settlement agreement, Matrix had stopped manufacturing the product, had not provided fresh letters of access to their DMF (for regulatory approval), had not filed DMFs in new countries and had not answered any regulatory questions (according to clause 6 of the Matrix settlement, Matrix agreed not to *"assist any third party to obtain any such Regulatory Approval"*).[922] Against this background, Matrix argued: *"Therefore, we have not supported any of the customers with the process of regulatory approval of their application. Further, even if they get regulatory approval, we will not offer API*

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[918] Matrix explained *ex post* that it "*was not in a position to licence the dossier to customers*". See ID1452, p. 19.

[919] ID0607, p. 1.

[920] ID0607, p. 2.

[921] ID0606, p. 1.

[922] ID0119, p. 149.

for them to launch the product in the market. While we respect the obligations undertaken by Matrix to Servier in letter and spirit, we believe that the above is the sufficient compliance with the obligations of Matrix to Servier under the agreement. Further, we are of the humble opinion that the terms of the agreement would not necessitate the withdrawal of DMFs already filed by Matrix".[923]

(646) The above demonstrates that Servier continued to monitor all applications for MAs by generic companies and was eager to enforce the provision in the settlement agreement prohibiting Matrix from filing any new MAs or assisting others with such applications. Servier even wanted to go beyond what was agreed by requesting Matrix to withdraw its DMFs that had already been filed.

4.3.1.5.3 Developments after termination of cooperation between Niche and Matrix

4.3.1.5.3.1 Niche/Unichem

(647) In 2008 Niche considered making use of the opportunity of launching perindopril. In an email of May 2008, one of Niche's employees, [employee name]* *"believes the agreement with Servier to not work on Perindopril comes to an end sometime this year* [2008]*"*. From internal email exchanges between 9 and 12 May 2008, it can be seen that Niche preferred working with an API source different from Matrix which would have meant departing completely from its original development arrangements with Matrix.[924]

(648) However, on 22 May 2008, Niche came to the conclusion that the launch of perindopril in the UK and Ireland would not be profitable due to generic competitors already being present on the market and Servier's switch to arginine salt.[925] Niche therefore decided not to invest into perindopril and, as such, is not currently present on the perindopril market.

4.3.1.5.3.2 Matrix

(649) In contrast to Niche, Matrix had been selling perindopril in the EU through its subsidiaries. Matrix explained that in June 2005 Matrix acquired two companies which sold (DocPharma) and currently sell (Apothecon) perindopril in the EU.[926]

(650) DocPharma operated in Belgium and entered into a distribution agreement with Servier in July 2008 for the distribution in Belgium of a generic version of perindopril erbumine sourced from Servier. After the '947 patent was annulled by the EPO in May 2009, DocPharma started selling perindopril in September 2009. [927] Apothecon obtained a MA in the Netherlands on 31 May 2005 (which was based on the Niche dossier and was not used). However, it only started selling perindopril in the Netherlands in November 2008 based on a licence and supply agreement for

923 ID0615, p. 1.

924 ID0026, p. 25. This document stated that *"I don't think Matrix our old source would be up to the job"* – unlike Servier's suggestion that the API was not suitable (reply to the Statement of Objections, paragraphs 364 and 473, ID10114, p.174 and 207), this may be due to a number of reasons (e.g. suspension of the development agreement between Niche and Matrix and no further work on the project as of June 2005, precisely as a result of the settlement agreements concluded with Servier).

925 ID0026, p. 29.

926 ID1452, p. 5. These companies are not subsidiaries of Matrix since 2010 (ID10830, p.1).

927 ID1452, p. 6, 11. Docpharma no longer sells perindopril today (ID10830, p.1).

perindopril with Krka[928] following the grant, on 10 July 2006 of a marketing authorisation based on the Krka dossier.[929]

4.3.2 Teva

(651) This section describes the settlement agreement that was concluded on 13 June 2006 between Servier and Teva.[930]

(652) The settlement obliged Teva to purchase perindopril erbumine for distribution in the UK exclusively from Servier for a period of three years. In return for the payment by Servier of GBP 5 million, Teva agreed to refrain from selling generic perindopril (other than that supplied by Servier) and from challenging Servier's patents (for the precise scope of the restrictions see section 4.3.2.5). In addition, liquidated damages were agreed between Servier and Teva in case of non-supply of perindopril as of 1 August 2006 and Teva had, in such case, no right to terminate the settlement agreement. Following the decision of the EPO to uphold the '947 patent and the injunction granted by the High Court against Apotex, Servier relied on the liquidated damages clause and thus, over a period of 11 months, Teva received a sum of GBP 5.5 million from Servier in compensation for the non-supply of perindopril. This led to an aggregated payment of GBP 10.5 million from Servier to Teva under the settlement agreement.

(653) Contrary to the other settlement agreements described in this Decision, the settlement between Servier and Teva concerns exclusively the UK market on which this section will therefore concentrate.

4.3.2.1 Preliminary remarks

(654) The chain of events leading up to the settlement between Teva and Servier is particularly complex, as Teva pursued – in parallel - three different options to launch generic perindopril. Teva tried to reach the market: 1) through the development of an own generic version of perindopril (through the Indian based API producer, Hetero Drugs Limited, "Hetero", bound by exclusivity to Teva); 2) in partnership with another generic company (Krka, e.g. by means of a licence or distribution agreement) and 3) through a distribution agreement with Servier (authorised generic). These options are described below.

(655) On 26 January 2006, i.e. about five months before the conclusion of the settlement agreement,[931] Teva merged[932] with Ivax Europe ("Ivax").[933] Before the merger, Teva and Ivax were each developing their own perindopril project separately. This calls for a description of the perindopril activities of Teva and of Ivax, even though Teva submits[934] that soon after the merger it became clear that Ivax's perindopril

928 ID1452, p. 5, reply to the Commission's RFI of 5 August 2009.

929 ID3319, p. 1 - 3.

930 The settlement agreement was signed by Teva UK limited (part of the Teva group of companies, whose ultimate parent company is Teva Pharmaceutical Industries Limited (all companies belonging to the Teva Group of companies are hereinafter referred to as "Teva", for details see section 1.2.5)

931 ID3624, p. 12.

932 Ivax became a wholly owned subsidiary of Teva, and ceased to be traded on the American Stock Exchange. Clearance by the European Commission was given on 24 November 2005.

933 Ivax Europe is a multinational generic pharmaceutical company based in India with several subsidiaries in the EU. For further details, see section 1.2.5.

934 ID1346, p. 29.

programme was more advanced than that of Teva and therefore was the one retained by the merged entity.

4.3.2.2 Efforts by Teva and Ivax to enter the perindopril market with their own generic

(656) The present section describes the efforts of Teva and Ivax to enter into the perindopril market with their own generic version and is divided in two separate subsections describing Teva's and then Ivax's activities to enter the market.

4.3.2.2.1 Teva's development of perindopril erbumine

(657) In the initial phase of its perindopril project (i.e. before the merger) Teva decided that it would source the API from a third party supplier rather than try to develop it internally. Teva's strategy was to find an API supplier who could provide a novel polymorph other than the alpha, beta or gamma forms of perindopril.[935] Teva's attempts to source perindopril API began in 1999 when it entered into negotiations with the [nationality]* pharmaceutical company [company name]* for the development and supply of perindopril.[936] [Company name]* collaborated with [company name]*, an API producer.[937] For the production of perindopril API, [company name]* and Teva exchanged drafts of a binding memorandum of understanding concerning the development and supply of perindopril.[938] According to Teva, [company name]* pulled out of negotiations in July 2001 before a binding contract had been concluded.[939]

(658) This is explained by the fact that during the same time period [company name]* had started negotiations with Servier's subsidiary [company name]*[940] for the sale of [company name]*'s patent application for perindopril. These negotiations were successfully concluded on […]* 2001, when the companies signed an agreement for the sale of a patent application[941] and a "chemical dossier" for perindopril API (see sections 4.2.1). Following this agreement, [company name]*/[company name]* were unable to supply API to generic companies.

(659) Teva then discussed the supply of perindopril with a number of other producers. For example, in October 2001 Teva contacted [company name]* but no deal was reached as [company name]* was only willing to grant a licence for [non-EEA jurisdiction]*.[942] In 2002 Teva explored potential agreements with [company name]*. Negotiations did not proceed since [company name]* wanted to exclude the UK.[943] In 2003 Teva negotiated with [company name]*, but contacts were discontinued as the product was considered to be covered by a Servier patent.[944]

(660) From 2003 to 2004 Teva negotiated with Azad.[945] Azad seemed a very promising route for Teva, as Azad had developed a novel polymorph of perindopril that was not

935 ID2481, p. 2.

936 Several documents outline the negotiations: ID2481, p. 2, ID 2477, p.1; ID2477, p. 2 - 5. For further details see also section 4.2.1.2.

937 ID8292, p. 2, ID2882, p. 3.

938 ID2477, p. 2 - 5.

939 ID2481, p. 2.

940 "**[Subsidiary of Servier]* is an entity of the Servier Group whose business is to fund research and development studies on Servier products*". ID1151 p.37.

941 […]*.

942 ID2481, p. 3.

943 ID2481, p. 3.

944 ID2481, p. 3.

945 ID2481, p. 3; for further details see also section 4.2.2.3.2.

covered by Servier's patents at the time. In October 2004, however, Azad stopped negotiating with Teva[946] which can be explained by the fact that Azad had simultaneously started negotiations with Servier on the sale of Azad's patent application relating to perindopril. Azad's negotiations with Servier were successfully concluded on 9 November 2004 with the signature of an assignment agreement.[947]

(661) In its submissions to the Commission's RFI of 7 July 2010, Teva explains that - because of the late termination of the cooperation by Azad just before filing for [non-EEA jurisdiction]* approval - Teva demanded full reimbursement for its development expenses which amounted to USD [0.5-1.5] million.[948] Azad agreed to pay the damages demanded[949] but it again left Teva without a supplier of perindopril API (for further details see sections 4.2.2.3.3 and 4.2.2.7.1).

(662) In 2004 and 2005 Teva negotiated a licence and supply agreement with Niche,[950] who had teamed up with Matrix (for details see section 4.3.1.1). However, on 8 February 2005 Niche concluded a settlement agreement with Servier, in which Niche agreed not to sell perindopril on the market and, as such, also brought its negotiations with Teva to an end.[951]

(663) In November 2004 Teva tested samples from Lupin and ordered materials for batch production.[952] Teva explains, in this regard, that: "*Teva received Lupin's material for bio-study in mid 2005 and filed its dossier [Marketing Authorisation] in December 2005"*.[953] However Teva's application for regulatory approval was withdrawn, as following the merger, the launch of Ivax's development programme on perindopril was given preference. [954] No supply agreement was therefore concluded with Lupin.[955]

(664) The multiple – mostly failed/frustrated - efforts of Teva show just how difficult it was for generic companies in the critical period from 2000 to 2008 to reach the European markets with a generic perindopril. This is also reflected in Teva's internal assessments of the situation. On the basis of a report by [employee name]* (Teva) during a Pan-European Licensing Meeting in Paris held on 27 January 2005, Teva noted: *"Teva development delayed as cannot acquire any API (Servier keep buying up API companies"*).[956] A few months later, another internal Teva communication of 3 October 2005 confirmed: *"The position with Perindopril is very complicated in terms of patents-particularly process patents which affect API manufacturers. This is partly why everyone is late (once an API manufacturer has got round the process patents Servier has bought the company, sourcing API has been very difficult"*.[957]

946 ID2481, p. 5.
947 ID0104, p. 180 - 190. See also section 4.2.2.5.
948 ID2481, p. 5.
949 ID2481, p. 5, ID3459, p. 1 - 4.
950 ID0025, p. 160 - 162.
951 ID0119, p. 136 - 145.
952 ID2481, p. 3. For further details see also section 4.3.4.2.
953 ID2481, p. 3.
954 ID2481, p. 3.
955 ID2448, p. 8.
956 ID0078, p. 62.
957 ID0082, p. 70.

(665) As indicated above, in its reply to the Commission's RFI of 7 July 2010 Teva explains that *"Following the merger with Ivax, the Ivax project was given preference"*.[958]

4.3.2.2.2 Development of Ivax's perindopril

(666) Around 2001/2002 Ivax had identified perindopril erbumine as a potentially attractive product for generic entry. During this period, and following an initial review, Ivax contacted Servier with a view to negotiating either a co-marketing or supply deal, whereby Ivax would receive a generic version of perindopril from Servier for sale in the UK.[959]

(667) These negotiations led to a confidentiality agreement being entered into on 5 June 2002 in order to facilitate the provision of general information about the product and its sales to Ivax with a view to agreeing *"the commercials for any co-promotion/supply"*.[960]

(668) However, by 2003 no significant progress had been made with Servier, so Ivax engaged in its own perindopril product development.[961] On 24 September 2003 an agreement for perindopril API supply was concluded with Hetero.[962] Hetero granted Ivax exclusivity status for Europe. In addition, on 21 December 2005 Ivax signed a manufacturing and supply agreement with the Indian API producer Alembic for the manufacture of perindopril as a final product, based on the API supplied by Hetero.[963]

(669) Internal documents suggest that the Hetero API was in the alpha crystalline form, possibly covered by Servier's '947 patent.[964]

(670) In addition, Ivax started discussions with Krka in 2003 which was, at the time, developing its own perindopril product. Teva argues in its reply to the Commission's RFI of 5 August 2009 that the Krka product […]*.[965]

(671) During 2005, several references to Servier's attempts to buy out all API producers can be found. For example, in an internal email (17 June 2005) Ivax stated: *"KRKA feel there is a strong likelihood that Servier will attempt to buyout all API manufacturers, (I have not advised them of our source except to say it is not Matrix, who were bought out with Niche)"*.[966]

(672) Another internal Ivax email dated 10 August 2005 stated: *"In any conversations with Servier, it is important that they are not given the name of our API supplier. The general Industry consensus is that Servier will attempt to take out API sources"*.[967]

4.3.2.2.2.1 The regulatory approval process in the UK

(673) Ivax's regulatory strategy focused on obtaining MA for its generic product (supplied by Hetero/Alembic) in the UK as RMS, which was to be subsequently extended to a

958 ID2481, p. 3.
959 ID1346, p. 28.
960 ID1346, p. 28.
961 ID1346, p. 29.
962 ID0345, p. 28; ID5424, p. 1 - 17.
963 ID1346, p. 29; ID2520, p. 1 - 27.
964 ID0087, p. 81; ID0350, p. 503.
965 ID1346, p. 29.
966 ID0346, p. 39.
967 ID0358, p. 545.

number of European countries pursuant to the MRP procedure (for further details on the regulatory process outside the UK, see section 4.3.2.8.2.3).[968] Ivax applied for MA in the UK on 30 November 2004.[969] As indicated in the document *"IVAX Europe-Strategic Plan for 2004-2009"*[970] of 13 July 2004, Ivax planned to launch perindopril in 2006.

(674) Teva explains[971] that, during the regulatory approval process, Servier raised bioequivalence concerns before marketing authorisation bodies: *"Teva was made aware of interventions made to at least two national regulatory authorities (AFSSAPS in France and the MHRA in the UK)"*. In March 2006, these authorities requested that Teva provide certain bioequivalence data.[972]

(675) Furthermore, Teva explains in its submissions to the Commission (RFI of 5 August 2009)[973] that to address this point a significant amount of re-analysis of retained plasma samples was required followed by statistical treatment. This was considered by Teva in April 2006 as a *"condition of approval that is going to cause a serious delay to launch. We had hoped to get approval this month but with the standards not being available until mid May we are looking at early June as the earliest response time. We will then have to wait even longer for MHRA final approval meaning that at this rate we may not even hit Q2. This would have very serious consequences for Teva UK performance"*.[974] Consequently, the UK MA was delayed by a number of months until the MHRA was satisfied with the data. According to an email from the Teva/Ivax UK regulatory team, the glucuronide issue was, by 5 May 2006, the only remaining barrier for the approval of Teva/Ivax generic perindopril. In the email a member of Teva's regulatory team states*: "I have just spoken to the Pharmaceutical Assessor […] at the MHRA. He has confirmed that the glucuronide issue is the only barrier remaining to approval of our dossier"*.[975]

(676) In a presentation from end June/July 2006, it is stated that the approval of the UK MA dossier is expected *"within one month or so"* following the final MHRA questions to be answered in August 2006, thus meaning an approval in September.[976] Finally, the UK MA was granted to Ivax/Teva on 12 December 2006,[977] i.e. a few months after the settlement between Teva and Servier.

4.3.2.2.2.2 Disputes and litigation with Servier

4.3.2.2.2.2.1 Dispute on the process patents

(677) Internal documents from April and May 2006 indicate that Teva and Ivax considered that their perindopril product did not infringe Servier's process patents '339, '340 and '341.[978] Between November 2005 and March 2006, Ivax requested opinions from

968 ID0350, p. 123 - 158 (in particular p. 134 - 135).
969 ID2538, p 1.
970 ID0345, p. 128.
971 ID1316, p. 1.
972 ID1346, p. 24, see also Teva's reply to the Statement of Objections, paragraph 171, ID8495, p.43 (quoting ID0358, p.621).
973 ID1316, p. 1.
974 ID1343, p.8, further disclosed in ID8280, p. 8. According to this exchange of emails, the MHRA requested certain bioequivalence data on 8 March 2006.
975 ID0346, p. 36.
976 ID0350, p. 647.
977 ID1315, p. 1.
978 ID0350, p. 743, ID0358, p.712, ID0350, p.1130.

scientific experts, patent attorneys and counsel whose overall conclusion was that the Hetero process was non-infringing, even after an inspection of Hetero's plant.[979] It is noted that, in respect of the '339 patent, the patent attorney expressed the view that *"the issue is not clear cut and there is some risk of infringement"*. However, the conclusion was that a court in the UK would, on the balance of probabilities, find that there is no infringement, based on the interpretation of claim 1,[980] and that there is *"room for legal argument"*.[981]

(678) Correspondence was exchanged with Servier on this issue as of January 2006.[982] A letter dated 1 March 2006 from Teva's to Servier's lawyers enclosed the confidential process description in respect of the manufacture of perindopril erbumine based on the Hetero process for perindopril API. It stated that the process takes place outside the UK and that the final product is not obtained by means of a process falling within any of Servier's process patents.[983] At the same time, Teva was considering arguments regarding the validity of the '339 patent which Servier threatened to oppose in infringement proceedings against Teva, and was looking for evidence on the absence of a collapse in price after generic entry in order to resist to an injunction.[984] In fact, by letter of 28 April 2006, Servier's lawyers refused to confirm that the importation of tablets would not infringe Servier's process patents and argued that the tablets containing perindopril imported by Teva/Ivax will be considered *"an infringement of at least Claim 5 of the 339 Patent"*.[985] In a letter dated 2 May 2006, Teva denied Servier's assertion of infringement of claim 5 of the '339 patent and refused to give a general undertaking not to import perindopril in the UK but indicated that it is *"willing to take part in discussions to see if this dispute can be resolved without having to resort to litigation"*.[986] Teva also gave an undertaking whereby it will not enter the UK market prior to 1 June 2006 so as to allow discussions regarding a possible settlement agreement.[987]

4.3.2.2.2.2.2 Litigation on the '947 patent

(679) Turning to the '947 patent, Teva/Ivax engaged in efforts to oppose Servier's '947 patent before the EPO and national jurisdictions. These efforts are described below.

1. The EPO proceedings

(680) In November 2004, Ivax filed an opposition before the EPO, through the company Norton Healthcare, against Servier's '947 patent.[988] As indicated above, nine other companies opposed this patent suggesting that the view of the generic sector at the time was that Servier's '947 patent did not meet the patentability criteria.[989] In June 2005, Teva considered that it had better arguments than other opponents *("It is*

979 ID0358, p. 31; ID0354, p. 471; ID0354, p. 971 - 973; ID0354, p. 1275 - 1307.
980 ID0354, p. 1277 and 1279.
981 ID0354, p. 971 (same as ID0354, p.928-929).
982 ID0358, p. 161.
983 ID0358, p. 35.
984 ID0358, p. 31-32.
985 ID0358, p. 73.
986 ID0358, p. 75.
987 ID0358, p. 75.
988 ID1346, p. 29. See also: EPO.
989 For more details see section 4.1.2.4.2.1.

fair to say that our arguments and KRKA's are similar at the EPO whereas most of the other Opponents are very poor").[990]

2. Litigation before the High Court

(681) On 9 August 2005, Ivax also requested the revocation of the '947 patent before the High Court.[991] Ivax claimed that the '947 patent was invalid due to: (i) lack of novelty having regard to prior art from the '341 patent; (ii) obviousness due to existence of the prior art; and (iii) insufficiency on the basis that the '947 patent is not more enabling than the cited prior art.[992] In a document summarising the litigation in the UK, it can be seen that Servier was due to respond by 6 September 2005 and discussions on a possible stay of the proceedings in return for a number of undertakings were on-going: *"Revocation documents filed. Servier response due on 6 September. Company approach being made to Les Servier. Undertakings offered. May consent to stay if suitable undertakings are agreed. Intercompany discussions continuing"*.[993]

(682) Following an application by Servier to stay the proceedings, Ivax and Servier agreed in October 2005 on the stay of the proceedings[994] pending the final determination of the EPO opposition proceedings. In return, Servier gave a number of undertakings to Ivax. Servier undertook:[995]

"(a) not to commence proceedings during the period of the stay against the Claimant or its licensees (if any) or any of their customers for any act of infringement of the Patent in the UK;

(b) not to seek an account of profits or any financial relief other than a reasonable royalty in respect of any acts of infringement of the Patent committed by the Claimant or its licensees (if any) in the UK during the period of the stay;

(c) not to seek injunctive relief or delivery up in the UK against the Claimant, its licensees (if any) or any of their customers as a result of any contracts entered into or fully negotiated by the Claimant during the period of the stay;

(d) to prosecute the EPO proceedings diligently including asking for the proceedings to be accelerated;

(e) not to seek an interim injunction against the Claimant, its licensees (if any) or any of their customer, in any infringement action brought by our client under the Patent following the final determination of the opposition proceedings before the EPO".

(683) The undertaking meant that Ivax could launch generic perindopril in the UK as Servier had agreed not to take any action against Ivax's perindopril based on the "Patent" (the '947 patent) during the pending EPO proceedings. Obviously, this commitment was under the condition that Ivax respected all other Servier patents. Thus, if Teva were to enter the market with an alpha-infringing product during the

990 ID1309, p. 1.
991 HC05C02131; ID1346, p. 29.
992 ID0354, p. 973.
993 ID0345, p. 466, Annex to Teva reply to the Commission's RFI of 16 January 2009.
994 ID1346, p. 47 - 48; ID0345, p. 233; ID0358, p. 89 - 91.
995 ID1323, p. 1 - 5.

period of the stay and the patent were to be upheld later, then Servier could only seek a reasonable royalty and no other financial relief.[996]

(684) The nature of Servier's undertakings was confirmed in the minutes of a meeting between Ivax and Servier of 13 October 2005. Ivax noted that it had agreed to stay its challenge in the UK until the outcome of the EPO proceedings and that *"Servier has given undertakings that will allow IVAX to launch a product containing alpha polymorph Perindopril (subject to non infringing to any other Servier patents)"*.[997]

(685) In its reply to the Commission's request of information of 6 April 2010 Servier stated that the undertaking given to Ivax was valid until the final decision adopted by the EPO Technical Board of Appeal,[998] which would mean that Teva/Ivax could have launched its generic perindopril in the UK even after the decision of the EPO Opposition Division of 27 July 2006 provided that this product did not infringe the process patents (see to that effect paragraph (677)).

(686) In its reply to the Statement of Objections,[999] Teva argues that the scope and duration of Servier's undertakings were not as clear as the Commission pretends. First, as to duration, the Commission notes that Servier's lawyers had sent a letter to Ivax's lawyers at the time of the stay. This letter explicitly stated that the undertakings given are in place *"pending the final determination of **all** matters before the EPO"* (emphasis added).[1000] Moreover, the Opposition Division's decision (expected in July 2006) is only an "**interlocutory decision*" and Teva cannot claim that it was not aware of the definition of *"final determination of all matters"*. As to the scope of the undertakings, in a witness statement prepared for purposes of the present procedure, Teva's lawyer, [name of Teva counsel]*, explains that the undertaking had been given to Ivax Pharmaceuticals UK Ltd who was the trading company of the Ivax group in the UK. It is alleged, however, that notwithstanding the fact that this had been confirmed to Servier's lawyers by 2 May 2006, around 10 May 2006, it was discovered that Ivax Pharmaceuticals UK Ltd. was in fact a dormant company. It was also discovered that the Ivax trading company would have been in fact Norton Healthcare (trading as Ivax Pharmaceuticals UK), another company of the Teva/Ivax group. Thus, it would have been unclear whether the benefit of the undertaking on the '947 patent could be transferred to Norton Healthcare or to other companies in the Teva group.[1001] The Commission observes that, first, the contemporaneous evidence does not reveal much questioning about the possibility for Teva to be able to take the benefit of the undertaking or as to the legal entity that could benefit from it. For example, an internal Teva document from May 2006 indicates with respect to the Krka product that there are *"no undertakings with respect to alpha polymorph in these [FR, NL, DE] countries"*.[1002] This suggests that *a contrario* there were undertakings for the UK with no discussion as to the possibility for Teva to be able to benefit from them. Secondly, no evidence of the fact that Ivax Pharmaceuticals UK Ltd. became a dormant company has been submitted and in any event [name of Teva counsel]*'s statement refers to the need to resurrect this company, which

996 ID1322.
997 ID2542, p. 2.
998 ID2365, p. 35.
999 ID8495, paragraphs 240-244, p.56-57. See also Teva's reply to the letter of facts, ID10250, p. 11-13.
1000 ID0087, p.130.
1001 Annex 2 to Teva's reply to the Statement of Objections (ID8497, p. 5-6).
1002 ID0350, p. 743.

implies that this was a possibility, as well as to the possibility of the court allowing an amendment of the undertakings to cover Norton Healthcare ltd. Thirdly, that Norton Healthcare Ltd. was trading as Ivax Pharmaceuticals UK was stated in the Manufacturing and Supply Agreement between Alembic and Ivax Pharmaceuticals UK which was concluded in December 2005. Thus, this fact would have been known to Teva at the time of the negotiations with Servier. Fourthly, the contemporaneous evidence speaks of discussions between Servier and Teva regarding the possibility of infringement only of the process patents. The '947 patent never appears as part of these discussions, which suggests that as far as Teva was concerned, that patent was not the subject-matter of the dispute on the infringement. For example, in a letter of 28 April 2006 from Servier's lawyers to Teva's lawyers, Servier sought commitments from Teva not to market its product in the UK in light of the alleged infringement of the process patents, but the '947 patent was not mentioned in this context (see paragraph 714).

4.3.2.2.3 Conclusion on Teva's/Ivax's option to enter the UK market with its own generic

(687) When assessing the commercial opportunities with its own perindopril in the UK, Teva considered a number of different market scenarios (depending in particular on the number of competitors). In an email of 28 April 2006[1003] from [employee name and function with Teva]* to [employee name and function with Teva]* the estimates for the product launch of Teva's perindopril in the UK for 2006 are summarised as follows:

*"If we are able to launch in May (ie MA is granted mid to end May) and we take three different assumption sets […]**

Scenario:	*Sales in Q2*	*EBIT in Q2*
Best	*[5–10]* m*	*[0–5]* m*
Medium	*[0–5]* m*	*[0–5]* m*
Worst	*[0–5]* m*	*[0–5]* m*

*The figures for the rest of the year then assume […]**

Scenario	*Sales Full Year*	*EBIT Full Year*
Best	*[10–15]* m*	*[5–10]* m*
Medium	*[5–10]* m*	*[5–10]* m*
Worst	*[5–10]* m*	*[0–5]* m"*

4.3.2.3 Teva's other options to enter the perindopril market in the UK

(688) Aside from preparing to enter the UK market with its own generic, Teva also explored other possibilities such as obtaining the final product either from another generic company or from Servier.

(689) An email from [employee name and function with Teva]* addressed to [employee name and function with Teva]* dated 6 May 2006 clearly summarises the options available to Teva in May 2006, i.e. shortly before the settlement: "*Is it possible for you to give me an updated assessment of the likelihood of success and timelines to approval for the synthesis of the required standards and the subsequent analytical*

[1003] ID0346, p. 23 – 24.

work, response and assessment on Tues or Weds of next week (latest). We are trying to assess this probability vs the supply offer from Servier and a supply offer from Krka. I appreciate the complexity of the situation but we are going to have to decide to either back our own project or sign up with one of the supply offers by the end of next week. The Friday deadline is driven by Servier legal action (infringement action) that will commence the following Monday am".[1004]

4.3.2.3.1 Negotiations with Krka

(690) In the pre-merger period Ivax started negotiating a potential distribution agreement for the UK, and possibly for other Member States, with Krka whose product was perceived by Ivax as superior. In an email[1005] from [employee name and function with Teva]* of 17 June 2005 it is stated that:

"KRKA would like to work with us on this molecule for mutual benefit, initially they would like to supply product as they assure me they would not settle with Servier. I said that our own development was patent free apart from the Polymorph issue which we were also concerned, and so it might be a problem to find a workable solution. I think we must assume KRKA will have a decent pack rather than our solution and that if they get on the market at the same time as us, their sales agent may find it easier to sell their product. That may be an additional reason to talk to them".

(691) Internal Krka documentation confirms the interest of Teva/Ivax in collaborating with Krka.[1006] A supply agreement for perindopril tablets was transmitted to Teva/Ivax by Krka, and a confidentiality agreement was signed on 25 January 2006.[1007]

(692) Teva/Ivax closely followed Krka's market movements in relation to perindopril. An internal Teva communication dated 14 March 2006 explains that Krka had, among others, launched in Hungary and that it might launch in the Netherlands where it was prepared to be challenged.[1008] Also, Krka had received MA for the UK on 11 May 2006.[1009]

(693) Teva's negotiations with Krka intensified in May 2006. The uncertainty about Krka's process, and the interdependence with Teva's discussions with Servier, are confirmed by an internal email exchange of 13 May 2006: *"[…] he believes there is more risk with Krka than with Hetero. […][Employee name of Teva]* had been in discussion with Servier and we are waiting for them to come back to him. It is possible they will increase the money they are offering"*.[1010] It appears from this email exchange that [name of Teva counsel]*, Teva's counsel, had reviewed the Krka process and came to the conclusion that it *"could be found to infringe the '340 patent"*. Another email from the same day stated that the Krka process *"looks as if it "worse" than ours and an injunction would be inevitable and almost certainly granted (cf possibly not with ours)"*.[1011]

1004 ID0346, p. 35.
1005 ID0346, p. 39.
1006 ID0044, p. 20 - 21.
1007 ID2532, p. 1 - 3.
1008 ID0358, p. 115.
1009 ID1307, p. 64.
1010 ID1331, p. 1.
1011 ID0078, p. 181.

(694) However, another internal email from 11 May 2006 notes: *"I have clarified this morning through D Young & Co that the ONLY issue with the Krka product is the alpha polymorph"*.[1012] The conclusion of this email exchange again reflects Teva's preference in obtaining Krka's product: *"Fingers crossed we can get a product from KRKA - it would be so much better than having a pile of cash from Servier"*. [1013]

(695) A communication of 12 May 2006 from [employee name of Teva]* to [employee name and function with Teva]*, providing an update on perindopril, describes Krka as an *"excellent option"*.[1014] An internal email from Teva's Patent Department of 15 May 2006 considers Krka's product as the only alternative for launch in other Member States and also considers extending the deal with Servier to other Member States.[1015] Furthermore, [employee name of Teva]* met Krka on 15 May 2006 to discuss the terms of a potential agreement.

(696) On 16 May 2006, [employee name]* (Krka) sent an email to [employee name of Teva]* referring to the constructive meeting held the previous day. The email announced that a draft contract would be provided by Teva shortly on the following terms:[1016]

"- [0–10] year exclusive purchase obligation from Teva*

- revenue share is [20–80] % of the net selling price. Including the existing product on stock at Teva*

*- […]**

*- […]**

- […]"*

(697) The next day, an email sent from Krka to Teva stated that D Young's expert considered that *"the UK is clear based on the opinion of Mr Thorley (barrister)"*.[1017]

(698) On 18 May 2006, [employee name of Teva]* informed [employee name of Krka]* of Teva's decision not to cooperate on perindopril in the UK due to Teva's risk assessment on Krka's route of synthesis (ROS) for perindopril. In his reply, [employee name of Krka]* remained sceptical about the real justification for Teva's decision.[1018]

(699) Teva explains in its reply to the Commission's RFI of 5 August 2009 that the risk of infringing Servier's patents was considered substantial and possibly worse than the infringement risks associated with its own perindopril as the Krka product might also be argued to infringe additional process patents.[1019] It is, however, evident that the possibility of a deal with Krka was being seriously considered and seen as the "best case scenario" as confirmed in an email from 12 May 2006: *"[…] Best case we get a*

1012 ID0358, p. 790.
1013 ID0358, p. 791.
1014 ID0358, p. 257.
1015 ID0358, p. 537.
1016 ID0346, p. 98.
1017 ID0088, p.40.
1018 ID0088, p. 39 - 42.
1019 ID1346, p. 3.

deal with KRKA on Monday and a product (exclusive?) in June (though not 8mg) and our own 8mg later. Next best we get a pile of money from Servier".[1020]

4.3.2.3.2 Negotiations with Servier up to the letter of intent sent on 19 May 2006

(700) Teva's other possibility of reaching the perindopril market was to conclude a settlement and supply agreement with Servier. As can be derived from the email of 13 May 2006 ("*Fingers crossed we can get a product from KRKA - it would be so much better than having a pile of cash from Servier"),*[1021] Teva's preferred option was to get supply from Krka but there were concerns that Servier would argue infringement. However, it was the Servier option that was ultimately retained.

(701) Since 2002 Ivax maintained regular contact with Servier as to the potential collaboration for the perindopril market in the UK.[1022] In the context of the patent revocation action launched by Ivax in August 2005, a meeting between [employee name and function with Teva]*, and [employee name of Teva]*, on the one hand, and [employee name]* (Servier), on the other, was held in Paris. At that meeting, Ivax suggested three alternatives: "(*a) IVAX launches its own generic and has royalty-free license to use Servier's alpha polymorph patent; (b) Servier supplies IVAX with generic Perindopril; or (c) IVAX co-promotes Coversyl with Servier"*.[1023] According to the minutes submitted by Teva, Servier appeared to prefer options (b) and (c) and was prepared to consider an agreement along those lines. Ivax also considered options (b) and (c) as attractive.[1024]

(702) [Employee name of Teva]* prepared Ivax's sales forecasts[1025] in September 2005 which could be used as the basis for negotiations with Servier on the supply quantities.[1026] Contemporaneous evidence from Servier[1027] confirms that these sales forecasts were received by Servier.

(703) In January 2006, Teva merged with Ivax and decided – as explained earlier – to retain Ivax's development programme for perindopril. From January to April 2006, Servier and Teva discussed whether Teva's (i.e. Ivax's) product infringes Servier's process patents.[1028]

(704) Teva started contemplating the possibility of entering into a supply agreement with Servier given the alleged delay from the originally set target date. [Employee name of Teva]* notes in an email of 10 February 2006: *"[Employee name of Servier]* (Directeur De Zone - Europe Du Nord) has just called me and requested a meeting (incl [employee name of Servier]*) in Paris 2nd March (5pm) to discuss the commercial terms for a UK supply agreement. My previous view on this stands in that it is worthwhile doing as it continues to give us another possible option of*

1020 ID0082, p. 93.
1021 ID0358, p. 791.
1022 See paragraph (666).
1023 ID0358, p. 497 - 498.
1024 ID3065, p. 7.
1025 ID2528, p. 1 - 8.
1026 ID1346, p. 29.
1027 ID0358, p. 723.
1028 ID0358, p. 161.

ensuring the earliest possible formation of a generic market as we continue to experience MHRA delay".[1029]

(705) According to the notes taken by [employee name of Teva]* from the meeting held in Paris on 2 March 2006 which was attended by [employee name of Teva]*, [employee name]* (Teva EU), [employee name]* (Servier) and [employee name of Servier]* ([employee function]*, Servier), Servier came up with a more concrete proposal: *"Their proposal is that if our differences continue [with] the process patents that we should look at settling to save legal costs [;] this settlement should be part cash to reflect the value in our claim and also as product supply from our MA but supplied by a Servier site. They were clear that our distribution of Coversyl is not attractive to Servier"*.[1030]

(706) At the meeting, [employee name of Teva]* reportedly explained that Teva had no experience in settlements so lawyers would need to be instructed to look at the proposed structure. Servier asserted that Apotex infringes Servier's patents and that multiple entrants were only expected in September 2008 when the key process patents were due to expire *("assuming alpha polymorph patent goes of course*"). In reply to an email from [employee name of Teva]* attaching notes of the meeting, [employee name and function with Teva]*, asserted that it was: *"Totally unclear what this is about. Either call me or do not send me e-mails like this"*.[1031]

(707) Handwritten notes by [employee name and function with Teva]*[1032] of another meeting held in Paris on 24 March 2006 attended by [employee name of Teva]* and [employee name of Servier]* provide further information regarding the on-going negotiations.[1033] The notes show that [employee name of Servier]* alluded to the *"need to agree on a value there to compensate commercial gain v[ersus] uncertainties"* and stated that the *"value of settlement depends on strength of our patent case ie. Strength of non infringement"*. According to the same notes [employee name of Servier]* also raised competition issues: *"generic will create issues. Patent settlement and Supply Agreement for an authorised generic"*. In this respect, it is stated *"[Employee name of Servier]* [has] taken comp advice that if 2 linked re. Settlement etc. there could be issues"*.

(708) Furthermore the meeting concerned the question of how to deal with Teva's API supplier. [Employee name of Teva]* indicated that that was going to be an aspect of the settlement value *"[…] lots of significant costs issues. Yes exclusive agreement. API has nowhere else to go. (I say comp issue can't restrict our API supplier if we stop)"*. Another Teva email concerning the meeting of 24 March 2006 indicates that Teva made it clear to Servier that *"any settlement will have to be for significant sums"*.[1034] The said email discussed first the payment to be made by Servier and then the supply of a product to Teva. Teva cannot claim that the Commission has distorted the meaning of this document[1035] - supply as an authorised generic was envisaged,

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1029 ID1332, p. 1. It should be noted that the MA mentioned in this communication relates to Ivax's perindopril product based on the Hetero API.

1030 ID0346, p. 48-49; ID0078, p. 69 - 70.

1031 ID0078, p. 69.

1032 ID0087, p. 110 - 114.

1033 ID3461; a transcription of ID0087, p.110-114 has been provided by Teva.

1034 ID0358, p. 32

1035 See Teva's reply to the Statement of Objections, paragraph 290, ID8495, p.67.

but the payment in this deal was essential (*"any settlement to be for significant sums"*).

(709) Contemporaneous evidence indicates that Teva did not consider that its own product infringed most of Servier's process patents. In an internal Teva email sent on 30 March 2006 by [employee name and function with Teva]* it is stated that: "*As you are aware we have taken several external opinions on infringement and in each case the opinion is that the Hetero process does not infringe the '339 or '341 patents (the main Servier patents)"*.[1036]

(710) On 28 April 2006, an internal Teva email notes that [employee name of Servier]* got back in contact with [employee name of Teva]* to propose a deal which included *"a £ [0–5]* million settlement paid by them* [Servier] *to us* [Teva] *up front followed by supply agreement that would begin in March next year at [20–40]* % margin to us"*.[1037] Servier confirmed the proposal in an email dated 28 April 2006 from [employee name of Servier]* to [employee name of Teva]* in which the first year of supply mentioned is April 2007-March 2008.[1038] Teva's internal emails from that time considered the offer to be insufficient and only a starting point for further negotiations: *"Clearly the offer is not acceptable to us and we have rejected it but at least it is not stupid (which we feared). They have gone away to consider increasing the offer. This does not yet count as good news but it is certainly encouraging"*.[1039]

(711) Reference is made to the above-mentioned conversation between [employee name of Servier]* and [employee name of Teva]* in an internal Teva communication from [employee name of Teva]* to [employee name of Teva]* (29 April 2006) which states: *"Yes he mentioned that the settlement is in relation to our exclusive contract with another party (so we can buy our way out to enable us to take supply from Servier) and that their offer was £ [0–5 million]*. I have confirmed to him that we would require a £ [5–10 million]* (!) compensation settlement and we would need to look at the supply price as well"*.[1040]

(712) Servier's settlement offer was enclosed in a letter sent from Bristows (Servier's lawyers) to Teva's lawyers on 28 April 2006 which set out Servier's request that Teva was to provide Servier with a commitment not to import generic perindopril made using the Hetero process.[1041] On 2 May, [name of counsel]* (Teva's lawyers) replied that Teva was not prepared to offer such a general undertaking, but for the sake of seeking to resolve the dispute Teva agrees not to enter the UK market prior to 1 June 2006.[1042]

(713) An internal Teva presentation from May 2006 mentions the *"discussion and correspondence with Servier"* with respect to the process patents and the Hetero API in 2006. Teva believed that the *"product is non-infringing"*, although *"Servier assert infringement"*. It was indicated in this presentation that the current negotiations *"may result in compensating payment upfront and launch in '07 with Servier product"*.[1043]

1036 ID0078, p. 49.
1037 ID0346, p. 23.
1038 ID0358, p. 486 - 487.
1039 ID0346, p. 23.
1040 ID0358, p. 76.
1041 ID0354, p. 981.
1042 ID0354, p. 982.
1043 ID0350, p. 743.

(714) Teva wondered what a deal with Servier could mean for itself both with respect to other generic companies trying to enter the market and with respect to its own API supplier. In an email[1044] dated 2 May 2006 [employee name of Teva]* explained to [employee name of Teva]* that: *"we would want an undertaking from Servier that they could enforce their patents against other parties intending to launch or launching; we should investigate options for compensation for the delay to us in entering the market as well as to [company name]*"*.

(715) Servier was building up the pressure on Teva to reach a settlement. For example, Teva stated in its reply to the Commission's RFI of 7 July 2010, that during a call between [employee name of Servier]* and [employee name of Teva]* on 7 May 2006 Servier threatened to commence legal proceedings absent Teva's agreement to the proposed settlement terms by close of business on Friday 12 May 2006. Teva declares that its understanding was that *"[…] this would involve the seeking of an interim injunction"*.[1045]

(716) Regarding the commitments to be given by Teva in the envisaged settlement agreement, the internal correspondence[1046] from [employee name of Teva]* to [employee name of Teva]* dated 9 May 2006 notes that Servier wanted a deal on terms that would prevent both Teva and Ivax from marketing any perindopril other than that supplied by Servier.

(717) These terms were considered by Teva as possibly anti-competitive: *"The present settlement negotiations are in relation to the Ivax/[company name]* agreement in purchase and sale of [company name]* product. Settling with Ivax in lieu of that potential litigation is one thing, but if Servier are seeking to extend this to preclude Teva - questionably not a party to the [company name]* agreement - from marketing Krka or any other product this could be anti-competitive"*. [1047]

(718) In an email of 11 May 2006, Teva expressed its fear that it may be served with an injunction if it discontinued its discussions with Servier: *"If we stop discussions with Servier and do not send the letter to Bristows we could have an application for an injunction filed against us early next week"*.[1048]

4.3.2.3.3 Conclusion on Teva's options to enter the perindopril market in the UK

(719) In summary, in May 2006 Teva essentially considered that it had three options for the launch of generic perindopril in the UK.

(720) Teva's first option was to pursue its own development project. However, Teva had not yet received MA and […]*.

(721) Teva's second option was to enter into a supply agreement with Krka, which had obtained MA for its generic version of perindopril (2 and 4 mg, not yet 8 mg). Whilst this was Teva's preferred option ("*Fingers crossed we can get a product from KRKA - it would be so much better than having a pile of cash from Servier"*, emphasis added),[1049] Teva was concerned that Servier would try to argue that Krka's product

1044 ID0085, p. 5 - 6.
1045 ID2519, p. 8.
1046 ID0088, p. 111.
1047 ID0088, p. 111.
1048 ID0085, p. 26.
1049 ID0358, p. 791.

infringed Servier's patents. In addition, Krka had asked Teva to bear the litigation risks.

(722) Teva's third option, and the one that Teva eventually chose, was to enter into an agreement with Servier. The advantage of this option was that Teva would receive "*a pile of cash*" and would become Servier's authorised generic/distributor, although it transpires from internal documents that Teva had concerns about competition law, particularly regarding the fact that Teva had to commit not to enter the market with other non-infringing perindopril.

4.3.2.4 Discussions leading to the conclusion of the Settlement and Exclusive Purchasing Agreement with Servier

(723) On 19 May 2006, Teva sent a letter of intent ("LOI")[1050] to Servier in view of the conclusion of a settlement agreement alongside supply of Teva by Servier.

(724) The LOI foresaw that Servier's envisaged lump sum payment would not be dependent upon the conclusion of the supply agreement. The *"initial payment"* would, instead, be linked to Teva's commitment not to enter the UK market with its own generic (the Hetero/Alembic product).[1051] The document reads: *"In consideration of TEVA's agreement to the terms hereof, including but not limited to its agreement to desist from the date of the Supply Agreement from importing and marketing in the UK generic perindopril manufactured pursuant to the process description provided to Servier's solicitors on 23rd March 2005, Servier shall pay to TEVA a non refundable one off payment of £5m ("initial payment') to be paid in full on signature of the Supply Agreement but in any event not later than 30th June 2006, regardless of whether a Supply Agreement is concluded"* (emphasis added).[1052]

(725) This commitment is further reinforced by another clause of the LOI:[1053] *"In the event of termination or expiry of this LOI or the Supply Agreement or if a Supply Agreement is not reached for the Products then Servier shall remain obligated to pay the Initial Payment"*. This was however refused by Servier who also stated that *"if we can settle the dispute between us, we are prepared to offer some payment towards any costs that you may have incurred in relation to that dispute. We are also prepared to contribute towards any costs that you may incur in preparing to do business with us"*.[1054]

(726) The LOI also foresaw that Teva could source the product from another supplier during any period that Servier would be unable to fulfil its supply obligations.[1055] In its submission of 10 December 2010, Teva confirmed that: *"In the event that Servier is unable to supply the Product at any time during the term then Servier will supply the TEVA forecast as packs of Servier brand UK Coversyl. Alternatively TEVA shall*

1050 ID0082, p. 97 – 102, ID0088, p. 70 - 75.

1051 In its reply to the Statement of Objections, Teva argues that the Statement of Objections appears to consider that Servier's proposed lump-sum could be viewed in isolation from the terms of Servier's supply offer (paragraph 307, ID8495, p.70). What is meant here by the Commission is that Teva's rationale behind the conclusion of the agreement was to ensure it received the lump sum as a consideration for delayed entry. In any event, it is clear that Servier also understood Teva's offer in the same way as the Commission and refused to bind itself to pay a non-refundable lump-sum without an agreement on other terms (see paragraph (725) of this Decision).

1052 ID0088, p. 71.

1053 ID0088, p. 71-72.

1054 Annex 08-16 to Servier's reply to the Statement of Objections, ID9061.

1055 ID0088, p 72 - 73.

be permitted to source the Product from another supplier for the period that Servier is unable to supply".[1056]

(727) On 26 May 2006, Servier sent a draft HoA to Teva based on the LOI which had remained unsigned.[1057] Some clauses of the draft HoA were widely discussed internally by Teva further to which a number of concerns were raised.

(728) In respect of clause 3.2 of the draft HoA[1058] setting out the prohibition on Teva to import or supply perindopril, a communication dated 26 May 2006 from Teva's lawyers highlights that: *"It is worth bearing in mind that clause 3.2 effectively stops us bringing a non-infringing product on the market whilst the patents are in force irrespective of whether the Formal Agreement is still in effect"*.[1059]

(729) Clause 7.3 of the draft HoA provides that *"Servier shall have the option to terminate the Formal Agreement at its absolute discretion by written notice to Teva given at any time prior to delivery by Servier of […] commercial stocks to Teva. Servier shall pay Teva in compensation for early termination […] the sum of [£]. Such sum shall be payable in equal quarterly instalments over the remainder of the original term of the Agreement"*. Concerns were raised in said communication of 26 May 2006 in relation to this clause which would prevent Teva from sourcing perindopril from a third party and which would survive termination pursuant to clause 7.4: *"They could therefore terminate and not supply product to us and we could not be able to source generic perindopril from elsewhere whilst the patent are in force and we are unable to challenge the validity of them. Also, this applied to any generic perindopril - whether it would be infringing the patents or not"*.[1060]

(730) In addition, Teva examined whether the clause regarding the upfront payment would be *"fine from a Legal perspective"*. In an email dated 30 May 2006 [employee name of Teva]* stated: *"as the payment is not linked (in the agreement) to the patent settlement this should be fine from a legal perspective […]"*.[1061]

(731) A comment from [employee name]* (Teva) on the draft HoA also makes it clear that Teva *"clearly believe that the patents are not infringed and invalid"*. In addition, he stated that the following words should not be included in the draft, i.e. that *"both parties recognise that the existence of the Patents generates considerable commercial uncertainty and risk for the parties"*. According to him, there is *"no reason for [Teva] to admit any risk or uncertainty as a result of the existence of the Patents"* and advised to avoid such wording.[1062]

(732) On 30 May 2006, Teva sent the revised draft HoA (draft 2) to Servier.[1063] The payment of compensation by Servier in case of early termination of the agreement

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1056 ID3065, p. 8.

1057 ID0358, p. 715, ID1346, p. 30.

1058 Clause 3.2 states that *"Teva […] shall not at any time while any of the Patents are in force (i) make, […] import, supply […] the Product in the UK either by themselves or in collaboration with any third party; (ii) directly or indirectly seek or assist or procure any third party to revoke, challenge or otherwise invalidate the Patents […]".*

1059 ID0358, p. 801.

1060 ID0358, p. 801.

1061 ID0088, p. 22 - 23.

1062 ID0358, p. 712.

1063 ID0088, p. 28 - 31 (draft 2 seemed to be an almost finalised version of the draft sent by Teva to Servier on 30 May 2006). See also Draft 3 (ID0089, p. 24 and f.) which was sent back from Servier to Teva and where the final version of draft 2 is apparent (knowing that track changes were inserted by Servier).

was put in brackets by Teva (clause 7.3). Clause 7.4 providing for the survival of clause 7.3 in case of termination was deleted. Clause 3.2 was also amended so as to make it possible for Teva to compete with perindopril if the agreement was terminated or expired. Given [employee name of Teva]*'s comment on the "uncertainty and risk stemming from the patents", this sentence was deleted as well.

(733) On 31 May 2006, Servier sent a version with tracked changes (draft 3) to Teva.[1064] Servier reintegrated the wording on the *"considerable commercial uncertainty and risk for the parties"* stemming from the existence of the patents. Servier also deleted clause 7.3 put in brackets by Teva and instead introduced, according to Teva,[1065] under clause 4.4., the following text: *"Servier shall pay Teva liquidated damages of [£] in respect of that month [case of failure to supply] and Teva shall have no other right or remedy (including without limitation any right of termination) in respect of such failure"*. Teva argues in its submission of 10 December 2010 that the liquidated damages provision was imposed on Teva by Servier during the final rounds of the negotiation.[1066]

(734) On the same day, Teva requested further changes (draft 4).[1067] It deleted the word "considerable" under the clause relating to uncertainty and risk generated by the existence of the patents. Teva also rearranged the liquidated damages clause so as to receive "customer compensation" in addition to a "lump sum". Finally, it is clear from the following quote that Teva understood that it would be "tied" to Servier for the duration of the agreement without any possibility of terminating it: *"as long as you are still happy [employee name of Teva]* to be tied exclusively to Servier material for three years with only the 6.3* [clause allowing for termination by Teva if floor price cannot be agreed] *get out, even after all the patents have been revoked or expired […]"*.[1068]

(735) After the exchanges of drafts referred to in the previous paragraphs, the HoA were signed on 2 June 2006. One day before signing the HoA, [employee name and function with Teva]* informed [employee name and function with Teva]* of the deal with Servier and praised [employee name and function with Teva]* for doing *"a great job in obtaining a deal that is good for TEVA. In summary we have an up front payment of £5m this month (we have moved our stock to Czech so there is no write off) plus a supply agreement starting in August or a £0.5m per month compensation for not supplying. Effectively £7.5m this year"*.[1069]

1064 ID0089, p. 24 – 27 (this draft, like other draft HoA exchanged between the parties were not binding, see clause 1.3 of draft 3).

1065 ID3065, p. 8.

1066 In its reply to the Statement of Objections, Teva reiterates that it had no room for manoeuvre left in the negotiation, given the timing constraints and the absence of any alternative viable option to achieve early entry (paragraph 330, ID8495, p. 74). Hence it could not negotiate an alternative to Servier's counterproposal. It is noted first that Teva agreed to this clause on 31 May 2006, 13 days before the final conclusion of the agreement, and therefore at a time when the Heads of Agreement were not binding. Second, Teva has not submitted any document evidencing that it was imposed on it. Third, if the clause was imposed as claimed by Teva, then this means that Teva would have negotiated better terms had it had the time to do so which is an implicit acknowledgment of its knowledge of the consequences that such clause may entail. Moreover, an earlier draft of the agreement (see paragraph (729)) enabled Servier to terminate the agreement earlier and pay a certain sum to Teva until the remainder of the contract during which Teva could not source or supply any generic perindopril.

1067 ID0089, p. 28 - 32.

1068 ID0085, p. 17.

1069 ID0358, p. 637.

(736) From a commercial perspective, [employee name]* (Teva) noted in an internal communication[1070] sent on 1 June 2006 that it was: *"a good deal as it will bring us the amount of profits that we had set ourselves as a goal for Q1 and the rest of the year in the work plan, despite the uncertainty around our own file"*. He concluded that even if Teva were to receive a marketing authorisation in the UK the launch of Teva's own product would not be more profitable than the deal with Servier: "*If the MHRA would decide positively we could revise our position, but it seems as if going it ourselves with our own product is not giving much benefits"*.[1071]

(737) According to Teva, Servier was fully aware that Krka and Teva were discussing a potential supply agreement. In an internal Teva email from [employee name of Teva]* to [employee name of Teva]* on 3 June 2006 it is stated that: *"Servier are aware that we had meetings with Krka re the UK and Europe more broadly (their competitor intelligence is very good). I am not sure if they know which territories were discussed. Servier believe we have two options 1. Our own file (which they believe is weak as it is taking so long at the MHRA) and 2. A deal with Krka. It was the risk of us doing a deal with Krka that accelerated the deal and added more value from Servier's original position with us"*[1072] (emphasis added).

(738) Before turning to the description of the settlement agreement, which was essentially based on the HoA, it is important to underline again two of the key elements of the settlement discussions between Servier and Teva.

(739) First, the upfront payment of GBP 5 million was originally proposed by Teva as an explicit payment for Teva's commitment to discontinue the import and marketing of its own product. In its counterproposal, Servier requested that Teva should also refrain from marketing any perindopril purchased from third parties (see clause 4.1, exclusive purchasing obligation, in draft sent on 26 May 2006). Teva was aware that *"this agreement under 4.1 ties Teva to exclusive supply from Servier for the three year duration of the agreement, but that the process patents expire in Sept 2008 and if the '947 is revoked in Europe then we could be in a position where we are tied to Servier for product even while there is no patent protection in place"*.[1073] The payment was independent of the supply agreement and non-refundable.

(740) Second, Teva was fully aware of the choice given to Servier of not supplying it. In return Servier would, however, be obliged to pay liquidated damages ("*we have an upfront payment of GBP 5m this month […] plus a supply agreement starting in August or a GBP 0.5 m per month compensation for not supplying"*).[1074] In other words, Teva agreed to give Servier – contrary to its initial demands – the option of non-supply but only against financial compensation.

4.3.2.5 The Settlement and Exclusive Purchasing Agreement

(741) The settlement agreement between Servier and Teva was concluded on 13 June 2006 ("Teva Settlement Agreement" or "Teva settlement").[1075]

(742) The preamble of this agreement states that Servier considered that Teva's process as disclosed on 23 March 2006 ("the process description") would infringe Servier's

1070 ID0358, p. 637.
1071 ID0358, p. 637.
1072 ID0346, p. 52.
1073 ID0085, p. 19.
1074 ID0358, p. 637. See also paragraph (785).
1075 ID0343, p. 21 - 39.

patents '339, '340, '341 and '947 and that Teva denied this allegation. Both parties recognised that the existence of said patents generated uncertainty and risk for the parties.[1076]

4.3.2.5.1 Terms of the "settlement of prospective litigation" part of the Teva Settlement Agreement

(743) The key clauses of the settlement part of the agreement can be summarised as follows:

- The relevant "Patents" are the UK 947, the UK 339, 340 and 341 patents.[1077]
- Subject to clause 2.2, Servier agreed to waive any claims against Teva in respect of any infringements in the UK of the *"Patents"* (clause 2.1).
- Teva had to destroy all perindopril that it owned or controlled and which was intended to be sold in the UK: *"Teva shall within 30 days of the Commencement date, destroy all perindopril owned or controlled by Teva and/or its Affiliates packed in packaging for the United Kingdom market or intended for sale in the United Kingdom and provide to Servier a certificate signed by the Chief Operating Officer of Teva confirming that such destruction has taken place"* (clause 2.2).
- Teva agreed, in the UK, not to *"make, have made, keep, import, supply or offer to supply or dispose of generic Perindopril manufactured in accordance with the Process description or infringe the Patents in each case by themselves or in collaboration with any third party"* until the earliest of termination or expiration of this Agreement or the expiration of Servier's '947 and process patents (clause 2.3).
- Teva agreed not to challenge Servier's patents in the UK, although Teva was not prevented from continuing its opposition against any of the patents at the EPO: *"For the duration of the Agreement, Teva shall not, and shall procure that its Affiliates shall not, directly or indirectly, seek or assist or procure any third party, to revoke, challenge or otherwise invalidate the Patents in the United Kingdom"* (clause 2.4).[1078] This clause will subsequently be referred to as a "non-challenge clause".

4.3.2.5.2 Specific terms relating to the exclusive purchasing obligation including the schedule on conditions of purchase

(744) The key clauses relating to the exclusive purchasing obligation can be summarised as follows:

- The "Product" was defined as a *"generic form of perindopril supplied to Teva by Servier or its affiliates in packs of 30 tablets of 2 mg, 4 mg and 8 mg"*.[1079]
- Teva had to purchase all of its requirements for perindopril for supply or disposal in the UK exclusively from Servier: *"For the duration of this*

[1076] ID0104, p. 140.
[1077] See "Definitions" section, ID0104, p. 140 – 141.
[1078] ID0104, p.142-143.
[1079] ID0104, p. 141.

Agreement, Teva shall purchase all Teva and its Affiliates' requirements for Perindopril for supply or disposal in the United Kingdom exclusively from Servier or Servier's Affiliates" (clause 3.1). The duration of the agreement was three years.

- Teva was not allowed to actively sell or promote Servier's perindopril to customers outside the UK (clause 3.3).
- Fixed quantities and delivery dates were agreed (clause 3.4).
- Subject to Servier receiving confirmed orders from Teva for the supply of generic perindopril, Servier agreed to supply Teva with 2 mg and 4 mg perindopril by 1 August 2006 and 8 mg perindopril by 1 January 2007 (clause 3.5).
- Teva had to provide 12 month rolling forecast of its requirements (clause 3.6).
- In case of failure to supply by Servier, Teva had no other right or remedy but the payment of liquidated damages of GBP 500,000 per month: *"Servier shall, subject to Clause 3.9 pay Teva the Liquidated Damages in respect of that month and Teva and its Affiliates shall have no other right or remedy (including any right of termination) in respect of any failure by Servier to supply Product to Teva"* (clause 3.8.3).
- It was agreed that Servier would seek, at its own cost, a marketing authorisation variation for Teva. In the meantime, Servier was to supply the products under its own generic livery and Teva agreed sell perindopril under Servier's generic livery (clause 4.2).
- Clause 5 contained detailed provisions on prices.

(745) It is interesting to compare the Teva settlement with a semi-exclusive distribution agreement concluded between Servier and a generic company relating to perindopril supplied by Servier in the UK. In this agreement, concluded less than a year after the Teva settlement, the generic company undertook to source its supplies of perindopril exclusively from Servier for the duration of the contract, i.e. 5 years. This agreement essentially stipulated that the first distribution date for the generic company be the earliest event to occur among the expiry of the '947 patent, its revocation or market entry of an independent generic. Contrary to the Teva settlement, however, the agreement did not contain an upfront payment to the generic company, and no liquidated damages were agreed in case of failure to supply by Servier.[1080] This may due to the fact that this company had not developed perindopril and was not engaged in a dispute with Servier, i.e. it was not a threat to its market position.

4.3.2.5.3 General clauses common to both parts of the Teva Settlement Agreement

(746) According to clauses 8.1 and 8.2, the entire agreement had a three years' duration and was renewable for an additional two year period.

(747) On signature of the agreement Servier had to pay Teva GBP 5,000,000 as a *"[…] contribution towards the costs incurred by Teva in preparing to enter into this Agreement, including, without limitation the costs of terminating its existing supply arrangements for the United Kingdom"* (Clause 10).

[1080] ID7488.

4.3.2.6 Developments from signature of the Teva settlement until actual product launch by Teva

(748) The Teva settlement foresaw that Servier would supply Teva with both 2 mg and 4 mg perindopril by 1 August 2006 and 8 mg perindopril by 1 January 2007. However, the agreement also gave Servier the option of not supplying Teva and paying Teva liquidated damages instead. Teva agreed that in such instances it would neither source perindopril from third parties nor terminate the agreement. Following the favourable EPO decision of 27 July 2006, Servier enforced its right of non-supply and paid Teva compensation of GBP 500,000/month, which was broadly in line with Teva's expected profits.[1081]

(749) The settlement agreement was revised in February 2007 (see below Amendment N°1) to better reflect how it was implemented by Servier and Teva in practice (i.e. non-supply by Servier). Further to this amendment, Teva was permitted to enter the UK market as of July 2007, when the High Court annulled the '947 patent and Servier began to depend on Teva, as a generic distributor, to defend its market share in the UK. The subsequent sections describe these events in more detail.

4.3.2.6.1 The EPO decision of 27 July 2006 and the Apotex litigation

(750) In its submission of 14 February 2011[1082] Servier explains that: *"*The date of 1 August 2006 was set by mutual agreement between the parties to allow them to take into account the decision of the EPO, expected on 27 July 2006. In the event of an EPO decision against Servier, the latter would have supplied Teva to allow it to start marketing the generic effectively as from 1 August 2006. The SEPA [i.e. the Teva Settlement] also provided for a deadline of 10 working days for Servier to supply Teva, following which the former would be liable to penalties, which left Servier time to try and obtain an injunction from the British courts in case the EPO confirmed the validity of the patent"*.

(751) In the same submission Servier furthermore explains[1083] that *"*Anyone familiar with the pharmaceutical sector naturally knew that, having won the case before the EPO and the UK courts, Servier was obviously not going to ruin its investments by giving rights to third party generic manufacturers through an 'early entry' without compensation and for a long duration"*.

(752) As mentioned earlier, the EPO Opposition Division upheld the '947 patent on 27 July 2006.

(753) In the aftermath of the EPO decision, most generic companies (including Teva on 15 November 2006) filed an appeal against said decision to the EPO Technical Board of Appeal. The '947 patent was eventually revoked by the Technical Board of Appeal on 6 May 2009. A subsequent appeal submitted by Servier was rejected on 19 March 2010 as plainly unfounded.[1084]

1081 This was confirmed by Servier in its reply to the Statement of Objections (paragraph 763)– *"*the monthly payment of liquidated damages for GBP 500 000 corresponded roughly to the profits foreseen by Teva"* (ID10114, p. 286).

1082 ID4518, p.10. Document originally submitted in the context of an investigation relating to the alleged provision of misleading and incorrect information by Servier (Case 39812).

1083 ID4518, p. 12.

1084 See section 4.1.2.4.2.1.

(754) The July 2006 decision of the EPO seems to have encouraged Servier not to supply Teva and to pay liquidated damages instead. There was, however, an additional competitive threat for Servier. Another generic challenger, Apotex, had received MAs for the UK for its generic perindopril in various doses. Hence, Apotex could decide to launch at risk, which would trigger the generic erosion of the market. Servier needed to consider how to fight this challenge and had – disregarding the settlement option - two main possibilities: a) make use of Teva to defend at least part of the market, albeit with the risk of significant price decreases; or b) to fight Apotex in court to protect its market exclusivity.

(755) Apotex took the initiative to launch at risk its generic perindopril in the UK, one day after the decision of the EPO upholding the '947 patent (i.e. on 28 July 2006).[1085] In parallel, on 27 July 2006, Apotex initiated an annulment action against Servier's '947 patent before the UK courts.

(756) Servier decided to fight Apotex's entry through litigation[1086] rather than through the launch of its authorised generics (Teva and another generic company). On 8 August 2006, Servier obtained the interim injunction against Apotex pending trial in the main case.[1087]

(757) In light of these developments, Servier could have made use of the option not to supply Teva, as it did not have to fear immediate generic entry any longer (for the subsequent litigation with Krka reference is made to section 4.3.3.5).

4.3.2.6.2 Actual implementation of the exclusive purchasing obligation (after August 2006)

(758) An internal communication[1088] to Servier's sales force of 30 June 2006 in relation to the upcoming EPO decision explains that: "*If the judgment is in favour of the generic companies then the following day, Friday 28th July, there will be one or more generic copies of Perindopril freely available in the market. A key element of our strategy has been to supply the generic Perindopril market ourselves through our partners [generic company] and Teva, this product will be known as the 'friendly' generic. Our partners will capture the majority of the Perindopril generic market share. Other 'hostile' companies will struggle to establish market share for their copies. This strategy will allow us to continue to maintain a good income from Perindopril"*.

(759) A key element of Servier's strategy to maintain control of the UK perindopril market was the conclusion of distribution agreements with Teva and another generic company. Entry by authorised generics was referred to by Servier in its internal documents as a "*nuclear weapon*". The strategic use of friendly generics was made clear in the following instruction: "*be prepared (registration, production*)", "*but launch only in case of absolute necessity"*.[1089]

(760) In its reply to the Commission's RFI of 5 August 2009, Teva explained that it *"was in regular contact with Servier at operational level to agree product codes and delivery*

1085 ID1591, p. 23.

1086 On 1 August 2006, Servier launched infringement proceedings against Apotex before the High Court, claiming infringement of the '947 patent. Servier also applied for interim injunction. In turn Apotex launched a cross-application for summary judgment which failed since – in the opinion of the court - Servier demonstrated a sufficient prospect of defending the '947 patent in trial.

1087 ID1591, p. 23.

1088 ID0033, p. 53.

1089 ID0032, p. 179.

logistics" prior to the EPO decision upholding the '947 patent.[1090] However, following the EPO decision, Servier ceased cooperation at operational level and did not supply the ordered products. Teva attributes the lack of supply by Servier to a "*regained confidence in its patent rights given that on 27 July 2006 the EPO rejected the opposition that Teva and other generic firms had filed against Servier's patents"*.[1091]

(761) An internal Teva communication[1092] of 31 July 2006 stated that Teva UK expected a stock of generic perindopril from Servier to arrive on 28 July 2006 but that these batches were never delivered. The communication suggests that Teva was "*not hopeful of any stock arriving in the future*" (emphasis added). In addition, the communication reports that *"For the time being Teva UK will not be launching Perindopril"* and that "*Teva has no stock of Perindopril and we do not anticipate marketing this product in the near future*". In relation to other companies it was reported that "*Rumours indicate that Apotex and Krka may launch this week, but they are likely to be in infringement of Servier's patent"*.

(762) A witness statement[1093] during the Apotex trial by [employee name of Servier]* provides further details on the reasons behind the lack of supply to Teva. [Employee name of Servier]* explains: *"On receiving information about Apotex's launch of generic perindopril, Servier had to decide whether to instruct UK lawyers to seek injunctive relief against Apotex or whether to proceed with the launch of our generic product via Teva and [generic company]. If Servier committed itself to launching its generic product, the entire perindopril market would become generic and it would therefore be extremely difficult, if not impossible, for Servier to regain its pre-generic upmarket position. The resulting downward price spiral and lost market share would have been very damaging to Servier. Therefore, in conjunction with our UK lawyers and following the decision of the EPO to uphold the patent, it was decided to make an application to obtain injunctive relief against Apotex before launching with our competing generic products"*.

(763) [Employee name of Servier]* goes on to remark that *"On 8 August 2006 [i.e. the date on which Servier obtained the interim injunction against Apotex], I informed [generic company] and my colleague […] informed Teva that we would not supply them with Servier product until further notice. Accordingly, Servier did not fulfil any of their orders. Servier's Coversyl product therefore remained the only product on the UK market until 9 July 2007"*. In response to a question posed by the court on what would have happened if Servier had not obtained the interim injunction against Apotex, [employee name of Servier]* replied that Servier would have supplied Teva and [generic company] immediately.

(764) It is interesting to compare this witness statement with Servier's reply to the Commission's RFI of 6 August 2009. In its reply to the Commission's request, Servier attributed *ex post* the lack of supply to Teva to regulatory and logistic difficulties*: "***As part of the implementation of the supply agreement, Teva sent forecasts of orders for boxes of perindopril for deliveries starting from 1 August 2006. Owing to logistical and regulatory difficulties (including the need to validate the packaging by the national regulatory authorities), Servier could not*

1090 ID1346, p. 30.
1091 ID1346, p. 4-5.
1092 ID0082, p. 105.
1093 ID1172, p. 10 - 11.

deliver to Teva the boxes of perindopril 2 and 4 mg as from 1 August 2006 and perindopril 8 mg as from 1 January 2007 and it had to pay the contractual penalties provided for"[1094] (emphasis added).

(765) In its reply[1095] to the Commission's RFI of 9 April 2010, Servier further specifies the impossibility of [company name]* (a Servier subsidiary manufacturing generics) to produce the appropriate number of blisters for Teva in accordance with the MA. Therefore, a variation of the MA was necessary and was obtained on 1 November 2006 before the MHRA.

(766) These statements are however difficult to reconcile with other parts of the witness statement of [employee name of Servier]* referred to above. [Employee name of Servier]* described the stock situation of perindopril as follows: "*I recall that there were some initial concerns that we would not have enough stock to be able to fulfil existing orders to both Teva and [generic company] by the end of July 2006. In particular, there was a concern that we may not be able to supply enough 4mg generic perindopril to satisfy the orders of both Teva and [generic company]. However, by the time that the EPO gave its decision at the end of July, I remember that this was no longer an issue and Servier had sufficient stock to satisfy all existing orders placed by Teva and [generic company] and more stock was being produced all the time"*[1096] (emphasis added).

(767) In the same witness statement, [employee name of Servier]* went on to explain that at the time: *"Whilst title to the generic perindopril and Coversyl product held by Healthcare Logistics*[1097] *was still retained by Servier and therefore subject to Servier's order, this ensured that all paperwork was completed and the product could be shipped to Teva and [generic company] immediately by a simple phone call without any delay"*.[1098]

(768) On the basis of the available documents it can be concluded that although Servier had products available for supply to Teva, from 1 August 2006, it preferred instead to make use of the possibility of non-supply under the Teva Settlement Agreement, and pay liquidated damages of GBP 500,000/month.

(769) In the subsequent months Servier paid liquidated damages of GBP 5.5 million to Teva (GBP 2.5 million for 2006 and GBP 3 million in 2007 up to the month of July 2007, when supply started).

4.3.2.6.3 Amendment No 1 to the Teva settlement

(770) On 23 February 2007, the Teva settlement was amended,[1099] confirming the actual implementation by Teva and Servier of the Exclusive Purchasing Obligation.

(771) The amendment fixed new conditions under which Teva might eventually enter the market. Article II[1100] of Amendment No 1 introduces a "first distribution date" before which Teva *"shall have no right to market, sell or distribute the Products"* (Article

1094 ID1151, p. 31.
1095 ID2365, p. 34.
1096 ID1172, p. 8.
1097 Healthcare Logistics Limited is Servier's distributor for perindopril in the UK. It supplies wholesalers and other companies within 24 hours maximum.
1098 ID1172, p. 9.
1099 ID0086, p. 7 - 9.
1100 ID0086, p. 8 - 9.

I). This first distribution date which did not exist in the original agreement is defined as follows:

"'First Distribution Date' means the earliest of the following three dates to occur:

- date as is notified by Servier to Teva in writing as the First Distribution Date

- the date on which the patent EP 296947 *covering the Product ceases to be in force, whether as a result of revocation or expiry;*

- the first date on which all of the following events have occurred:

a final determination has been made of the proceedings, including any appeal, brought by Servier and Servier Laboratories Limited against Apotex Inc […] Canada, Apotex Pharmachem Inc […] Canada, Apotex Europe Limited […] and Apotex UK Limited […] in the UK High Court (Case No HC06C03050 (the" Judgment");

the Judgment lifts any orders previously imposed by the UK Courts injuncting the disposal of generic perindopril by Apotex in the UK;

and following the Judgment, Apotex has commenced distribution of generic perindopril in the UK".

(772) It should be stressed - as noted by Servier and Teva (see below) - that Amendment No 1 did not allow for an early – let alone immediate – entry for Teva. Servier and Teva agreed to tie Teva's entry date to the resolution of the UK proceedings between Apotex and Servier (or the expiry/revocation of the '947 patent). Servier submits:[1101] *"*The amendment to the contract with Teva specified the starting date for the marketing of perindopril by Teva, taking into account the pending litigations and in particular the injunction against Apotex by the High Court (Servier could not implement distribution contracts for generics of perindopril without losing the benefit of the injunction)".*

(773) However, neither at the time of the settlement agreement, nor at the time of the amendment could Teva have known whether or not Servier would try to settle its dispute with Apotex – as Servier had done with all other generic challengers. It seems as though Teva was hoping for such settlement between Servier and Apotex, as can be derived from a communication from [employee name of Teva]* to [employee name of Teva]* of 27 February 2007, i.e. four days after the conclusion of Amendment No 1: *"this would be a good result for us (…)? If the settlement keeps other generics off the market in the UK then we keep our present arrangement with Servier. (…) I have asked [employee name of Teva]* to keep an eye on the court lists to see if this case gets withdrawn".*[1102] Obviously the same result would be obtained if Servier were to win its court case against Apotex, which was also seen favourably by Teva in the same communication: *"at the same time we do so without getting an adverse decision in the UK (which is the only other way we could keep the present arrangement)".*

(774) In its reply to the Commission's RFI of 5 August 2009, however, Teva provides a slightly different interpretation of Amendment No 1.[1103] Teva underlined the importance of the supply on a consignment basis, which would allow earlier entry. In

1101 ID2365, p. 34.
1102 ID0350, p. 1068.
1103 ID1346, p. 5-6.

its submission of December 2010[1104] Teva also stressed: *"Teva thus negotiated the Amendment as the only means of entering the market. Although Servier would agree to let Teva on no earlier than others were entering the market, Teva did negotiate a simultaneous entry. As a result, the terms of the amendment allowed Teva to supply Servier's products at the earliest possible date in view of the UK proceedings".*

(775) On 30 May 2007 – when the decision in the Apotex litigation was approaching – [employee name and function with Teva]* signed a declaration whereby Teva undertook not to supply or offer to supply any perindopril until the lifting of any injunctions ordered in the proceedings against Apotex.[1105]

4.3.2.6.4 Actual market entry by Teva

(776) As a result of the High Court's ruling of 6 July 2007 declaring the '947 patent invalid and lifting the interim injunction, Apotex could enter the perindopril market immediately.

(777) Servier reacted by giving - as foreseen in the amended Teva settlement - its consent to Teva to start marketing Servier's perindopril products, that Teva was keeping on consignment.

(778) Teva started selling on 12 July 2007. These distribution arrangements lasted until 13 June 2009.[1106]

(779) On 1 August 2008, a second amendment (Amendment No 2) to the Teva settlement was concluded.[1107] Essentially, the floor price had to be amended to take into account the new market situation in the light of generic entry and price decrease.

4.3.2.7 Parties' considerations for entering into the Teva Settlement Agreement

(780) For the purpose of examining the parties' considerations for entering into the Teva Settlement Agreement, it is worthwhile presenting first the contemporaneous evidence, or evidence *in tempore non suspectu*, before turning to the *ex post* explanations of each party following the launch of the investigation.

4.3.2.7.1 Teva's considerations prior to the launch of the investigation

(781) Teva's considerations for entering into the settlement are well reflected in the contemporaneous documents drafted or exchanged during the period of negotiations (see section 4.3.2.4.). Regarding documents *in tempore non suspectu* reference can be made to a number of documents, which relate primarily to the assessment of the settlement from a financial perspective shortly after the conclusion of the settlement.

(782) A number of contemporaneous documents show that Teva celebrated the conclusion of the settlement with Servier as a success and financially very attractive (see also correspondence with CEO of Teva Europe[1108]). For example, in an internal document called "Highlights Memo" of 16 January 2007 the positive effects of the settlement agreement on Teva's financial result for 2006 are stressed. The memo reads:

1104 ID3065, p. 12.
1105 ID0371, p. 145.
1106 ID1346, p. 5-6.
1107 ID0104, p. 425 - 426.
1108 See paragraphs (736) and (737).

"A significant feature of the year has been the other income received of £ 6.5m re the Perindopril supply agreement with Servier. Without this income the legal loss would have been £ [5–10 million] (2005 loss of £ [0–5 million]*).*

During Qtr 4 £ [0–5 million] (Qtr3 £[0–5 million]* as first supply scheduled for August) damages have been claimed against non-supply of perindopril from Servier. During Qt 2 Teva UK signed a supply agreement for minimum quantities of the product. Since the signing of the agreement, no other party has obtained a licence so it is in Servier's best interests not to supply us and pay damages instead.*

We place orders with them, they default and we raise a default invoice which is due for payment 30 days later. The £ 1.5m has actually been received and reported as other income (PC 9002).

At the time of signing the contract Teva UK received expenses of £ 5.0m, which after writing off stock available for sale in the UK (£ [0–5 million] m), resulted in the net of £ [0–5 million]* m being reported as other income in Qtr 2".* [1109]

(783) The last paragraph of this quote indicates a difference of GBP [0–5]* million between the upfront payment of GBP 5 million and the amount relating to the writing off stocks of about GBP [0–5]* million. Concretely as to the value of perindopril stocks, an earlier email[1110] from [employee name of Teva]* (14 June 2006) had confirmed that the *"Perindopril that is 'at risk' has a value of £ [0–2 million]*. This is all product packed in UK packaging. Some of this is held in [company name]* (£ [0–1 million]*) and some is held by [company name]*, our contract manufacturer in [non-EEA jurisdiction]* (£ [0–1 million]*)".* As indicated above, the Teva settlement foresaw the destruction of Teva's perindopril earmarked for sale in the UK. Alembic confirmed in an email of 28 July 2006 that the perindopril goods had been destroyed as of 26 July 2006.[1111]

(784) In another Teva internal presentation[1112] the perceived value of settling with Servier is described as follows: *"The profits resulting from settlements are high. This is because they concern big products that we started selling a while ago + Teva UK limited is the exclusive distributor in the United Kingdom for [another product] + big lump sum for Perindopril*" (emphasis added).

(785) A more detailed presentation on the financial aspects of the deal was prepared for a Teva internal meeting in July 2006.[1113] The presentation, entitled 'Perindopril Analysis and Background', reads as follows: "*If Servier chooses not to supply, they will pay Teva 500K Pounds per month".*[1114] Moreover, it states that: *"1. Servier's payment of [5–10]* million Euros represents [20–30]* % of the annual estimated sales of Teva UK at Servier prices (Assuming UK market share of [20–30]* %) 2. The [5–10]* million pounds ([5–10]* million Euros) per year that Servier will pay us assuming that we are not supplied finished product also represents [20–30]* % of our estimated sales at Servier prices. 3. Extending the logic of the Servier UK proposal indicates that we should ask for [5–10]* million Euros of upfront, a supply*

1109 ID0080, p. 23.
1110 ID0358, p. 736.
1111 ID0087, p. 69 - 70. Also the amount of finished packs of perindopril held by Alembic was 95,230 packs of perindopril 4 mg and 48,880 packs of perindopril 8 mg (ID2521, p. 1).
1112 ID2539, p. 4 (undated document).
1113 ID0350, p. 645-655.
1114 ID0350, p. 649.

agreement and additional payments of [5–10] million per year should we not be supplied by Servier*" (emphasis added).[1115]

(786) On the other hand, the distribution agreement was described internally, at least once, as *"similar to many of Teva's existing exclusive supply agreements, and should enable Teva to compete with generic competition as it emerges"* (see memorandum[1116] dated 25 January 2007).

(787) Two years after the settlement, an email prepared by [employee name of Teva]* (on 18 June 2008 in the context of the Commission's sector inquiry and containing an assessment of the settlement agreement) still praises the upfront payment of GBP 5 million: *"The £5m payment which was intended to cover our write off of stock and API was however a bit of a coup in the end as it did not in the end cost us that amount to write off our manufactured stock. (Not that we could have sold it as we had no MA approval!)"* (emphasis added).[1117]

(788) Other internal correspondence sheds light on the true purpose of the payments received from Servier, as understood by Teva. In an email dated 18 July 2006, [employee name and function with Teva]* described the upfront payment as: *"Revenue recognition: My understanding is that the economic effect of the agreement is that Teva is being paid an amount of GBP 5m in order to both cease its plans to launch a generic product in the UK and enter into a supply agreement with Servier"* (emphasis added). The email further states that: *"the GBP 5m should be viewed primarily as an incentive to enter into the contract"*.[1118] In other words, the upfront payment was made for the purpose of keeping Teva out of the market rather than for the reasons added to the settlement text.

(789) Similarly, an internal memorandum[1119] of 25 January 2007 states that: *"[…] part of the £5m compensation payment received may relate to a non-compete aspect of the contract, since the contractual terms of the supply agreement prevent Teva from launching its own generic product or seeking alternative suppliers in the UK"*. However, following discussions with management it was noted in the same memorandum that a different interpretation of the agreement should be adopted: *"Management's overall assessment of the contract is that the above terms will allow Teva to compete with its competitors (by selling branded Perindopril) when generic competition enters the market*" (emphasis added).

(790) As will be seen in the following section, Teva claims *ex post* that it was misled by Servier's claims that its supplies of perindopril would start shortly before 1 August 2006 allowing Teva to enter the market on that date. However, as can be seen from an email of 22 June 2006 to Teva's management, Teva was well aware that it had given Servier the option of not supplying Teva. The email reads: *"As a result of Servier deal - £5.0 to be paid in June. For the rest of the year Servier will supply Perindopril in order to achieve sales £ [5–10 million]* GM £ [0–5 million]* or will pay compensation for non-supply of £ [0–5 million]**" (emphasis added).[1120]

1115 ID0350, p. 655.
1116 ID0080, p. 39.
1117 ID0087, p. 128 - 129.
1118 ID0358, p. 133.
1119 ID0080, p. 39.
1120 ID0078, p. 164.

(791) An internal Teva correspondence also admits that *"we [Teva] are in the hands of Servier here due to our supply agreement"*.[1121]

(792) In the previously quoted email at paragraph (787), which also explains other factors Teva considered when deciding whether to enter into the settlement agreement with Servier (i.e. lack of marketing authorisation for its own product), the issue of compensation through liquidated damages was discussed. The email reads: "*So we reached this settlement agreement to ensure that we could enter the generic market with a 'good' product once Servier commenced to supply us (some elements of the agreement were not ideal from a commercial perspective ie Servier insisted on the option of a compensatory (Liquidated Damages') payment if they were unable to supply us with actual product)"* (emphasis added).[1122]

4.3.2.7.2 Teva's considerations after the launch of the investigation

(793) In its reply to the Commission's RFI of 5 August 2009, Teva described *ex post* its considerations for concluding the agreement as follows:[1123]

"The reasons for concluding the settlement agreement have to be seen in the context of Teva's key considerations for market entry of any given product. These considerations are as follows:

- achieve quick entry given the considerable first mover advantage;

*- […]**

- […]".*

(794) In the same submissions, Teva goes on to explain that:[1124]

"Teva did not view the arrangement as a non-compete arrangement. Rather, it believed that Teva would receive generic perindopril with which it would achieve early market entry (and thus compete promptly and directly with Servier's branded product) in the UK. It allowed Teva a period of 3 years within which it would be able to develop its own product and obtain a marketing authorisation for its product. The settlement sum of £5m in clause 10.1 of the settlement agreement should therefore not be looked at in isolation. Most of the value of the agreement was in the product supply which, as the documents on the Commission's file demonstrate, was Teva's key priority. The lump sum was not calculated in any elaborate way but reflects the outcome of commercial negotiations based on the parties' perceived bargaining powers. In arriving at the £5m settlement sum (and more broadly at the question of whether or not to settle) Teva evaluated a number of considerations. These included the direct costs (such as product destruction, the value of products destroyed, actual and projected legal fees at first instance and possible appeals etc.) but also other less clearly quantifiable costs. […] For Teva (and probably for most generic companies), reaching a settlement in patent litigation that allows immediate entry and removes the vagaries, cost and effort of litigation is in most cases preferable to pursuing a full court case".

(795) In its Position Paper of December 2010[1125] and the complementary document of March 2011,[1126] Teva argued, in particular, that it was Servier's unilateral decision

1121 ID0358, p. 683, further disclosed in ID10052.
1122 ID0087, p. 128 - 129.
1123 ID1346, p. 32 - 34.
1124 ID1346, p. 36 – 37.

not to supply Teva with perindopril in summer 2006 and that Teva could ultimately enter the market at the same time as all other generic companies.

(796) Teva also argues that it could not have entered into the agreement without the individual payment provisions.[1127] Furthermore, Teva submits[1128] that the lump sum was negotiated in order to compensate the costs incurred by Teva for entering into the agreement, including the litigation costs and the costs of terminating the Hetero/Alembic arrangements and destroying the existing stock of the products. It was also described as a *"premium"* to *"ensure the commercial attractiveness of Servier offer versus, in particular, Krka's supply offer"*.

(797) Prior to entering into the Teva Settlement Agreement, Teva reported UK litigation costs of less than EUR 100,000. Teva's costs related to the EPO opposition were in the range EUR [50-150,000][1129.]

(798) An internal document from July 2006 suggests that GBP [0–5,000]* was spent in the destruction of the stock worth GBP [0–2 million]*. This document is the only contemporaneous document concerning the destruction costs that the Commission has been provided with by Teva.[1130]

(799) Teva reports that between 2003 and 2009, direct R&D and regulatory expenses amounted to EUR [0.5 – 1.5] million. Teva also estimates that research and development and legal costs were around EUR [1.5 - 2.5] million for the period 2004 - 2008 at the time of seeking internal Ivax product approval.[1131]

(800) Teva also underlined in its submissions that the liquidated damages provision was introduced by Servier in the last rounds of negotiations and *"Considering Servier's bargaining power and the timing constraints confronting Teva, Teva could not negotiate an alternative to Servier's counterproposal"*.[1132] Nonetheless, Teva accepted this clause and entered into the agreement knowing that there was a risk that Servier would not supply it.

4.3.2.7.3 Servier's considerations before the launch of the investigation

(801) Turning to Servier, an internal undated document entitled "United Kingdom Operational Audit"[1133] casts some light on the contemporaneous evaluation by Servier and, in particular, on the exclusive purchasing agreement with Teva and the reasons behind the arrangements: *"To protect market share against generics, an exclusive purchasing agreement for Perindopril was concluded with TEVA UK in 2006 for three years. A one-off payment of 5 million GBP was fixed for the implementation of contract. Consequently to a first favourable injunction of the court, generics have been fortunately momentarily removed from the market. As per contract, the Company is now required to pay damages of 500'000 GBP for each month Servier does not supply TEVA with Perindopril. The cost generated by the*

1125 ID3065, p. 1 - 13.
1126 ID3509, p. 1 - 7.
1127 ID3509, p. 2.
1128 ID3509, p. 5.
1129 ID1346, p. 41.
1130 ID0358, p. 131.
1131 ID1346, p. 9.
1132 ID3065, p. 8.
1133 Servier has not been able to trace back the date of this document collected at Servier's premises during the inspection but estimates that it could date from 2007- ID3842, p. 16.

agreement in 2005-2006 amounts therefore to 6 million GBP (5 million + 2 months damages fees)".[1134]

(802) Another contemporaneous document drafted around the end of the financial year (30 September 2007) refers to the supply agreement as an "intangible asset" and gives details on the contract and amounts paid to Teva: *"SLL* [Servier Laboratories Ltd.] *have an agreement in place with the main distribution partner, TEVA, under which TEVA agree to source all Perindopril exclusively from SLL. The contract was set up in the prior year on Servier making an upfront payment of £5m. Additionally, Servier had to make penalty payments of £500k per month for every month in which no Perindopril was supplied. Due to the extension of the court injunction to prevent the introduction of the generic drug until July 2007, the total of such penalty payments in the current financial year was £4.5m (compared with just £1m last year, as the contract was only in place for 2 months)".*[1135]

(803) In addition, shortly after the settlement, an internal presentation of 19 June 2006 by [employee name of Servier]*, makes reference to the *"partnership with Teva",*[1136] i.e. the Teva Settlement Agreement. This presentation entitled *"Coversyl: defense against generics"* gave an overview of measures to combat generic entry and referred not only to the Teva Settlement Agreement, but also to the patent settlements concluded with Niche and Matrix. Therefore, this document suggests a clear connection between Servier's anti-generic strategy and the reverse payment patent settlements.

(804) On a more general note, Servier celebrated its defensive actions against generic entry in the EU and most prominently in the UK. Following the Apotex judgment revoking the '947 patent Servier concluded: "**[…] 4 years gained = great success*" (emphasis added).[1137] Thus, despite "losing" the '947 patent Servier still considered the extension of exclusivity by virtue of its activities as a "**great success*".

4.3.2.7.4 Servier's considerations after the launch of the investigation

(805) In addition to the comments concerning Servier's reasons for not supplying Teva in 2006,[1138] Servier provides the following general explanations in relation to the Teva settlement:[1139]

*"*The agreement with Teva UK Limited of 13 June 2006 was aimed at putting an end to a dispute and was implemented mutually: from the date of its signing, none of the parties started a litigation in connection with the patents (whether before or after the conclusion of the first amendment).*

Originally, the litigation was the result of a contentious initiative by the company IVAX.

The proceedings were stayed pending the decision of the European Patent Office.

After the acquisition of IVAX by Teva, the latter expressed its interest in concluding a supply and distribution agreement, allowing:

1134 ID0115, p. 275.
1135 ID0030, p. 169.
1136 ID0105, p. 180.
1137 ID0116, p. 51.
1138 See paragraphs (764)-(765).
1139 ID1151, p. 31.

(i) the termination of the litigation without awaiting the outcome of the proceedings before the EPO, for a payment of £5 million to Teva;

(ii) Teva to get its supplies of perindopril notwithstanding the intellectual and industrial property rights of Servier which were then still valid;

(iii) Servier to access Teva's distribution network".

(806) It should be emphasized that according to the statement above in paragraph (i) Servier recognises that the payment was instrumental to settling the dispute in the UK. In the same submissions Servier asserts however that *"*The agreements concluded thus accelerated rather than delayed the entry of Teva's generic on the market"*[1140].

(807) In addition, Servier identified the cost of UK litigation proceedings with Ivax/Teva, which were stayed at an early stage, and then settled following the agreement between Teva and Servier, at EUR 159,900.[1141]

4.3.2.8 Other developments after the conclusion of the Teva settlement

(808) This section summarises other developments in the UK and other European markets after Teva's market entry in the UK in July 2007. In particular, it describes the damages claims of Apotex, which sheds light on how the High Court viewed the Teva Settlement. The section also reports Teva's activities in other Member States.

4.3.2.8.1 The damages claims of Apotex

(809) Following the favourable judgment on the '947 patent, Apotex sought damages from Servier for being prevented from distributing generic perindopril as of August 2006 when the injunction was granted. During summer 2008 Servier sought to settle with Apotex *"[...]*"* but no agreement was reached.[1142] On 13 October 2008, the High Court awarded Apotex damages of GBP 17.5 million based upon a figure of GBP 74 million as the estimated sales made by Servier during the period when the injunction was in force.[1143] A judgment dated 29 March 2011 however ordered Apotex to repay the sum of GBP 17.5 million to Servier based on the application of the *ex turpi causa* rule.[1144]

(810) The judgment of 13 October 2008 referred to the Teva settlement in the following terms. The Court stated:

"In June 2006 (at a time when the judgement of the EPO was awaited and Apotex had yet to obtain its marketing authorisations) Servier entered into an agreement with AG2[1145] *for the supply of 2 mg and 4 mg dosages of perindopril (and eventual supplies of the 8 mg formulation) of in excess of 200,000 units per month. The arrangement was thus directed at Servier's participation in the generic market in the*

1140 ID1151, p. 31.

1141 ID1144.

1142 ID1591, p. 17 - 18.

1143 Two scenarios were used by the Judge to calculate Apotex´s damages; Servier competing only with Apotex and market entry of Teva and another generic company considered as authorised generics. The Judge calculated the total damages of GBP 17.5 million by adding 67% of Apotex's estimated loss in a duopoly scenario (67% of GBP 22.5 million) to 33% of Apotex' estimated loss in a market competing with authorised generics (33% of GBP 7.9 million).

1144 EWHC 730 (Pat) (29 March 2011). Available at: http://www.bailii.org/ew/cases/EWHC/Patents/2011/730.html

1145 "AG2" stands for Authorised Generic 2, i.e. Teva.

event that the EPO invalidated the 947 patent. Under the terms of the agreement AG2 agreed not to challenge Servier's patent in the United Kingdom and not to import or sell generic perindopril. In return Servier agreed to provide stated quantities of perindopril by 1st August 2006 at a guaranteed margin (subject to a floor price): but crucially Servier had the option to pay liquidated damages instead of actually effecting supply, and if it exercised that option then AG2 had "no other right or remedy (including any right of termination) in respect of a failure by Servier to supply…". Because the agreement bound AG2 not to sell perindopril manufactured other than by Servier, but did not bind Servier to supply perindopril to AG2, it gave Servier the right to exclude AG2 from the market. Servier obtained this right by agreeing to pay AG2 £5 million, and further to pay £500,000 per month for each month of non-supply (irrespective of the amount of perindopril that AG2 would have ordered in that month). Servier was initially preparing to supply AG2 in anticipation of the revocation of patent 947 on the 27th of July 2006. But then in August 2006 Servier exercised the option not to supply, and continued to do so throughout the period for which the injunction against Apotex was in force. Servier thus paid AG2 approximately £10 million to keep it out of the market" (emphasis added).

4.3.2.8.2 Teva's perindopril activities after the Teva Settlement Agreement

(811) Teva had plans to launch generic perindopril in other Member States, besides the UK, and was seeking to do so with its own product or through a supply agreement with Krka or Servier.

4.3.2.8.2.1 Cooperation with Servier

(812) Regarding cooperation with Servier a meeting took place on 5 July 2006 to discuss a European settlement agreement for perindopril.

(813) In an internal communication[1146] from [employee name of Servier]* copied to [employee name of Servier]* the main elements of the possible cooperation were summarised and related to a: *"European agreement (for up to 17 countries but list not yet validated)*

settlement and exclusive purchase perindopril 2mg, 4 mg and 8 mg

Teva will not challenge our patents in any of the countries

Teva will cease any action they have to invalidate our patents in Europe (in particular EPO case)

Teva will not make, supply... any perindopril infringing our patents in any of the countries

generic perindopril to be provided to Teva in each country at a time decided by Servier

supply either in Servier livery or in Teva livery (which might require transfer of MA in some countries)

supply price to be 60% of Net Selling Price

floor price to be 2 Euros per pack of 30 tablets

[1146] ID0115, p. 260.

contribution to costs incurred by Teva = x millions Euros payable at signature (50%) and in January 07 (50%)

3 years agreement".

(814) However, according to Teva's submissions in response to the Commission's RFI of 7 July 2010, the above-mentioned discussions did not progress beyond that single meeting of 5 July 2006. Teva explains that at the meeting it became clear that Servier was not interested in such a supply deal. Teva therefore concentrated on its other options.[1147]

4.3.2.8.2.2 Cooperation with Krka

(815) Following the Teva Settlement Agreement, Teva continued negotiating a potential supply deal with Krka for Member States other than the UK.

(816) Contemporaneous evidence shows that before the EPO decision in July 2006 upholding the '947 patent, Teva was considering a product launch in France, the Netherlands and Germany on the basis of the Krka product. The main obstacle was the '947 patent which, if maintained by the EPO, would have reportedly triggered injunctions from Servier in all territories. However, if the patent was revoked by the EPO the focus would have then been on the potential infringement of Servier's process patents. According to an internal email of 19 May 2006,[1148] Teva received advice from its external patent attorneys stating that there are good arguments about the non-infringing nature of Krka's product with respect to the process patents in the Netherlands, Germany and France.

(817) On 29 November 2006, [employee name]* (Teva) informed his colleagues by email that, as a result of the patent settlement between Servier and Krka, the supply of generic perindopril from Krka was no longer possible.[1149]

(818) The cooperation between Teva and Krka was reactivated following the annulment of the '947 patent. In the UK, Teva entered into a supply agreement with Krka on 28 October 2009 following the expiry of the supply agreement between Teva and Servier in June 2009.[1150]

4.3.2.8.2.3 Cooperation with Hetero/Alembic

(819) Regarding its own product development (Hetero/Alembic process), after receiving regulatory approval in the UK in December 2006, Teva applied for MA through the MRP in Germany, the Netherlands, Italy, Hungary, Spain, Austria, Belgium, Denmark, Greece, Ireland, Luxembourg, Portugal, Bulgaria, Estonia, Lithuania, Latvia, Romania, Slovenia and Slovakia.[1151] Much earlier, Teva had applied for marketing authorisation through the national routes in Poland (11 February 2005) and the Czech Republic (31 January 2005).

(820) The Member States where Teva has been (and is possibly still) selling generic perindopril are the following (referred to in chronological order on the basis of the

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1147 ID2519, p. 6.

1148 ID0088, p. 50.

1149 ID0346, p. 55: *"Servier have settled alpha polymorph case with Krka - this means no alpha polymorph Krka Perindopril in the UK (Krka are developing another stable polymorph but have some issues with conversion to alpha during shelf life thus are months and months away, they will stay close to us on this in any case)"*.

1150 ID2530.

1151 ID1316, p. 2 - 3.

first date for commercialisation): the Netherlands, Ireland, Spain, Italy, France and Romania.[1152] In a number of Member States, Teva does not currently sell generic perindopril but has undertaken preparations for product launch. The decision not to market perindopril is linked to the fact that in 2008 Servier launched a new version of perindopril based on a different salt, the arginine salt, in a number of Member States.[1153]

4.3.3 Krka

(821) Krka, a generic company established in Slovenia, initiated own development of perindopril (both API and formulation) as of 2003. In the period 2005 - 2006, it received marketing authorisations for 2 mg and 4 mg tablets of perindopril erbumine for a number of markets across the EU. Krka actually launched perindopril in several Central and Eastern European ("CEE") Member States, including Poland, in late 2005 - 2006 and was preparing to launch in other Member States, including France, the UK and Netherlands either alone or in cooperation with other companies.

(822) Krka, whose perindopril product contained the alpha polymorph protected by the '947 patent and was amongst the EPO opponents to that patent, had been in contacts with Servier in 2005 and had contemplated an arrangement with Servier comprising the withdrawal of its opposition to the '947 patent and obtaining a licence for the patent, transferral of certain Krka IPRs to Servier, and a payment therefor. When the '947 patent was upheld at the intermediary level of the EPO Opposition Division in July 2006, and Servier initiated a court action against Krka in the UK (including a preliminary injunction), the discussions were resumed. These discussions led to the conclusion of three agreements concerning perindopril. The first two, the Settlement Agreement and the Licence Agreement,[1154] are both dated 27 October 2006 and bring an end to the disputes and essentially allow Krka to commercialise perindopril in seven CEE Member States on the basis of a licence for the '947 patent, while restricting Krka's entry in 20 other EU markets. The third is the Assignment and Licence Agreement dated 5 January 2007, whereby Krka assigned, within one year, two patent applications concerning perindopril to Servier and received EUR 30 million and a back-licence with no right for Krka to sub-license it.

4.3.3.1 Development of Krka's perindopril

(823) Krka started developing perindopril tablets and line extension perindopril/indapamide combinations in 2003, starting with an internal assessment of the market situation. Instructions to constitute a project team and embark on a feasibility study were given in March 2003,[1155] and the study was completed by September 2003.[1156]

(824) The feasibility study contains an overview of therapeutic characteristics and the market position of perindopril with an emphasis on the markets of CEE, in particular Poland. The document identifies the relevant applicable patent barriers: the staggered expiry of the perindopril compound patent, as well as the alpha, beta and gamma polymorph patent applications and the patent application for orodispersible tablets.

1152 ID1316, p. 2, ID1346, p. 8, ID2519, p. 11, ID2538, p. 2.

1153 For further information on the arginine salt, see section 4.1.2.7.

1154 As further amended by Annex No. 1 to the Licence Agreement concluded on 2 November 2006 (ID0043, p. 124-125).

1155 ID0045, p. 115.

1156 ID0047, p. 7 - 10.

As to API production, it identifies two alternatives for the polymorph issue: 1) production of alpha polymorph or a combination of alpha and beta (possible supplies from Glenmark, Azad, or own manufacture), given Krka's observations to the EPO on the patentability of the alpha polymorph, or 2) reliance on a new polymorph, i.e. the independent polymorph by Azad. The study notes that the relevant process patents do not exist in Poland. Perindopril formulation would be developed in-house for all three strengths of perindopril erbumine: 2 mg, 4 mg, and 8 mg.

(825) With respect to Poland, the feasibility study contains a timeline with envisaged MA applications in 2004 (Q3), registration in 2005 (Q3), and product launch in first half of 2006. The study mentions Glenmark and Azad as two amongst a limited number of producers of intermediate products for the synthesis of the API, with the effect of them having a better control over prices of intermediates. The document also contains projected API prices and wholesale formulation prices for Poland.

(826) The feasibility study contains the following conclusion:

*"*Perindopril is a product where we can control both the economics on the API as well as the preparation of technological formulation. Securing a stable formulation and a succesful BEQ study will however be the main elements of added value to this product.*
In Poland, the sales of perindopril in 1st half of 2003 reached 31% of the entire ACE inhibitors market. Market data indicates that perindopril can serve as a very good complement to Krka's assortment of ACE inhibitors in PL, therefore PL is our targeted market. With an appropriate solution (economic, patent) we will, upon agreement with marketing [department], further extend the market".[1157]

(827) The feasibility study was subsequently approved by Krka's Development Board on 23 September 2003, authorising the continuation of development of perindopril as a new Krka product. The Development Board decided to develop perindopril erbumine containing alpha polymorph, and concluded that Krka would oppose the relevant patent applications in Poland. In line with the conclusions of the feasibility study, the focus of the preparations was to be on Poland, in view of high sales as compared to Western Europe (also "WE"), but target markets could be extended as the product was gaining medicinal value due to recent clinical studies.[1158]

(828) In January 2004, it was decided to develop perindopril in the alpha form and to initiate EPO opposition proceedings for the '947 patent protecting the alpha form. In addition, a patent assessment was ordered in view of possible other markets.[1159]

(829) Following the grant of the '947 patent on 4 February 2004, Krka continued its preparations for the launch of perindopril erbumine containing the alpha polymorph. Hungary was selected to be the RMS for the regulatory MRP in a number of CEE

1157 Courtesy translation. "*Perindopril je proizvod, pri katerem bomo obvladovali tako ekonomiko na učinkovini kot tudi pripravo tehnološke formulacije. Priprava stabilne formulacije in uspešna BEQ študija pa bosta glavna faktorja, ki bosta dala izdelku dodano vrednost.*
Na PL je dosežena prodaja perindoprila v 1. pol. 2003 31% celotnega trga ACE inhibitorjev. Tržni podatki kažejo, da je perindopril dobro dopolnilo Krkine palete ACE inhibitorjev na PL, zato je zaenkrat PL naš ciljani trg. Ob ustrezni rešitvi (ekonomski, patentni) pa bomo po dogovoru z marketingom trg še razširili".

1158 ID0047, p. 13.

1159 ID0043, p. 206 - 207.

Member States.[1160] This was confirmed by October 2004, and it was agreed with the Hungarian authorities to be the RMS for the MRP in the CEE Member States and potentially also in Western Europe.[1161]

(830) In November 2004, Krka filed a Notice of Opposition before the EPO against the '947 patent, against which thus 10 opposition proceedings were initiated in total.[1162] The Notice of Opposition included three main arguments. Firstly "*the process for preparing perindopril erbumine according to the article by L. Pichat is […] representing novelty destroying prior art in combination with the Affidavit of Dr. Merslavič*". Secondly, "*commercially available tablets of perindopril erbumine such as Coversyl® contain the α crystalline form*". Thirdly, "*stage 3D of the Example of EP 0 308 341 is novelty destroying for the subject-matter of claim 1, since all the features even of the preferred process for preparing form α according to the patent are disclosed in this example*".[1163]

(831) In view of the grant of the Eurasian patent[1164] for alpha crystalline form, [employee name and function with Krka]*, outlined two possibilities to react to the situation in an email of 19 November 2004 addressed among others to [employee name and function with Krka]*, [employee name and function with Krka]*, and [employee name of Krka]*:[1165]

"**1. an agreement with Servier*

2. immediate filing of opposition (EA, Ukraine […])

Asking for confirmation whether we file opposition immediately or wait a little while for point 1. If there is no agreement, legal strategies need to be worked out for the countries where we intend to launch […]. A large chunk of the "task" will rest on the shoulders of the first one to launch the alpha […]"

(832) Although this email directly relates to the grant of the Eurasian patent for the alpha polymorph, reference was also made to opposition proceedings before the EPO. According to Krka, in particular the Niche litigation would be informative of the situation surrounding a launch (interim injunctions, polymorphic form).[1166]

(833) In a direct reply to this email [employee name of Krka]* outlined the priority countries for perindopril: Slovenia, Poland, Hungary, Czech Republic, Slovakia, Russia, and, potentially, the UK.[1167]

1160 ID0043, p. 204 - 205.

1161 ID0047, p. 29.

1162 See section 4.1.2.4.2.1.

1163 ID0043, p. 243 - 244.

1164 Eurasian patent is to be understood as a patent granted by the Eurasian Patent Office, a body of the Eurasian Patent Organisation, which brings together certain countries on the territory of ex-Soviet Union: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, and Turkmenistan. For more information see: http://www.eapo.org/en/ea.html.

1165 ID0043, p. 202.

1166 Courtesy translation:
"1. dogovor s Servier-om2. takojšnja vložitev opozicije (EA, Ukrajina […])
Prosim za potrditev, če takoj vlagamo opozicijo ali počakamo krajši čas na točko 1. Če do dogovora ne pride, bo potrebno razdelati pravne strategije po državah, kjer bomo lansirali […]. Velik del "posla" bo verjetno na ramenih tistega, ki bo prvi lansiral alfo. […]"

1167 ID0043, p. 202.

(834) In December 2004, Krka received an assessment of the infringement risks related to the alpha polymorph patent when using Krka's process prepared by a European patent Attorney Firm Uexküll & Stolberg. The assessment found that Krka's process was covered, literally or by the doctrine of equivalence, by five claims of the '947 patent. However, the assessment questioned the validity of each of these claims describing that where claims are infringed literally, the claims were "*in our view not valid in view of the available prior art and [would] likely be cancelled or restricted during opposition proceedings*". Where claims would be possibly infringed in an equivalent manner, it appeared "*very likely that these claims will be considered to be invalid*". Finally, the document stated that the claims giving rise to possible infringement "*should definitely be cancelled in the opposition proceedings, in order to minimize the infringement risks of your process*".[1168]

(835) Another patent assessment was carried out in December 2004 by the same firm in relation to any other patents relevant for Krka's process for preparing perindopril. The document assessed the possible risks for infringement of 30 patents by Servier and others, including generic companies. Of all the patents assessed, the most substantial risk came from a process patent application of Lupin (WO 2004/075889)[1169] as the Krka process "*may be considered to represent equivalent use of the process*". It was recommended to establish a patent watch for this application. According to the document, the relevance of a number of Servier's, and its affiliate ADIR's patents and patent applications depended on the synthesis used for precursors.[1170] Other patents by Servier were not considered relevant.

(836) In January[1171] and February 2005, representatives of Krka followed the patent litigation between Niche and Servier in the UK. In an email of 24 February 2005,[1172] [employee name of Krka]* informed Krka top management (including [employee name and function with Krka]*, [employee name and function with Krka]*, and [employee name and function with Krka]*) of the settlement between the companies and that by consequence, Niche withdrew its opposition to the '947 patent. Reportedly, Niche was, apart from Krka, the only opponent to claim that Servier's products had contained the alpha polymorph before the application for the '947 patent was filed.[1173] In a direct reply to this email, [employee name of Krka]* instructed [employee name of Krka]* to propose to attempt to make an agreement for Krka's markets. [Employee name of Krka]* responded as follows:

1168 ID0043, p. 276 - 277.

1169 This patent application was later assigned to Servier by virtue of the Settlement Agreement between Servier and Lupin dated 30 January 2007 (see section 4.3.4.7).

1170 In patent assessments by Uexküll & Stolberg dated 27/4/2005 and 5/7/2005, risks of infringement of patents using the Glenmark process for preparation of these intermediates were assessed. The latter assessment identifies a way without an appreciable risk of infringement. See ID0045, p. 5 - 14. In a patent assessment by Uexküll & Stolberg dated 7/7/2005, intermediates by Menovo were found possibly infringing the '340 and '341 patents of Servier, due to use of either water or ethanol as a solvent in the production of alanyl.

1171 ID0043, p. 201.

1172 ID0043, p. 199.

1173 "*Niche je v opoziciji predložil dokaz, da je Servier prodajal obliko alfa (kar je najenostavnejši način za* razveljavljanje *produktne zaščite za alfo). Podoben dokaz smo od 10 oponentov (brez Nicha 9-tih) dali samo še mi*". Courtesy translation: "**In the opposition, Niche submitted evidence that Servier had been selling the alpha form (which constitutes the easiest way of annulling the product protection for alpha). Of the 10 opponents (9 without Niche), we were the only ones to submit similar evidence".*

"[Employee name of Krka]* called me shortly after our conversation and I have suggested this to him. I have prepared the information hereunder in agreement with him, the way I understand [employee name of Krka]* is that [employee name of Krka]* is in contacts with Servier".*[1174]

(837) In March 2005, [employee name of Krka]* participated in a meeting with [employee name]* of Servier and the director of [subsidiary of Servier]* in Budapest. Among the issues discussed was, first, the potential for Krka's cooperation with Biogaran, and, second, perindopril in relation to which [employee name of Krka]* reported as follows:[1175]

*"*Perindopril: the heart of Servier, they do not want to see us on any of the markets until 2008, when the patent is out. He warns of the manufacturing process patent and the polymorph patent, claims to have checked material from all sources (Lupin…)".*[1176]

(838) In April 2005, Krka accelerated all activities related to the product launch in view of the expected grant in July 2005 of the MA in Hungary (the RMS for the MRP). All documentation supportive of in-house production of perindopril was to be completed immediately, and the feasibility of own production of a key intermediate was to be reviewed.[1177]

(839) Accordingly, Krka was exploring various possible sources of intermediates in the course of April 2005. The launch plan foresaw regulatory approvals throughout virtually the entire EU from third quarter of 2005 to second quarter of 2006, while the respective product launch would ensue in roughly the same period. At this stage, the planning also related to EU15, where launch was planned for the first quarter of 2006. Envisaged API quantities for the first launch year amounted to 140 kg for Slovenia, Poland, Hungary and Russia and to 800 kg for the EU15. Krka was securing different sources of intermediates for CEE and WE markets in view of the patent situation.[1178]

(840) In June 2005, the Development Board confirmed that the activities concerning regulatory approval and product launch were well underway. Technology for production of the API was successfully transferred to a contract manufacturer. At the Development Board meeting, Krka CEO stated that products like perindopril are of exceptional importance for Krka, and need to be accorded a corresponding priority status. The need for sufficient capacities was equally outlined.[1179]

(841) In August 2005, Krka received a MA in Hungary, which served as a basis for the MRP in a number of other Member States.[1180]

1174 Courtesy translation. *"[Employee name of Krka]* me je klical malo zatem, ko sva govorila in sem mu to predlagal. Spodnjo informacijo sem pripravil po dogovoru z njim, kot razumem [employee name of Krka]* je g. [employee name of Krka]* v kontaktih s Servierom".*

1175 ID0042, p. 36-38.

1176 Courtesy translation. *"Perindopril: srce Servierja, nas ne želijo videti na nobenem trgu do sept. 2008, ko pade patent. Opozarja na manufactur[i]ng process patent in na patent na polimorfih, pravi, da ima pregledane surovine iz vseh virov (Lupin…)".*

1177 ID0047, p. 28.

1178 ID0043, p. 154.

1179 ID0047, p. 27.

1180 ID1307, p. 64.

(842) In an email exchange between [employee name and function with Krka]*, and [employee name and function with Krka]*, dating from August-September 2005, issues of litigation and generic competition were analysed in view of [employee name of Krka]*'s original question, namely when API and the final product could be produced free of patents in Krka's facilities in Slovenia.[1181]

(843) Both in Western and Central Europe the likelihood of Servier launching litigation was estimated as very high, at 90%, especially if Krka were to be the first to launch. Reference was made to the differences in the patent landscape, whereby process patents of Servier would have lower or no coverage in some CEE Member States. In addition, neither the '947 patent nor its national equivalents were at the time granted in e.g. Poland and the Czech Republic.

(844) In the email, reference was made to the assessment by Krka's patent attorney that the '947 patent should be annulled, and reportedly Ratiopharm (a possible cooperation partner) considered the risk as acceptable. While litigation could have been protracted past 2010, annulment actions in the UK were presented as a quick but expensive solution. [Employee name of Krka]* contended that the '947 patent would fall if the court took seriously into account the argument that tablets preceding the '947 patent application already contained the alpha form. If this evidence was considered to be sufficient, it would entail a revocation of the '947 patent, according to [employee name of Krka]*, however "**thereby unfortunately opening the market for everybody*".[1182]

(845) The question how Servier assessed Krka's evidence that the alpha form was already present on the market was considered crucial by [employee name of Krka]* for Krka's relations with Servier.

(846) On the issue of generic competition, [employee name of Krka]* expected several entrants in 2006. According to him, the patent situation could in principle be resolved (reference was made to a polymorph developed by Cipla), but the registration issues (stability, kinetics, scaling-up) would remain problematic. Lupin, Glenmark, VULM (source Glenmark) and Specifar were mentioned alongside Niche. Lupin's process patents remained an issue for Krka. The display of interest from partners in Western Europe was considered as an indication that Krka was ahead of others.

(847) In the Development Board meeting of 27 September 2005, the following state of play was established regarding the MAs. Based on the MA granted in Hungary, a MRP was launched with the UK, France, Denmark, Finland, the Netherlands, Germany, Portugal, Spain, Belgium, Luxembourg, Italy, the Czech Republic, Poland, Slovenia, Slovakia, Estonia, Lithuania and Latvia as the Concerned Member States where approval of 2 mg and 4 mg tablets was expected by 6 March 2006. In addition, national applications for 8 mg tablets were filed in Hungary, Slovenia, Poland, Finland, Portugal (and Russia). Launch preparations were on-going, but manufacturing orders in Poland were not yet placed pending patent approval on an intermediate.[1183]

1181 ID0043, p. 159-162.

1182 Courtesy translation. "*Če bi dokaze ocenilo kot zadostne, bi alfa moral pasti (s čimer se žal odpira trg za vse […])*". ID0043, p. 159-162.

1183 ID0047, p. 26.

(848) Krka's criterion of competitiveness was defined as the ability to be the first generic to launch in select key markets.[1184]

4.3.3.2 Krka's strategy email of 29 September 2005 concerning Servier

(849) In an inspection document, an email by [employee name and function with Krka]*, to [employee name and function with Krka]*, dated 29 September 2005, Krka's perindopril strategy is elaborated:

"**Herewith we summarise Krka's key advantages vis-à-vis Servier, divided into two time intervals, and our thinking on opportunities after 2008:*

1) present *agreement, which would run until 2008;*

2) agreement *on joint activity to control the market;*

*3) its [*Servier's*] theoretical options, idea for "strategic" development cooperation with mutual advantages after 2008".*[1185]

(850) The three aspects which were further detailed in the said email of 29 September 2005 could be summarised as follows:

1) Present agreement, which would run until 2008

(851) The email explains Krka's position as follows:

- API ("Surovina") – positive results of Krka's patent application PCT/EP2005/005048 against Servier's patents (Lupin not taken into account), Krka also controlled several sources of both key intermediates, enabling the launch both in Central and Western European markets given Servier's process patent.
- Formulation (both perindopril and perindopril + indapamide) – Krka's patent application PCT/EP2005/003277 had been filed, the "dry mixing" process can have technological/economic advantages.
- Opposition to the alpha polymorph patent – opposition to the EPO (and Eurasian) patent was considered as a potential threat to Servier. The analysis of Servier's tablets (affidavit Grčman) was perceived as Krka's strategic advantage, as the only other opponent with the same arguments was Niche, who had reached an agreement and withdrawn its opposition. Krka can withdraw its opposition to the EPO and Eurasian patents.
- Registrations: summarises state of play as described in the Development Board meeting of 27 September 2005 (see above).

(852) The agreement as referred to above is not described in the said email, neither as to its exact content nor as to the parties to the agreement. In its reply to the Commission's RFI of 4 August 2009, Krka explained that "*there is no other agreements* [sic], *either*

[1184] ID1270, p. 3.

[1185] ID0046, p. 25. Courtesy translation. *"Povzemamo ključne prednosti Krke napram Servierju, razdeljene v dva časovna intervala in povzetek našega razmišljanja o priložnosti po 2008:*
1) sedanji dogovor, ki bi veljal do 2008;
2) dogovor o skupnem delovanju za kontrolo trga;
3) njegove teoretične opcije, ideja za "strateško" razvojno sodelavo za prednosti za oba po 2008".

written oral or any other form, except those already quoted".[1186] In its reply to the Commission's RFI of 8 December 2009, Krka further elaborated its explanation:[1187]

(1) "[Employee name of Krka] used the term "sedanji dogovor" as a technical expert in a sense that in case Krka and Servier agreed on license for alpha patent in 2005 (Servier grants license to Krka for certain markets), such license agreement should have been valid until 2008, as Krka has reckoned that nullification of the alpha patent would be final. Respectively, he had in mind that […] in period between 2005 and 2008 the "fate" of alpha patent was pending, thus it means that from patent perspective, it was reasonable for Krka to try to clear the way and minimise risks for selling the product in that period".*

2) Agreement on joint activity to control the market

(853) This section of the email advocates an "*agreement on joint activity to control the market*" which would need to continue beyond 2008 (in particular with respect to the alpha polymorph, otherwise no agreement would be effective):[1188]

- API: Krka would maintain all sources of intermediates, whilst Servier would enable Krka to manufacture in Slovenia by not pursuing a patent dispute on the synthesis and the alpha polymorph.
- Formulation: Krka would offer to Servier the transition to Krka's formulation[1189] at least for certain markets, for which Servier would pay compensation immediately, and for which registrations were ready.
- Opposition: an agreement between Servier and Krka would eliminate the sole remaining opponent with material evidence that the patent protected alpha polymorph was prior art.
- Registrations: Krka would keep all registrations. If Servier acquired Krka's formulation, Krka (and Servier) would launch another MRP.

(854) In its reply to the Commission's RFI of 4 August 2009, Krka provided the following explanations of the term "*control of the market*":

"[Employee name of Krka] as scientific person has used the term "kontrola trga" (in translation "control of the market") in technological/factual, non-legal manner.*

[Employee name of Krka] had in mind a factual (technological) situation which was a mix of patent and regulatory measures. Servier would have retained valid patent for alpha form, while Krka would get immediate access to the CEE markets – in such way the '947 patent would protect Servier and its market, while [Krka] would get access to sell immediately on its traditional markets. Such solution would also enable minor number of competitors. Thus, a license of '947 for alpha form on markets in CEE was meant by [employee name of Krka]* as a common control of the market.*

Krka seemed to be one of the rare companies (if not the only one in 2006) which developed and managed to control the whole chain – from intermediates, API,

1186 ID1307, p. 107.
1187 ID1730, p. 8.
1188 ID0046, p. 25 - 26.
1189 In its reply to the RFI of 8 December 2009, Krka explained that this technology corresponds to patent application WO 2005/094793 (ID1730, p. 8).

finished dosage formulation – to have a pure product which met purity requirements of Phar. Eu.– and has commercial quantities ready for launch at "launching pad"".[1190]

3) Servier's theoretical options

(855) Krka perceived the following possible scenarios in respect of Servier until 2008:[1191]

- Switch to a different salt. Krka notes that Servier had taken regulatory steps but new EU legislation would not entail any new data exclusivity. Krka thus takes the view that this would not stop generic companies.
- Development of a once daily formulation, possibly in combination with indapamide could be Servier's "*ace up the sleeve*", according to Krka. But it is difficult to believe that Servier would start a promotion campaign emphasising overnight the deficiencies of its existing product. Krka would be interested to learn more about this from Servier.

(856) Krka reported that in the period September – October 2005, its representatives ([employee name of Krka]*, [employee name of Krka]* and [employee name of Krka]*) met [employee name of Servier]* in Paris. According to Krka, several topics were discussed in relation to perindopril, including a possibility for Krka to get a licence on the '947 patent for the CEE Member States, supply by Krka of certain APIs (probably amlodipine, carvedilol). Krka's patented technology and combination products were also discussed in the meeting.[1192]

(857) According to Krka's submission in reply to the RFI, "*there was no follow up or any implementation; purpose of the document – e-mail was an internal wrap up for CEO (at that time IP department reported to [employee name of Krka]*); as Servier was not prepared to negotiate a license agreement for alpha patent, Krka simply waited the outcome of opposition, still believing that patent would be revoked*".[1193]

(858) According to Servier, the company had always been interested in improving the synthesis process for perindopril, and started negotiations with Krka to that effect in 2005.[1194] In this context, a draft assignment agreement for Krka's patent application WO 2005/094793 was prepared, but in the end was not concluded. According to Servier, Krka did not accept the sum proposed by Servier (EUR 10 million) nor the payment modality (i.e. a promissory note).[1195] According to Krka, *"[h]owever, later on Krka decided to rely on revocation of the alpha patent – its confidence that the patent would be revoked was high*".[1196]

(859) According to Servier, negotiations failed due to a disagreement on financial conditions and were subsequently interrupted in 2006 because of the court proceedings in the UK between Servier and Krka concerning the '947 and

1190 ID1307, p. 107.
1191 ID0046, p. 26.
1192 ID1307, p. 82.
1193 ID1307, p. 107.
1194 The two companies also discussed possible supplies of amlodipine for Servier's perindopril amlodipine combination product. See ID1723, p. 4.
1195 ID1723, p. 13.
1196 ID1730, p. 8 - 9.

'340 patents. The negotiations reportedly only resumed after the Settlement Agreement was concluded by Servier and Krka.[1197]

4.3.3.3 Period of market launches and related preparations

(860) Upon grant of the MAs for 2 mg and 4 mg tablets in August 2005,[1198] Krka launched perindopril 4 mg tablets in Hungary in December 2005.

(861) During a Development Board meeting on 19 December 2005, the grant of the MA in Poland based on the MRP was defined as the key priority. Poland was considered as the most important market. All activities in the first quarter of 2006 were to support manufacturing of perindopril tablets. Preparations for the testing of intermediates, including their patent position, and for internal inspections of production sites were on-going.[1199]

(862) At roughly the same time, an internal document of Servier of 12 January 2006 prepared by [employee name of Servier]* presented an analysis of Prenessa 4 mg tablets as produced by Krka Polska. The main findings of the analysis can be summarised as follows:

- tablets comply with all purity requirements both for the API and finished product;
- API purity complies with the requirements of the European Pharmacopoeia Monography;
- none of the impurities which were specifically sought for, and which would indicate the likely use of dicyclohexylcarbodiimide in the synthesis, and consequently a breach of Servier's patents, was detected;
- the RX profile of the tablets indicates the alpha form of perindopril;
- certain other impurities were found but not in excess of the Monography requirements.[1200]

(863) This analysis, which thus contained indications that Krka's perindopril contained the alpha crystalline form, but no indications that Krka would breach Servier's synthesis patents, was transmitted, amongst others, to key Servier staff involved in the perindopril project, including [employee name of Servier]* and [employee name]* (Servier [employee function]*).

(864) In the first months of 2006, Krka discussed supplies of its generic perindopril with several generic companies.

(865) [Employee name and function with Krka]*, discussed the possibility of Krka perindopril supplies to Teva. According to an internal report by [employee name of Krka]* of its conversation with the Senior Director New Business Development at Teva Europe, on 19 January 2006, Teva Europe was very interested in supplies of Krka generic perindopril for Western European markets, in particular for France and the UK and was firmly determined to launch the product in these markets.[1201] Teva was aware of the risk due to the alpha form of perindopril and considered it as

1197 ID1723, p. 4.
1198 ID1307, p. 64 - 65.
1199 ID0047, p. 23.
1200 ID0104, p. 37.
1201 ID0044, p. 20 - 21.

manageable. Krka's advantage was seen in the timing, especially for France, where Servier was seen as switching the product to another (i.e. the arginine) salt with different dosages (2.5 mg, 5 mg and 10 mg). This product switch was perceived as possibly preventing or impeding generic substitution by perindopril erbumine.

(866) The report also explains that draft contracts for the purchase of regulatory dossiers and for the supply of perindopril tablets were transmitted to Teva by Krka, and a confidentiality agreement was signed. Teva's agreement on the principal elements of the contracts was necessary prior to the inspection of the dossiers. Teva was reportedly particularly interested in the appropriateness of the dossier for the most demanding country, i.e. France. According to Krka, a letter of intent was signed on 31 January 2006 for France, Germany, the Netherlands and optionally the UK. A Purchase and Supply Agreement was not signed as the terms could not be agreed upon.[1202]

(867) In the same period, Krka was also in discussions with Stada, with which an agreement was signed in February 2006.[1203] According to an email from Stada, Stada's patent attorney was of the view that "*Krka's nullity suit [was] among all the others the most promising one*", and suggested that parts of the experiments be carried out by external, independent laboratories.[1204]

(868) Krka and Ratiopharm concluded an agreement on dossier purchase and registration purchase concerning perindopril for the whole of Europe on 25 January 2006. The agreement also stipulated an exclusive purchasing obligation[1205] for Ratiopharm for a period of five years following the launch.[1206] According to Krka' internal minutes of a later meeting between Krka and Ratiopharm on 29 March 2006, Ratiopharm was expecting to launch generic perindopril in 2006 in the Netherlands, France, Finland, Portugal, Czech Republic and Poland, and in 2007 in Belgium (and Switzerland).[1207] In Italy, Ratiopharm intended to launch not earlier than 2008 due to the compound patent / SPC issues in Italian legislation. At the time of the meeting, no decision as to the UK had been taken by Ratiopharm.

(869) Against the background of the commercial relationship between Krka and Ratiopharm concerning perindopril, two aspects of the launch strategy were discussed, i.e. polymorph alpha patent and synthesis. Ratiopharm was a party to the opposition proceedings concerning the '947 patent. In addition, according to Krka's minutes, Ratiopharm intended to launch or launched annulment actions against the alpha polymorph patent in France, the Netherlands, Finland, and Portugal[1208]. Krka and Ratiopharm discussed litigation strategies with respect to these proceedings, namely the opposition, annulment actions and any interim injunction procedures. It was pointed out that the court practice on interim injunctions varies significantly

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1202 ID2301, p. 6.

1203 ID1034, p. 8.

1204 ID0044, p. 18 - 19. Stada later explained that the term "nullity suit" referred to the EPO opposition procedure (See ID5613, p. 13).

1205 To the Commission's knowledge, neither of these agreements contained an exclusive supply obligation for Krka.

1206 A supply agreement was accordingly concluded between Krka and Merckle GmbH. The agreement relates to geographic Europe, sets the floor prices and minimum purchase quantities. See ID1302 p. 1 - 15.

1207 ID0043, p. 171.

1208 However, it appears that such litigation strategy was not pursued. See e.g. ID0746.

from one Member State to another. Concerning the synthesis, Ratiopharm was positive about Krka's process but intended to verify further.

(870) Other distribution partners for Western Europe included Aliud for the German market and Generis for the Portuguese market.[1209]

(871) In parallel to launch preparations for plain perindopril, Krka was also developing a generic version of perindopril indapamide, which at the time was still subject to protection through data exclusivity rules. The minutes of the product launch meeting of 28 March 2006 provide a state of play of preparatory work.[1210] At the time, national MAs were expected during the second half of 2006 in Slovenia, Hungary, Poland, Lithuania and Portugal (plus Russia), or still to be filed in Latvia and Czech Republic. MRP for EU25 would be launched on the basis of the MA in Hungary, depending on the applicable data exclusivity regime in the EU. Depending on the data exclusivity protection, MRP was planned for the first quarter of 2007 and for the fourth quarter of 2007. Market launches were expected within a few months from the time of grant, and could take place as early as the fourth quarter of 2006 in Slovenia, Hungary and Czech Republic. By means of example, planned quantities for the Western European markets were 15 million tablets of 4 mg/1.25 perindopril indapamide in 2007 and 50 million tablets in 2008. Patent situation for the perindopril indapamide combination product was qualified as analogous to the one of plain perindopril, that is to say depending on the '947 patent, which influenced the choice of manufacturing facilities.

(872) Concerning plain perindopril, by April 2006, in addition to Hungary, Krka also launched 4 mg perindopril tablets in Slovenia and Czech Republic, and preparations or actual manufacturing of API and final formulation were underway both for the CEE and WE markets. For launches in Western Europe (the UK was explicitly mentioned) reference was made to the need for a safety stock and to the bioequivalence study.[1211]

(873) Final preparations were also underway for launches in Denmark and Finland, expected for May and June 2006, as shown by an email chain from April 2006.[1212] For these territories, too, the '947 validity was the crucial issue, and there was a need to reflect on the reservations needed for potential damage claims. In an email of 21 April 2006 addressed, amongst others, to [employee name and function with Krka]* and [employee name and function with Krka]*, [employee name of Krka]* explained that they expected the EPO to revoke the '947 patent, and national patent applications would subsequently not be granted in Poland, Czech Republic and Hungary. However, if the patent was upheld, perindopril in alpha form could not be sold for as long as the '947 patent or its national equivalents remained in force, or until an agreement was reached. Alternatives were considered possible (reference to salts and Cipla hydrate), but would entail delays. [Employee name of Krka]* concluded with the following words: "**An agreement with Servier concerning alpha would be ideal"*.[1213]

1209 ID0043, p. 158, ID1301, p. 1 - 9 (Generis).

1210 ID0044, p. 10 - 13.

1211 ID0047, p. 4.

1212 ID0044, p. 3 - 4.

1213 Courtesy translation. "*Idealen bi bil dogovor s Servier glede alfe*".

(874) In an exchange of emails between [employee name of Krka]* and [employee name of Krka]* on 23 and 24 April 2006,[1214] the former inquired whether Krka was the strongest among the remaining opponents before the EPO. [Employee name of Krka]* took the view that if that were the case, and others were relatively weak, Krka could reach an agreement with Servier: "*In the affirmative, while others in opposition being relatively weaker, we could agree with Servier".*[1215] In reaction to this, [employee name of Krka]* explained that Stada considered Krka opposition as the best one, while other oppositions with the exception of that of Ivax (now part of Teva) were deemed of inferior quality. He also affirmed that an agreement[1216] on alpha, analogous to the agreement Krka concluded with originator company Grünenthal, would be sensible, especially if Ratiopharm, as Krka's UK distribution partner, would also withdraw its opposition to the '947 patent before the EPO. According to [employee name of Krka]*: "*A successful opposition namely opens the market to everybody".*[1217]

(875) For ease of reference, the agreement between Grünenthal and Krka referred to above was concluded in May 2000 in order to *"settle amicably the dispute before the European Patent Office*". By the terms of the agreement, Krka undertook to withdraw its opposition to a specific patent held by Grünenthal, and not to challenge its equivalents in other jurisdictions. In turn, Grünenthal committed not to file any infringement suits under any of these patents.[1218]

(876) In the period spanning from March to June 2006, Krka carried out internal comparative studies comparing Krka's generic version of perindopril erbumine to both Servier's perindopril erbumine and perindopril arginine tablets. As for the comparison between Krka's and Servier' perindopril erbumine tablets, Krka's internal study showed that Prenessa (Krka's brand name) had lower results for related substances (impurities) and was more stable at higher temperatures than Servier's perindopril erbumine or arginine tablets.[1219] Some of these findings have been used in promotional materials in the countries of launch, such as Poland, and have given rise to complaints by Servier with the competent authorities, such as the Head Pharmaceutical Inspectorate in Poland, notably on grounds of unfair competition.[1220]

(877) Following earlier launches in the Czech Republic, Hungary and Slovenia, Krka launched its 4 mg generic perindopril in Poland and Lithuania in June 2006.[1221] For 2007, Krka forecast a profit of EUR [3-8] million with respect to the sales of

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1214 ID0044, p. 5.

1215 Courtesy translation. "*Če da, drugi v opozicijah pa relativno slabi, se lahko dogovorimo s Servierjem".*

1216 Krka claims that the "agreement" to which reference is made both in paragraphs (821), (826) and here refers to an ordinary licence agreement with Servier (Krka's reply to the Statement of Objections, paragraph 61, ID8742, p. 34) . The context in which "agreement" is brought up does not support Krka's claim that the notion of the agreement is strictly limited to a licence agreement. On the contrary, paragraph (826) mentions the "agreement" in the context of the information concerning Niche's settlement with Servier. The same applies a fortiori to para 869, which makes an explicit reference to the strength of Krka's opposition arguments as possible leverage for the agreement.

1217 Courtesy translation. "*Uspešna opozicija namreč odpira trg za vse.*"

1218 ID2298, ID2302, p. 155-157.

1219 ID0043, p. 76 - 97.

1220 ID0043, p. 60 - 71, 74.

1221 ID0043, p. 143.

perindopril-based plain and combination products in the largest CEE markets, Czech Republic, Hungary and Poland.[1222]

(878) Awaiting the outcome of the EPO opposition proceedings, Krka was planning to launch perindopril in Denmark, Finland, the Netherlands, and the UK in July 2006 and in France, Portugal and Slovakia in September 2006.[1223] Krka was expecting gross margins of EUR [2.5-7] million in the first year of launch in Western Europe.[1224]

4.3.3.3.1 UK launch preparations

(879) In preparing for the launch in the UK, Krka was in intense discussions with a number of possible generic partners in the first half of 2006, namely Teva, Ratiopharm and Consilient Health.

(880) Krka was discussing possible cooperation with Teva, and also appeared to have learned about on-going settlement discussions between Servier and Teva. Krka then internally discussed the need for Krka to file an action for patent annulment / finding of non-infringement in the UK if Teva reached an agreement with Servier, while Krka could not reach such an agreement with Servier. Krka was seeking a strong commitment from Teva on the commercial agreement.[1225]

(881) On 18 May 2006, Teva UK informed Krka of its decision not to cooperate on perindopril in the UK, allegedly due to Teva's risk assessment on Krka's route of synthesis for perindopril.[1226] Shortly thereafter, on 13 June 2006, Teva concluded a settlement agreement with Servier for the UK market. At the same time, Teva continued to be interested in supplies from Krka for other markets. An internal mail of 19 May 2006 (only a day after the above mentioned notice) to [employee name and function with Teva]* states that "*We have received opinions from Germany, The Netherlands and France in respect of the Krka process. In all instances we believe that there are good arguments that the Krka product does not infringe the relevant process patents [...] In all territories we believe that the chance that we won't be injuncted off the market is better than even [...]"*.[1227]

(882) Krka continued to prepare entry with other generic partners, such as Ratiopharm.

(883) In parallel, from at least May 2006, Krka was intensely considering legal options for the launch, including taking steps with a view to "clearing the way", i.e. obtaining a declaration of non-infringement either from Servier or through court proceedings. It therefore contacted Servier to that effect by the end of May. Krka committed to Servier not to launch before the self-initiated deadline of 14 June 2006 for Servier's reply on whether or not Krka's product was in breach of Servier's process patent. At the same time, Krka was taking steps with a view to a possible action against the '947 patent in the UK, for which Krka's legal representative found a reasonable likelihood of success. Three scenarios for after 14 June 2006 were tabled: i) no launch, ii) launch, no interim injunction granted (risk of damages if validity of the '947 patent was confirmed or if infringement of Servier's process patents was established), iii) launch and an interim injunction is granted to Servier (whereby

1222 ID1307, p. 5-28.
1223 ID1244, p. 1.
1224 ID1307, p. 29, ID5422.
1225 ID0046, p. 27.
1226 ID0088, p. 39 - 42.
1227 ID0088, p. 50.

cross undertaking in damages would be requested). According to [employee name and function with Krka]*, and to [name of Krka counsel]*, the preferable option was to launch with an assessment of risk and accompanying risk-containing measures.[1228]

(884) In addition, [name of Krka counsel]* considered the likelihood of Servier requesting an interim injunction as high and also advised Krka to file a summary judgment on invalidity of the '947 patent (chances of success estimated at 70 - 80%), which would increase Krka's chances to overturn an application for interim injunctions.[1229] If Krka launched in the UK through Ratiopharm, an interim injunction could also be aimed against Krka as having a common design with Ratiopharm to import into the UK.[1230][Name of Krka counsel]* provided Krka with an estimate of litigation costs, which could reach GBP 0.9 million.[1231]

(885) The timing of filing the summary judgment motion was considered. According to [employee name of Krka]*, Krka would thus "*start the discussion regarding alfa running with Servier – as reaching an agreement with Servier on alfa appears to be the only quick option to get around it*".[1232]

(886) Servier's presentation *"Coversyl: defense against generics"* dated 19 June 2006 referred to patent settlements with Niche and Matrix in the context of measures against generic entry. It also reveals that Servier was following the development of two advanced sources[1233] of perindopril: Apotex, against which a legal action was "in progress" and which was believed to be infringing a process patent, the '947 patent, as well as a Canadian API patent and Krka, which was mentioned to be marketing perindopril where no patent was in force (Hungary, Poland, Czech Republic, while the launch in other countries was depending on the EPO hearing on 27 July 2006.

(887) As of the second half of June 2006, Krka considered the appropriate launch procedure and the timing to minimise risk, and announced to Servier it would launch in July 2006. Should Servier not prevent the launch with an interim injunction, Krka was intending to place 40,000 packages on the market, which would ensure it a 10% market share within 30 days.[1234]

(888) In July 2006, final arrangements were discussed[1235] with Ratiopharm/Merckle, which led to an agreement effective as of 18 July 2006.[1236] The main features of this agreement were: exclusive purchasing obligation for Merckle, supply prices at 70% of Merckle's net selling prices, floor prices, and minimum purchase quantities for 2 mg and 4 mg tablets, respectively. Krka and Ratiopharm also considered the possibility of a common legal representation by a joint external lawyer and cost-sharing in case of litigation in the UK.[1237]

(889) In preparation of possible litigation with Servier, [employee name and function with Krka]*, described the launch strategy for the UK in an email dated 5 July 2006. At

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1228 ID0043, p. 34 - 36.
1229 ID0043, p. 33.
1230 ID0043, p. 23.
1231 ID0043, p. 20 - 21.
1232 ID0043, p. 24 - 25.
1233 A third source, Glenmark, was found inferior in quality (stability, residual solvents) and patent position. ID0105, p. 178.
1234 ID0043, p. 18 - 19.
1235 ID0046, p. 39 - 41.
1236 ID1302, p. 1 - 15.
1237 ID0044, p. 25 - 26.

that time, Krka intended to use an agent who would offer distribution services, while Krka would take all risks, including the patent risk, and would pursue own pricing policy. Krka was examining ways to prevent patent risk exposure for the agent. Krka's intentions regarding their sales / pricing strategy were as follows, "*At first step we intend to launch 40.000 packs at the highest possible price. With small quantities we do not want to disturb originator to be too aggressive and with no substantial price erosion we would like to minimize potential damages*".[1238]

(890) On 21 July 2006, Consilient Health, Krka's appointed agency distributor for perindopril launch in the UK received a warning letter from Servier.[1239]

(891) The importance of the UK launch for Krka is demonstrated by the following quote: "*We found out that UK situation can be a decisive factor to get access to markets of interest (Krka's opposition seemed to be one of the best; immediate launch in UK – trucks with the Krka's product at UK border)*".[1240]

(892) On 27 July 2006, at the hearing before the EPO Opposition Division concerning the opposition to the '947 patent, the decision to uphold the patent with slightly amended claims was issued. The grounds for the decision were issued on 21 September 2006.[1241]

4.3.3.4 Reactions to the decision by the EPO Opposition Division

(893) Ratiopharm informed Krka on 31 July 2006 of its decision not to launch in the UK, France and the small markets (Finland and CEE countries were explicitly mentioned) as a consequence of the '947 patent having been upheld by the EPO Opposition Division. Later in August, the same decision was also taken with respect to the Netherlands.[1242]

(894) Ratiopharm also exchanged correspondence with Servier concerning possible infringement of the latter's patent in the UK in the event it distributed Krka's perindopril. On 25 August 2006, Ratiopharm offered an undertaking "*not to import or commercialise generic perindopril erbumine in the UK pending the conclusion of the Krka Proceedings [...] in return for an cross-undertaking in damages from [Servier]*". If it transpired that the contested patents were declared invalid and/or Krka product non-infringing, Servier would be obliged to compensate Ratiopharm for the losses suffered as a consequence of this undertaking.[1243] Servier accepted the terms of the (cross)undertaking on 31 August 2006. For the sake of completeness, it should be said that Ratiopharm invoked Servier's cross-undertaking and set out a claim for losses allegedly suffered as a result of Ratiopharm being restrained from launching perindopril product in the UK in 2006. Servier intended to reject this claim. Servier also intended to inform Krka of this, although Krka was not a party to the undertaking.[1244]

(895) In the words of [employee name of Krka]*, "*[they were] still in shock after such an unfavourable outcome with respect to the polymorph alpha litigation. Especially what bothers us is that the trial was discriminative against generic industry and we*

1238 ID0045, p. 126.
1239 ID0043, p. 14 - 17.
1240 ID1307, p. 86.
1241 ID0043, p. 181 - 196.
1242 ID0045, p. 120 - 122.
1243 ID0031, p. 22.
1244 ID0102, p. 237 - 238.

shall not let them go just like that". Seemingly both Ratiopharm and Krka considered that the hearing was not fully balanced, and Ratiopharm had reportedly sent a letter to the Vice-President of the EPO, Dr Hammer to this effect.[1245] According to [employee name of Krka]*, "*it [was] obvious that they have been biased against generics and that irreparable damage was made to the generic industry and national health systems".*[1246]

(896) Ratiopharm took the view that Krka and Ratiopharm "*should try as much as possible to revoke this strange decision of the Opposition Division*".[1247]

(897) From Krka's internal documents, it appears that in the aftermath of the above described decision of the EPO Opposition Division and its immediate adverse commercial consequences, Krka was also exploring alternatives to the settlement route and/or litigation. Namely, Krka's R&D department reoriented on finding a solution to replace the alpha form perindopril with a novel form. Minutes of a perindopril R&D meeting of 13 September 2006[1248] state the following: "**As the originator's patent application protecting alpha form of perindopril erbumine is still valid in Europe, all work on the alpha form is discontinued in Krka. Simultaneously, activities for the development of new stable polymorphic form of API and the development of new stable formulation form are to be accelerated. The objective is to find a solution allowing the earliest possible entry onto the market".*[1249] Krka also filed a new patent application on 30 August 2006 for a novel form of perindopril erbumine, and for the use thereof in various formulations (dry solution, granulation with a sodium salt). However, depending on the specific solution, new bioequivalence studies would need to be carried out across the EU.

4.3.3.5 Discussions and litigation between Servier and Krka

(898) In an immediate reaction to the EPO outcome, a telephone contact took place on 28 July 2006 between [employee name]* of Servier and [employee name]* of Krka, during which Krka expressed interest to get a licence to sell Krka's perindopril in the CEE countries. According to Krka, during that conversation, Servier agreed to grant a licence in certain countries, and it was agreed that terms and conditions would be defined.[1250]

(899) In parallel, Servier launched proceedings before the High Court against Krka for infringement of the '340 patent (28 July 2006), for infringement of the '947 patent (2 August 2006) and filed a motion for grant of an interim injunction against Krka (also on 2 August 2006).[1251] This coincided with Servier's launch of infringement proceedings, including an interim injunction, against Apotex at the beginning of August 2006.[1252]

1245 ID0044, p. 27.

1246 ID0044, p. 29.

1247 ID0044, p. 28.

1248 ID0046, p. 34 - 35.

1249 Courtesy translation. "*Zaradi tega, ker je v Evropi še vedno v veljavi patentna prijava originatorja, ki ščiti uporabo polimorfa alfa perindopril erbumina se v Krki takoj prekine vse delo na alfa obliki. Istočasno pa se pospešijo razvojne aktivnosti na razvoju nove stabilne polimorfne oblike API in razvoju nove stabilne oblike formulacije. Cilj je poiskati rešitev, ki nam omogoča čimhitrejši prihod na trg".*

1250 ID1307, p. 83.

1251 ID0214, p. 62 - 69.

1252 See section 4.1.2.4.2.2.1.

(900) On 28 August 2006, Krka and Servier signed a confidentiality agreement in view of their wish "to pursue exploratory discussions concerning a possible settlement agreement between them in relation to the Patent No EP 1 296 947".[1253]

(901) On 29 August 2006, a face-to-face meeting between Servier and Krka representatives, headed by [employee name of Servier]* and [employee name of Krka]*, respectively, took place in Paris. At this meeting, according to Krka, Servier confirmed its agreement to grant a licence to Krka to sell the product in alpha form in seven Central and Eastern European countries. In turn, Krka agreed not to challenge the validity of the alpha patent.[1254]

(902) On 1 September 2006, Krka launched a counter-action before the High Court for annulment of the '947 patent, and on 8 September 2006 also for annulment of the '340 patent.[1255]

(903) According to Krka's reply to the Commission's RFI of 4 August 2009, in September 2006, first drafts of settlement and licence agreements were circulated, and in October 2006, negotiations for the finalisation of the agreements took place, and several emails were exchanged.[1256]

(904) On 4 October 2006, the High Court granted Servier's motion for a preliminary injunction against Krka.[1257] By the same decision, it also rejected Krka's summary judgment motion of 1 September 2006 for invalidation of the '947 patent[1258] as insufficient to avoid a full trial. However, the High Court found in October 2006 that Krka had strong arguments with which to question the validity of the patent, and that certain of its evidentiary assumptions were compelling[1259] The judge found that "*it was impossible to say that there is no issue to go to trial on the question of anticipation or obviousness of the Patent over 341*" and thus ordered a full trial, it also considered that Krka had "*a powerful base for the attack on the validity of the patent for lack of novelty or obviousness over 341*".[1260]

(905) In a draft Licence Agreement dated 19 October 2006, references to Krka's generic perindopril development and launches have been deleted, alongside with references to Servier's patent infringement claims and to litigation.[1261]

4.3.3.6 The Settlement Agreement and the Licence Agreement of 27 October 2006

(906) Krka and Servier concluded two agreements on 27 October 2006: (i) the Settlement Agreement and (ii) the Licence Agreement. On 2 November 2006, they also agreed on an amendment to the Licence Agreement, entitled "Annex No. 1 to the License Agreement".[1262] These agreements are described in detail in dedicated sections below.

1253 ID0043, p. 134 - 135.
1254 ID1307, p. 83.
1255 ID0214, p. 62 - 69.
1256 ID1307, p. 83.
1257 ID0214, p. 62 - 69.
1258 ID2301, p. 6.
1259 ID0103, p. 75.
1260 ID9835, p. 5-6. See also Servier's reply to the Statement of Objections, paragraphs 920 and 921, ID10114, p. 324.
1261 ID0042, p. 21.
1262 ID0043, p. 124 - 125.

4.3.3.6.1 Terms of the Settlement Agreement

(907) The preamble to the Settlement Agreement,[1263] amongst others:

1. identifies "*Generic commercialisation countries*" where Krka has already launched, by reference to Appendix A to the Settlement Agreement, which lists the following Member States: Poland, Hungary, the Czech Republic, Lithuania and Slovenia; and

2. acknowledges that "*Krka has been making serious preparations to launch the Specialty in other countries*".

(908) The key clauses of the Settlement Agreement[1264] can be summarised in the following way:

- Servier withdraws litigation against Krka based on claims of infringement of its '947 and '340 patents, including motions for interim injunctions, worldwide (clause I(i));
- likewise, Krka withdraws any claims against the '340 and '947 patents (clause I(ii): "*In turn, as of the Effective Date, Krka shall withdraw any and all existing claims against the SERVIER's ['947] Patent worldwide and the EP (UK) 308 340 in the UK"*), and commits not to challenge either the '947 or the '340 patent in the future (clause I(iv): "[…] *KRKA and/or its affiliates agree not to either directly and/or indirectly through any third parties initiate any legal action against SERVIER, and/or its respective affiliates, in relation to the ['947] Patent and/or the patent EP 308 340 (such as but not limited to revocation, challenge or otherwise invalidation of [the '947] Patent and or the Patent EP 308 340), world wide"*.);
- the '947 patent also encompasses national counterpart patents; (Appendix B to the Settlement Agreement);
- each of the parties bears their own legal cost (clause I(iii));
- the restriction on Krka not to enter the market is laid down as follows in clause V: "*For the duration of the validity of the* ['947] *patent, Krka and/or their respective affiliates shall not directly or indirectly launch and commercialize any generic form of Specialty [defined as "active ingredient perindopril in the crystalline form alpha of perindopril tertbutylamine salt (hereinafter the "API") and pharmaceutical products containing the API"] and/or combination products containing the generic form of the Specialty which would infringe the* ['947] *Patent, in the countries in which the Patent is still valid, unless otherwise expressly authorised by Servier*";
- in addition, Krka will "not supply to any third party the *Specialty that would infringe the Patent provided that the Patent is still valid in the respective country or unless otherwise expressly authorised by Servier*" (clause V, 2nd paragraph);
- the agreement stipulates no payment on either side;

1263 ID0119, p. 24 - 29.
1264 ID0119, p. 24 - 29.

- the agreement remains in force until the expiry and/or termination of validity of the '947 patent and/or the '340 patent. At all times, the Settlement Agreement does not apply to jurisdictions where no valid national counterparts of the '947 patent and/or '340 patent exist. (clause II).

(909) On 1 December 2006, UK patent infringement proceedings for both patents ('340, '947) were discontinued as a result of the settlement, and the preliminary injunction was also lifted.[1265]

4.3.3.6.2 Terms of the Licence Agreement (including Annex No.1 to the Licence Agreement)

(910) The key clauses of the Licence Agreement,[1266] including its Annex No 1,[1267] can be summarised in the following way:

- *"Servier hereby grants to KRKA the exclusive, irrevocable licence on the '947 Patent, and KRKA accepts it to use, manufacture, sell, offer for sale, promote and import Krka products which contain crystalline form alpha of perindopril terbutylamine salt in the Territory during the term of this Agreement"* (Article 2)

  "Notwithstanding the above, SERVIER shall be entitled directly or through one of its Affiliates or through solely one third party per country, to use the '947 Patent to do any of the above stated operations in the Territory. […]" (Article 2);

- Annex No 1 modifies Article 2, acknowledging that Servier's licence on the '947 patent also applies to Krka's affiliates, which "*are granted the following licences from Krka:*

  a) to apply for marketing authorisations for Krka Product (as defined in the License Agreement) and hold them as marketing authorisation holders for the benefit and behalf of KRKA;

  b) to import, distribute, use, promote and/or sell KRKA Product under the obtained marketing authorisation for KRKA Product in the Territory, either alone or through third party distributors".

  The last paragraph of Article 2 was changed to read as follows:

  "Other than as outlined in this Article above KRKA is not allowed to grant sublicences without a prior written consent of SERVIER";

- the "Territory" means: Czech Republic, Hungary, Lithuania, Latvia, Poland, Slovakia and Slovenia. (Article 1);

- remuneration is defined in Article 3: in each country of the Territory, Krka pays 3% royalties on Krka's net sales prices (less discounts, taxes etc., as defined in Article 1). Krka shall provide half-yearly reports as the basis for Servier's royalty invoices;

[1265] ID0214, p. 62 - 69.
[1266] ID0119, p. 35 - 39.
[1267] ID0043, p. 124 - 125.

- Krka bears "*full responsibility and liability for the manufacture, promotion, marketing and sales of the KRKA Product in the Territory*";
- The Licence Agreement "*shall be valid until the '947 Patent is valid"*. (Article 5).

(911) Krka paid approximately EUR 730,000 in royalty payments to Servier for the period from 27 October 2006 to 30 April 2010 for its sales in Czech Republic, Hungary and Poland[1268]. It needs to be noted that in Poland, royalties were only paid until mid-2009, and in the Czech Republic, until 31 October 2009.[1269]

4.3.3.6.3 The parties' explanations for the Settlement Agreement and the Licence Agreement

(912) Apart from the evidence presented above, there are no other contemporaneous documents explaining Krka's considerations for entering into the Settlement Agreement and the Licence Agreement. According to Krka's reply to the Commission's RFI of 4 August 2009, "*UK market and litigation could have had a substantial importance to force Servier to finally seriously consider a proposal to grant license for CEE countries".* According to Krka:

"Both companies were faced in July 2006 with serious threats:

a) Krka: as long as the alpha patent was valid, Krka could not have entered any markets where alpha patent was valid (until non-alpha technology has been developed).
b) Servier believed that Krka had one of the best and most comprehensive evidence in the opposition before the EPO and in UK revocation".[1270]

(913) In the same reply, Krka further described its considerations to conclude these two agreements, which in its view were connected:[1271]

"[…]after the patent '947 (alpha patent) was upheld by the EPO on July 27, 2006, the final outcome of opposition became very unpredictable. […]

Krka has invested substantially into development of the perindopril, thus we were looking for the most reasonable solution to come on our core markets in CEE as soon as possible and to harvest the investement.*

Krka had its predominant business interests [in] countries of CEE (Central and Eastern Europe) where Krka had strong marketing teams and it is promoting its own trademarks and house name. Markets in Western Europe (EU 15) were less significant for Krka, as Krka had not [been] selling its products directly, they were not sold on the market under its marketing authorizations and brands, thus we were prepared to sacrify them for getting immediate access to markets in CEE.

Also, in CEE markets Krka earned higher margins than in WE (EU15) – for reasons mentioned above.

Krka neither had sufficient human and financial power to litigate in number of countries. Crucial was also time factor – a license enabled us immediate access to CEE markets to take advantage of being the first generic and take major market share – first entrees usually take the highest market share. […]

1268 ID2287, p. 1.
1269 ID4968, p. 3 - 4.
1270 ID1307, p. 84 - 85.
1271 ID1307, p. 85 - 86.

In view of above mentioned facts, Krka found that it would be commercially acceptable, if Servier would have been prepared to grant Krka licence rights in certain CEE countries. […]

Krka did not find its taking part in oppositions/nullifications as a decisive for revoking of '947 patent; however, it was crucial for Krka not be precluded from entering EU markets, if '947 was revoked.

Getting a license and withdrawing oppositions was considered as the best option for Krka at that time - to be able to sell perindopril on Krka's key markets in CEE immediately, it means in 2006.*

According to all other scenarios, a launch was not possible earlier than in at least 2 years after July 2006, and even after such period a launch was not warranted (risk that '947 is maintained, development risks for non-alpha).

Krka believes that its reasoning proved to be correct – until June 2008, it was the only supplier of generic perindopril on the licensed markets in CEE. By the settlement Krka indeed revoked its opposition to the '947 patent, but by getting a license for alpha form, Krka got immediate access to CEE markets where EPO maintained alpha patent valid, without any exposure to damages, retained all rights to enter any market with perindopril in alpha form, if '947 patent had been revoked and to develop any other, non-alpha form of perindopril". (original emphasis by Krka)

(914) An additional advantage explicitly recognised by Krka is that *"Such solution would also enable minor number of competitors".*[1272]

(915) Also third party observers shared such an understanding of the Settlement Agreement and the Licence Agreement. For example, Lupin internally considered that "*Krka did a well published* [sic] *settlement with Servier to allow them to launch in CEE countries and withdraw from W. Europe".*[1273] *"By allowing Krka to enter branded generic markets of CEE it creates 'brand' competition amd* [sic] *more controlled erosion, but does not lead to a 'land-slide' switch to generics".*[1274]

(916) Krka argued that the Settlement Agreement was not restrictive, as it did not restrict competition beyond legitimate exclusionary effect of '947 patent, as "*the subject matter of the agreement was not perindopril as moiety, but only one form of perindopril".* [1275] Moreover, "*EPO confirmed the validity of '947 patent in July 2006 […] and thus de iure strengthened Servier's monopoly rights".* According to Krka, the agreement did not delay the entry of Krka's product, but enabled it to have an early launch. Krka also claimed that it retained the freedom to invent around the '947 patent, which it did with the development of perindopril in non-alpha form, which was granted marketing authorisations in the autumn of 2009 and in 2010. Finally, Krka retained the right to immediately enter the markets in which the '947 patent or its counterparts were revoked.

(917) In the same answer, Krka contended that in case the Commission considered the Settlement Agreement and the License Agreement, either alone or in combination with the Assignment and License Agreement (see below), to be restrictive, the

1272 ID1307, p. 107.
1273 ID0539, p. 47
1274 ID0054, p. 147.
1275 Reply to the Commission's RFI of 29 April 2010, ID2301, p. 13.

agreement should be exempted by virtue of Article 101(3) of the Treaty.[1276] Its arguments why the agreement should be exempted can be summarised as follows: (i) exclusionary effect is inherent in the nature of patents, and courts protect the patent holders, (ii) courts encourage settlement of litigation; (iii) responsibility that patents are granted only for real inventions lies on patent authorities, while there is no obligation for a third party to file an opposition/revocation procedure; (iv) uncertainty and cost of patent litigation, in relation to which obtaining a licence was considered more beneficial to shareholders than exposure to litigation risks, (v) *" Settlement and license agreement enabled Krka to enter its key markets in Central Europe where it has [strong] marketing teams and sell its own products (Krka owns marketing authorizations and trademarks) with its perindopril products as the first competitor on the market and without any business risk; in all these markets prices have decreased".*

(918) Based on this, Krka stated that: [1277]

"In conclusion, the settlement agreement (either alone or in combination with a related agreement) meets each of the four conditions of Article 101(3) of the Treaty, technical/economic efficiencies (development of a new product which enables export outside EU to markets where valid patent monopolies prevent marketing of alpha form of perindopril), fair share of resulting benefit for consumers (early market entry in 2006, market entry, if patent monopolies cease to exist), indispensability of restrictions (no restrictions beyond legitimate exclusionary effect of '947 patent, no elimination of competition (no restrictions beyond legitimate exclusionary effect of '947 patent.

The most relevant factor, according to our best opinion is the fact that the settlement agreement (either alone or in combination with a related agreement) has not restricted competition beyond legitimate exclusionary effect of '947 patent" (emphasis by Krka).

(919) For the UK litigation, Krka reported EUR [250,000-600,000] of external cost, and for the EPO opposition procedure EUR [30,000-90,000].[1278]

(920) In addition, the reported internal costs of development of Krka's generic perindopril (chemical, analytical and pharmaceutical R&D for API and finished dosage form, internal studies for regulatory purposes) amounted to EUR [1-4] million at the stage of settlement with Servier. In addition, the costs of obtaining marketing authorisation amounted to EUR [0.25-0.7] million.[1279]

(921) Concerning Servier's consideration for entering into the Settlement Agreement, reference is made to section 4.3.1.4.3.1[1280] laying out its general considerations.

(922) In relation to the Licence Agreement, Servier provided the following explanation:[1281]

*"*We have also in the case of Krka taken into account the interest presented by the licence agreement which we could conclude in terms of potential development of our sales in the EEA countries covered by the agreement".*

1276 ID2301, p. 11 - 14.
1277 ID2301, p. 11 - 14.
1278 ID1307, p. 93.
1279 ID1307, p. 90.
1280 Paragraph (608) and subsequent.
1281 ID1151, p. 20.

4.3.3.7 Assignment and Licence Agreement

(923) In addition to the Settlement Agreement and Licence Agreement of 27 October 2006, Servier and Krka concluded a third agreement which bears the date of 5 January 2007 (the Assignment and Licence Agreement)[1282]. This agreement foresees the transfer of two Krka patents to Servier in return for EUR 30 million.

(924) Krka explained that a telephone call took place in the beginning of December 2006 between [employee name of Servier]* and [employee name of Krka]*, whereby Krka was asked if it was interested to assign two patents.[1283] Krka replied in the affirmative, indicating that the patents would not be assigned for less than EUR 40 million, and requested a licence-back to Krka. According to Krka, in another telephone call in the beginning of December 2006, the aforementioned representatives of Servier conducted price negotiations and agreed on a price of EUR 30 million for the assignment. Krka furthermore submits that "*a simple assignment agreement was drawn up by [employee name and function with Krka]* in December 2006*",[1284] and that two to three faxes were exchanged in December between the companies concerning the draft of the assignment agreement. Neither Krka nor Servier were able to produce any of the allegedly exchanged faxes or any other preparatory documents from December 2006, when the agreement was allegedly negotiated. According to Krka, a meeting took place on 4 January 2007 between Servier and Krka to finalise the assignment agreement, while the agreement was signed on 5 January 2007.[1285]

(925) The reply Servier submitted in response to Question 22 of the Commission's RFI of 6 August 2009 ("**In the case of KRKA, we decided to acquire two of the three patent applications offered by the generic manufacturer after the conclusion of the settlement agreement […]*"[1286]) is somewhat inconsistent with Krka's statements that it was Servier who took the initiative for the assignments (see above), as well as with Servier's own explanations that negotiations had started already in 2005 but were interrupted until the conclusion of the Settlement Agreement.

4.3.3.7.1 Terms of the Assignment and Licence Agreement

(926) Servier's considerations for the acquisition of Krka's intellectual property rights are stated in the preamble of the Assignment and Licence Agreement:[1287] "*Servier wishes to obtain additional preparation processes for its API and related industrial property rights protection*". (recital 5)

(927) The key features of the Assignment and Licence Agreement are as follows:

- Krka transfers and assigns to Servier two Patent Applications, WO 2005/113500 (patent application A), and WO 2005/094793 (patent application B) (Article 1, paragraph 1, and recital 4 of the Preamble);
- Krka confirms it has made available the documentation directly relating to the patent procedure for the two patent applications (Article 1, paragraph 3);

1282 ID0043, p. 114 - 118.
1283 Reply to the Commission's RFI of 4 August 2009 ID1307, p. 83.
1284 ID1730, p. 4.
1285 Reply to the Commission's RFI of 4 August 2009 ID1307, p. 83.
1286 ID1151, p. 18.
1287 ID0119, p. 42 - 46.

- Servier confirms to be aware and fully acquainted with the technical features of the Patent Applications A and B and the embodied inventions. Servier also confirms it understands the price as an adequate and fair price for the acquisition of the Patent Applications (Article 1, paragraph 4);
- Krka gives no warranties for the technical utility or completeness of the applications and the embodied inventions and that the patents will finally be awarded (Article 1, paragraph 4);
- Krka undertakes not to challenge the validity of either of any patents granted on the basis of either of the two applications (Article 3);
- Transfer of title is connected to payment; the second instalment and corresponding assignment are deferred by a full year (Article 2):
    - First instalment: transfer of EUR 15 million to Krka on 10/1/2007; upon receipt, Krka executes all acts and activities necessary to complete the transfer of the ownership title for patent application WO 2005/113500;[1288]
    - Second instalment: transfer of EUR 15 million to Krka on 10/1/2008; upon receipt, Krka executes all acts and activities necessary to complete the transfer of the ownership title for patent application WO 2005/094793;
- once ownership title is transferred to Servier, the latter grants to Krka a non-exclusive, irrevocable, non-assignable, royalty free licence with no right to sub-license (other than to Krka's affiliates) on the applications / ensuing patents (Article 4).
- a confidentiality clause defines confidential information as comprising the Assignment and Licence Agreement and "*all data and information prepared by KRKA and/or its employees, agents, subcontractors within the scope of this Agreement including but not limited to scientific, technical and pharmaceutical data, written documents, samples, blue prints, models or more generally all other forms, media which KRKA has chosen to disclose hereunder*". (Article 6)
- the agreement contains the following main types of warranties:
    - Krka and Servier warrant to have the power and the authority for the transaction,
    - Krka and Servier warrant that there are no regulatory hindrances to the transaction;

[1288] While this payment for the first patent application was indeed carried out as stipulated in the agreement, by the abovementioned letter of 5 January 2007 (ID0043, p. 108), Servier instructed Krka to proceed with the transfer of the patent application on 10 August 2007. This appears to have delayed the actual transfer of the ownership title to the patent application WO 2005 113500 by seven months, although Servier had, under the law of obligations, the right to transfer the ownership title as of Krka's receipt of the corresponding payment.

- Krka and Servier warrant that there are no other contractual or other obligations inconsistent with the Assignment and Licence Agreement (Article 5);
- Krka declares to be the owner and holder of all rights, and that there are no liens or other legal defaults on the respective IPRs; (Article 1).

(928) For the sake of completeness, it needs to be mentioned that the agreement contains no provisions on Krka's obligations relating to the activities necessary for the prosecution of the patent application WO 2005/094793 during the one year period between the entry into force of the agreement and the date of the effective assignment of the said patent application.[1289]

4.3.3.7.2 Links between the Settlement Agreement, the Licence Agreement and the Assignment and Licence Agreement

(929) In a reply to Question 22 of the Commission's RFI of 6 August 2009, Servier replied as follows: "**None of the settlement discussions in which Servier participated depended on the granting of intellectual property rights by the other party"*.[1290]

(930) In contrast to Servier's statement, Krka acknowledged that the Licence Agreement and the Settlement Agreement were interdependent. This is demonstrated, for example, in the following statement from Krka's reply to the Commission's RFI of 8 December 2009: "*f) [Employee name of Krka]* and [employee name of Servier]* agreed on main points: defined territories, defined commercial terms (royalty), Krka agreed to withdraw opposition against '947 matter and not enter any market as long as '947 patent was valid*".[1291]

(931) Concerning the Settlement Agreement (and the Licence Agreement) on the one hand and the Assignment and Licence Agreement on the other, Krka stated that discussions were separated, and that the agreements were not interconnected.[1292]

(932) According to Servier, even though the Assignment and Licence Agreement and the Settlement Agreement were not linked, the latter created a favourable context for the conclusion of the former.[1293]

(933) This is however in contradiction with the information Servier has provided in its reply to the Commission's RFI of 2 April 2008 in the context of the Sector Inquiry, that is to say, prior to the Commission's first investigative steps in the present proceedings. Servier was requested to provide all patent settlement agreements and any agreements related to the patent settlement. In its reply of 5 May 2008 Servier, amongst other agreements (with Niche, Matrix, Teva and Lupin), submitted the

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1289 By contrast, in an assignment agreement concluded on 29 September 2008 by Servier and Krka concerning Krka's patent application PCT/EP2008/058258, related know-how and regulatory dossiers for perindopril products for the territories of Australia and South Africa, Krka undertook *"to use all reasonable care and skill to complete the Dossiers and to pursue the filing, prosecution and maintenance of the patents […]"* Article III (ID0117, p. 165 - 169). Contrary to Krka's contention (Krka's reply to the Statement of Objections, paragraph 166, ID8742, p. 85), the transfer did not relate to a granted patent, but to a patent application and the respective national patents issued from this application.

1290 ID1151, p. 17.

1291 ID1307, p. 86.

1292 Reply to the Commission's RFI of 4 August 2009, ID1307, p. 105.

1293 ID1723, p. 3 - 4.

Settlement Agreement, the Licence Agreement, and the Assignment and Licence Agreement concluded between Servier and Krka.[1294]

(934) Servier explained this submission as follows: "**The Assignment and Licence Agreement of 5 January 2007 is not directly related to litigations or disputes. […] In no way did we suggest in the framework of the sector inquiry, that the two Licence Agreements are Settlement Agreements, or are related to settlement agreements resolving disputes"*.[1295]

(935) However, in its reply to question 50(e) of the aforementioned Commission's RFI of 2 April 2008, Servier also indicated that, under the settlement agreement, it had transferred EUR 15 million to Krka.[1296] Servier later reviewed the amount of the value transfer to Krka and indicated that in relation to the Settlement Agreement with Krka, the value of the transfer to the generic company was EUR 30 million for all the countries listed (as mentioned above, only Czech Republic, Hungary, Lithuania, Poland and Slovenia were listed).[1297]

(936) Moreover, the transfer of Krka's technology to Servier had been mentioned as a part of a possible scenario of cooperation with Servier in the email of [employee name of Krka]* of 29 September 2005, whereby Servier would grant Krka a licence for alpha and any litigation would be avoided or discontinued.[1298] In its reply to question 25 of the abovementioned Commission's RFI of 8 December 2009,[1299] Krka confirmed that the formulation referred to in that email forms the subject-matter of patent application WO 2005/094793 (EP 1 729 739).[1300] This was in fact one of the two patent applications which were later assigned to Servier by virtue of the Assignment and Licence Agreement.

4.3.3.7.3 The parties' explanations for Assignment and Licence Agreement

(937) According to Servier's reply to the Commission's RFI of 6 August 2009,[1301] "**SERVIER has always sought to improve the quality and the synthesis process of perindopril and to this end talks were initiated with KRKA as from 2005"*.[1302]

(938) On a general note, without referring to any particular acquisition, Servier explains the rationale for its acquisitions of patents and patent applications as follows:[1303]

*"*Patent applications were purchased in order to improve our manufacturing processes and thus increase production capacity while optimising production costs. The improvements we are seeking are mainly on three levels of the production process:*

- the first aims to reduce process cycle times,

- the second aims to optimise the method of synthesising perindopril and its purification,

1294 ID2083, p. 16 - 17, ID2111 - ID 2117 (agreements submitted in reply to Question 48).
1295 Reply to the Commission's RFI of 8 December 2009, ID1723, p. 3.
1296 ID2083, p. 17.
1297 ID2058.
1298 ID0046, p. 25 - 26.
1299 ID1712, p. 12.
1300 ID1730, p. 8.
1301 ID0904.
1302 ID1723, p. 4.
1303 ID1151, p. 24.

- the third aims to improve the tablet manufacture process.

The amounts invested in the purchase of these patent applications resulted from negotiations with the companies holding these rights and the evaluation of our internal experts".

(939) However, Servier was not able to provide any document with an assessment of the value of the negotiated patents/patent applications prepared by its internal or external experts.

(940) During the inspections at Servier's premises in November 2008, [employee name of Servier]*,[1304] project manager responsible for perindopril, explained that the feasibility studies regarding the patent applications acquired from Krka were still in preparation.[1305] According to him, it would be difficult to imagine that a clause in the agreement would allow its entry into force before such analyses are carried out:

"[Commission]: [Employee name of Servier]*, do you think it is likely that an agreement with Krka has already been reached even though the feasibility studies are still ongoing?*

[[Employee name of Servier]]: I find it hard to imagine that there is no clause, if indeed the case is as you describe it, which specifies that any contract signed takes effect without such analyses having been made".*

(941) In addition, in its reply to the Commission's RFI of 7 February 2011[1306] Servier explained that the evaluation of patents or patents applications that Servier might acquire is done in an informal way and *"*trusting the knowledge and expertise of the key people in the company who are subject to the pressure induced by the negotiations, particularly in terms of deadlines imposed by the companies holding industrial property rights. The Management has entrusted the decision to purchase patents to a small group of internal experts belonging essentially to the Technology Department and the Patents Department, which are in the best position to determine the quality of the patents in question as well as the potential interests of the invention in the complex manufacturing process of perindopril".*

(942) Concerning the fact that the warranties in the Assignment and Licence Agreement appeared to offer a lower level of comfort to Servier than for most of the other assignments (such as [company name]* and Azad), Servier claimed that these various agreements were not comparable as they reflected the specific negotiating outcome with each partner:[1307]

*"*The difference as to the warranties given by the (potential) transferor of the patent does not necessarily reflect a different wish of SERVIER from one contract to another, but is the result of the negotiations between SERVIER and the trading partner and expresses the compromise which the parties could have been able to reach on the matter".*

1304 [Employee name of Servier]* was interviewed pursuant to Article 20(2)(e) of Regulation 1/2003. As [employee name]* was not authorised to represent Servier, Servier had the opportunity to submit pursuant to Article 4(3) of Commission regulation 773/2004 any rectification, amendment or supplement to [employee name of Servier]*'s explanations as recorded by the Commission. Apart from comments relating to the accuracy of the transcript, Servier did not resort to this possibility.

1305 ID3443, p. 12 - 13.

1306 ID3842, p. 10 - 11.

1307 Reply to the Commission's RFI of 8 December 2009, ID1723, p. 12.

(943) In the context of the Lupin agreement, Servier contended more generally that where the transfer of IPRs takes place in the context of a settlement agreement, the need for warranties may be different than in pure IPR transfer agreements:[1308]

*"*The warranties regarding the ability to commit, the lack of contrary commitment vis-à-vis third parties and the existence and availability of rights appear in the majority of contracts, with the exception of the "Settlement agreement" with Lupin in which none of these warranties are included, which is not unusual in the context of a settlement agreement contract, in particular, when the purchase is associated with a licence fee to the seller. […] As the purchase of Lupin's rights was part of a settlement agreement as opposed to a simple purchase contract, commercial pressures were different. Having weighted this, SERVIER considered that these guarantees were not essential in this case".*

(944) Concerning the deferred IPR assignments and related payments, Servier made the following statements:[1309]

*"*Given the timing of the financial transfers, payments were staggered in order to spread the load over multiple fiscal years for Servier.*

Since the partner undoubtedly wanted to link the date of transfer to the date of payment, the actual transfer of the ownership of certain patents was delayed compared with the date of signing of the agreements. However the purchase commitment of SERVIER was firm and final upon signature of the agreement (clause 2.2 of the contract with Lupin and Article 1 of the contract with KRKA)".

(945) The considerations behind the conclusion of the Assignment and Licence Agreement on the side of Krka, as set out in Krka's reply to the Commission's RFI of 5 August 2009, were as follows:

"Internal considerations were simple:

we got licence [on the '947 patent] for our core markets where we had our marketing teams;

we insisted on back license which enabled Krka manufacturing and selling of the product for licensed markets;

by assuring a license to manufacture and sell [Krka's] perindopril product in alpha form in Krka's core markets in CEE, and by developing a non-alpha product, and finally also in view of provisions of the settlement agreement (Krka had never committed not entering any market, if alpha patent had been nullified, respectively the settlement agreement had the opposite provision), Krka found the offer to assign patent applications to Servier attractive (thus not having control over them as patent holder), provided however that a price would be satisfactory high".[1310]

(946) In reply to the Commission's RFI of 5 August 2009, enquiring among others why the agreement elected the form of assignments, and not, for example, exclusive or non-exclusive licenses, Krka replied as follows:[1311]

1308 ID1723, p. 12.
1309 ID1723, p. 13.
1310 ID1730, p. 4.
1311 ID1307, p. 97 - 98.

"We assumed that Servier feared that patents could have been assigned or licensed to any third competitor who could have developed a product with required Phar.Eu. purity, even i[f] alpha form had been revoked – Krka's patents solved "purity problem".

(947) Furthermore, in its reply to the Commission's RFI of 29 April 2010, Krka explained technology deals were more likely between originators and generics. It also indicated that no generic company expressed an interest in licensing in or acquiring Krka's perindopril related IPRs:[1312]

"The reason lies in the nature of generic industry – a) on one side, marketing oriented generic companies are interested in getting a registration dossier and a final product – a package which [enables] them immediate marketing of a product; b) on the other side, manufacturing oriented generic companies which develop products and manufacturing technologies, like Krka, being the case also with perindopril, have ultimate interests to sell finished products, not only a technology (to fill up their production facilities) – generic manufacturers are marketing and manufacturing oriented organizations, and not contract research organizations (CRO) offering services.

Later technologies can have substantial value for an originator company for various reasons, thus it is our estimation that technology deals are more likely between originators and generics".

4.3.3.7.4 Assigned intellectual property and its market importance

(948) In their replies to the Commission's RFI of 4 August 2009 and 6 August, Krka and Servier respectively provided the following descriptions of the patent applications which were the subject matter of the Assignment and Licence agreement. Krka confirmed that the processes protected by these applications "*yield alpha form as it is the only stable [form] of perindopril erbumine form per se"*.[1313]

1) Patent Application - WO 2005/113500

(949) Krka explained the following features of the patent application protecting the "*Process for the preparation of perindopril and salts thereof*":[1314]

- the invention relates to the preparation/synthesis of perindopril – key step in the production of active substance and it salts, and is not limited to a specific salt;
- the examples in the application disclose perindopril erbumine salt and process for preparation of polymorph alpha;
- the process is efficient high yield process giving a high quality product with purity required by European Pharmacopoeia;
- the invention is applied in Krka's industrial production of perindopril active substance;
- no formal evaluation was carried out for the conclusion of the Assignment and Licence Agreement.

1312 ID2301, p. 4.
1313 ID2301, p. 8.
1314 ID1307, p. 93 - 94.

(950) Servier's answer to the same questions was the following:[1315]

*"*Krka – WO 2005 113500: method of coupling the two key intermediates to access to Perindopril base. This method relates to a stage in the process that precedes the salification.*

Desired objective: optimisation of the synthesis of perindopril base to ultimately gain both the tert-butylamine salt and the arginine salt".

(951) Amongst all the acquisitions listed by Servier, patent applications WO 2005 113500 is the only one for which Servier reports to have been actually used in the production process:[1316]

*"*Currently among the applications purchased, the lesson learnt from the technique described in the application Krka WO 2005/113500 has enabled us to develop a method of accessing the arginine salt by reducing the manufacturing process by one step".*

(952) In reply to the Commission's RFI of 16 January 2009, Servier submitted a document "*Assessment and prospects for development of the Perindopril production process*"[1317] which was created during Servier's deadline for reply to the RFI,[1318] i.e. on 12 February 2009. The document refers to the saturation of production capacities by the use of Servier's production process in view of the estimated perindopril API demand from 1997/1998 onwards. The document discusses the increased costs of the newly introduced arginine salt which would be […]* perindopril erbumine. According to the document, cost reductions had been sought and achieved as a result of […]*. In [5–10]* years of commercial exploitation, EUR [75–100]* million would be saved by […]*. According to Servier's reply to the RFI of 7 February 2011,[1319] […]* would be based […]* [company name]* […]*, which is however not at all mentioned in the Assessment. The Assessment does mention Krka's (and Lupin's) patent application. Firstly, the teaching of the work of Servier's competitors (Krka's WO 2005/113500 is mentioned as an example) contributed to Servier developing its own method to produce perindopril […]*. According to Servier, this allowed savings of EUR [30-40] per kg of API,[1320] totalling EUR [1,950,000 - 2,400,000] over a period of six years,[1321] but Servier was unable to substantiate this despite the Commission's request. However, when asked how these savings were possible more than a year before the patent applications were acquired from Krka, Servier revised its position and claimed that Krka's patent application was only cited to provide an example, and that in fact, information from patent applications acquired from Lupin[1322] and Azad was used.[1323]

(953) Servier also relied on the argument that future improvements were still possible using the WO 2005/113500 patent, which would allow the replacement of an expensive reagent with a cheaper one. This method however still required "*a lot of*

1315 ID1151, p. 25.
1316 ID1151, p. 24 - 25.
1317 ID0376.
1318 ID3842, p. 25.
1319 ID3842, p. 25.
1320 ID4517, p.5.
1321 ID3842, p. 23 - 24.
1322 WO 2005/037778.
1323 ID4517, p. 5.

development work"[1324] An internal documents cataloguing the various perindopril-related patents, including those acquired from Krka and Lupin, suggests that, at least in the US, Servier had some difficulties proving that the patent application presented an inventive step over a synthesis patent applications with similar claims, as acquired from Lupin.[1325]

2) Patent application - WO 2005/094793

(954) Krka explained the following features of the patent application protecting the "*Process for preparing a solid pharmaceutical composition*":[1326]

- the invention comprises a process for preparing a solid pharmaceutical composition of perindopril or its salts and a pharmaceutical composition (formulation) by dry mixing and dry processing using specific excipients, and is not limited to a specific salt;
- examples in the application disclose perindopril erbumine salt and also combinations with indapamide;
- the process is economic and solved the issue of preparing stable and high quality formulation of perindopril in terms of impurities (with purity required by Eur. Pharmacopoeia), polymorphic stability and bioequivalence;
- the invention is applied in Krka's industrial production of perindopril active substance;
- no formal evaluation was carried out for the conclusion of the Assignment and Licence Agreement.

(955) Servier's answer to the same questions was the following:[1327]

"Krka - WO 2005 094793: manufacturing process of tablets of perindopril tert-butylamine or arginine

Desired objective: improvement of the tablet manufacturing process".

4.3.3.7.5 General explanations of the perceived value and use of the technology

(956) During an interview conducted on 25 November 2008 in the context of inspections at Krka, [employee name and function with Krka]*, provided the following explanations:[1328]

*"*I believe that when Servier saw our patent applications, the file, it realised that they have a certain market value. As for us – we didn't see any, as it included alpha, apart from the pleasure of seeing their interest in this area.[…] I need to say that we had no internal assessments. We work like this – this is, as I've said three times already, […] a negotiation, and obviously these papers, these products, both on the active substance as well as on the final product meant so much that we bargained as*

1324 ID0376, p. 6 - 7.
1325 ID10081.
1326 ID1307, p. 93 - 94.
1327 ID1151, p. 24.
1328 ID0478, p.6. [Employee name of Krka]* was interviewed pursuant to Article 20(2)(e) of Regulation 1/2003 and was, in his function [employee function with Krka]*.

we did. Having said this, I do not consider this to be a high amount. Even less for Servier, but Krka, too, as we are almost at a one billion euro sales level".[1329]

(957) In addition, as already mentioned above, Krka did consider that these patent applications could be of particular value for Servier. The head of Krka's IPR department stated that for Servier, the use of the acquisition was in *"blocking to competitors very economic processes. […] We think we were able to block two economic and viable options".* He added that *"[t]here could be other [viable options] but I am not aware of any other".*[1330] Krka also acknowledged the following:[1331]

"We assumed that Servier feared that patents could have been assigned or licensed to any third competitor who could have developed a product with required Phar.Eu. purity, even i[f] alpha form had been revoked […][Krka] patents could have been "a key" for entering markets with a product having required purity – set of the assigned patents enabled any company to have a product/API of a purity required by Phar.Eu. […] Phar.Eu has set very high purity standards for perindopril. Krka's patents were solving very concrete technological problems and this was the value of the assigned patents. ***A company which held title of these patents (in particular the process patent) or have a license, would have a commercial product***" (emphasis added by Krka).

(958) On the same issue, Servier provided the following explanations.[1332] *"*The amounts invested in the purchase of these patent applications resulted from negotiations with the companies holding these rights and the evaluation of our internal experts".*

(959) Servier has not provided any documents with an internal assessment of the relevant patent applications or of their possible market value as mentioned in the above quote.

(960) With the exception of the abovementioned patent application acquired from Krka, Servier did not report any other instance where acquired patented inventions were actually used by Servier in its production process. In this respect, Servier provided the following explanation[1333]:

*"*The implementation of the techniques and processes described in these patent applications requires extensive testing at the pilot and then at the industrial level in order to confirm whether these techniques can lead to effective improvement of the existing processes in terms of product quality and/or manufacturing cost savings.*

This process can take several years. Meanwhile, the examination and approval of patent applications purchased also takes many years".

1329 Courtesy translation. *"[j]az verjamem, da je firma Servier, ko je videla naše patentne prijave, file, videla, da imajo neko tržno vrednost. Mi – mi nismo videli nobene, ker je imel notri alfo, razen seveda dober občutek, ko smo videli, da njih to področje tudi zanima. […]*
Moram povedati, da nismo imeli nobenih notranjih ocen. Mi delamo tako – to je, kot sem že prej trikrat rekel, […] pogajanje, in očitno so njim tisti papirji, tisti izdelki, tako na zdravilni učinkovini kot na samem gotovem izdelku, toliko pomenili, da smo priglihali na toliko, kot smo pač priglihali. Zdaj pa, da bi bil to en visok znesek, pa jaz ocenjujem, da niti ne. Najmanj za firmo Servier, pa tudi za Krko ne, saj smo na nivoju prodaje že skoraj miljarde evrov".

1330 ID0479, p. 4 - 5.

1331 ID1307, p. 97 - 98.

1332 ID1151, p. 24.

1333 ID1151, p. 25.

(961) During the inspection in November 2008, the following statement was provided in the context of oral explanations requested from [employee name]*, [employee function]* at Servier[1334] ("SJ"):

"[Employee name of Servier]*: And you cannot change such an industrial process as easily as that.*

[Employee name of Servier]: They are still years of work etc., and it is still very, very long. Changing a manufacturing process also involves changing a number of things at the regulatory level, though I am not competent in regulatory matters but it cannot be done like that. […]*

[Commission]: OK. … ok so reasonably speaking, let's say, for the most advanced patents, … do you think you can start using them as from 2010?

[Employee name of Servier]: Yes, perhaps, I do not have the review procedures yet, yes".*

4.3.3.8 Developments after the conclusion of agreements between Krka and Servier

(962) On 11 January 2007, Krka issued an instruction to its patent attorneys to file a withdrawal from opposition and appeal proceedings before the EPO,[1335] in the context of which [employee name of Krka]* stated the following:[1336]

*"*Yes, let's withdraw from the opposition as soon as possible, as we should have done that already. I hope that all activities against Servier on all markets have been stopped pursuant to the Settlement Agreement!?"*

(963) Agreements with a number of other generic partners to be supplied by Krka under an exclusive purchasing obligation for the markets in the UK, the Netherlands, France and Portugal were "*terminated/suspended until alpha patent remain in force*".[1337]

(964) Krka continued the development of non-alpha perindopril formulations as initiated in September 2006[1338] (see above). According to Krka, the company "*needed at least 2 (two) years to develop a commercially viable technology and get marketing authorization for non-alpha perindopril – with all development risks […]*".[1339] According to Krka, the delay in the launch of its perindopril is estimated at approximately two to three years as compared to a situation where Krka would have been able to launch based on its marketing authorisations as of 27 July 2006 (i.e. the date of the decision of the EPO Opposition Division). Instead, Krka had to develop the non-alpha form of perindopril and succeeded, but only received MAs in autumn 2009 and 2010.[1340]

1334 ID10080. [Employee name of Servier]* was interviewed pursuant to Article 20(2)(e) of Regulation 1/2003. As [employee name of Servier]* was not authorised to represent Servier, Servier had the opportunity to submit pursuant to Article 4(3) of Commission regulation 773/2004 any rectification, amendment or supplement to [employee name of Servier]*'s explanations as recorded by the Commission. Apart from comments relating to the accuracy of the transcript, Servier did not resort to this possibility.

1335 ID0043, p. 145.

1336 ID0043, p. 145, courtesy translation. *"Da, čim preje se umaknimo iz opozicije, saj bi to že morali storiti. Upam, da smo ustavili vse aktivnosti proti Servierju na vseh trgih, kot to izhaja iz Settlement Agreementa!?"*

1337 ID1307, p. 99 - 100.

1338 ID0044, p. 23.

1339 ID1307, p. 88.

1340 ID1307, p. 109.

(965) On the other hand, Krka was marketing perindopril in the seven CEE markets where it received a licence for the '947 patent. Although the level of royalties (3% on net sales) for Krka's sales of alpha perindopril erbumine in the seven CEE Member States led to relatively low payments to Servier,[1341] this nonetheless led to a disagreement between Krka and Servier from October 2007 to May 2008 on the exact sum of royalties due, apparently owing to divergences between (higher) sales figures reported by the IMS data and Krka's own internal sales data with lower figures.[1342] Servier was not interested in launching its own generic version while only Krka was on the market, as can be seen from an internal communication from November 2008 concerning Slovakia: "*no interest in it [Egis, part of Servier group] launching as long as there is no proven risk of a generic other than Krka capable of launching*".[1343]

(966) In relations to royalties, [employee name of Krka]* also provided the following oral explanation during the inspection:[1344]

*"*Because to pay royalties in the long term… If the alpha patent will continue to exist for I don't know how many years, we will need to pay quite a lot. This signifies a certain burden, we do not want it, but we are living with it".*

(967) It appears that Krka was monitoring the Apotex litigation closely (a Krka representative attended the trial on 13 – 20 March 2007 as a member of the public).[1345] In what seems to be a fax from [employee name and function]* of Krka, to [employee name]* of Servier, the former wrote: "*[Employee name of Servier]*, Any additional territory for us in East Europe? Rgds*".[1346] An unsigned statement by Krka relating to the Apotex / Servier trial in the UK was attached, according to which Krka would undertake not to launch, directly or indirectly, any generic perindopril product containing the alpha crystalline form for the duration of validity of the UK part of the '947 patent.[1347] The reply by (presumably) [employee name of Servier]*, which bears a handwritten mark "*Apotex - UK*" was worded as follows: "*[Employee name of Krka]*, In response to your question, the answer is: Sorry, not for the time being".*[1348] All three documents were found during the inspection at Servier's premises.

(968) After the '947 patent was annulled by the EPO Technical Board of Appeal in May 2009, Krka received marketing authorisations for its perindopril CET products (Krka's internal denomination for non-alpha form of perindopril) in autumn 2009 and in 2010.[1349]

1341 See paragraph (911).

1342 See e.g. ID9972, p. 31, 50 - 53, 59.

1343 ID0117, p. 278.

1344 ID0478, p. 6, courtesy translation. *"Ker tudi plačevati royalty dolgoročno. Če bo ta patent alfa še ne vem koliko let, bomo morali kar dosti plačati. Je pa tudi obremenitev, mi si je ne želimo, ampak s tem pač živimo".*

1345 ID0042, p. 29 - 35.

1346 ID0102, p. 269.

1347 ID0102, p. 268.

1348 ID0102, p. 267.

1349 ID2301, p. 13.

Table 9: Overview of market entries of Krka's generic perindopril plain in selected Member States:

Member State	Date of 1st MA [1350]	First sales	Status of '947 patent at launch[1351]
CZ	4/2006	March 2006	National patent annulled 6/2010[1352]
FR	10/2006	May 2009	'947 annulled by EPO in 5/2009
HU	8/2005	December 2005	National application pending
IT	10/2006	Intention to launch 2009/2010	'947 annulled by EPO in 5/2009
NL	10/2006	November 2008	'947 annulled by UK court in 6/2008
PL	5/2006	June 2006	National application granted
UK	5/2006	May 2008	'947 annulled by UK court in 7/2007

Source: ID1307, p. 5 - 25, 99 – 100.

(969) In the UK, Krka's perindopril was only launched in July 2008 although the UK part of the '947 patent had been annulled already in July 2007. According to Krka's reply to the RFI of 29 April 2010, the patent was only invalidated at first instance and was thus legally valid and enforceable. To avoid potential damages in case the patent would be reinstated on appeal, Krka decided to wait until the final revocation by the Court of Appeal.[1353]

(970) On 8 September 2008, Krka signed another "exchange of proprietary information and non-disclosure agreement" with Servier, this time with a view to "*pursue exploratory discussions concerning a possible licensing of KRKA's intellectual Property Rights to SERVIER*".[1354] These discussions led to the conclusion of three further agreements on 29 September 2008 between Servier and Krka:

- Licence Agreement for Krka's three patent applications[1355] and regulatory dossiers for Bulgaria and Romania until 1 April 2010,[1356] whereby Krka granted an exclusive licence to Servier (even excluding Krka). The patent applications relate to possible (alternative) perindopril salts and purification of key intermediates.[1357]
- Assignment Agreement relating to Krka's patent application PCT/EP2008/058258 and regulatory dossiers for Australia (for EUR high seven digit figure) and South Africa (for EUR low seven digit figure);[1358]
- Licence Agreement for Krka's application PCT/EP2008/058258 and regulatory dossiers for Russia and Ukraine until 1 April 2010, whereby

1350 Krka's reply to question 16, ID1307, p. 64 - 67, ID4968, p. 7 - 9, ID5051.
1351 ID0746, ID0427.
1352 ID3842, p. 3.
1353 ID2301, p. 7.
1354 ID0043, p. 132 - 133.
1355 The licensed patent applications were as follows: EP 1963265, EP 1792896 (patent applications based on the patent application WO 2007/062865 concerning processes for the preparation of perindopril and salts thereof (ID0214, worksheet Question 11), and PCT/EP2008EP/058258 (patent application relates to a calcium salt of perindopril – ID0214, worksheet Question 11 and ID1307, p. 96).
1356 ID0102, p. 35 - 39.
1357 ID1307, p. 94 - 95.
1358 ID0102, p. 40 - 45.

Krka granted an exclusive licence to Servier (even excluding Krka) against a total payment of EUR [low seven digit figure].[1359]

(971) Concerning the licence agreement for Bulgaria and Romania, Krka explained that the agreements had no impact on its commercial use of the patents or on its perindopril sales, as the marketing authorisations for the non-alpha perindopril form (perindopril CET were only expected during the first half of 2010). As the '947 patent had been revoked, Krka either commenced selling or was preparing the launch of perindopril alpha in these two countries.[1360]

(972) Following the annulment of the '947 patent by the EPO in May 2009,[1361] Krka marketed non-alpha perindopril (perindopril CET) where national counterparts of the '947 patents were still valid and enforceable.[1362] Where the '947 patent or its counterparts were revoked (e.g. Czech Republic), Krka ceased paying running royalties. In Poland, Krka stopped paying running royalties mid-2009 pending the procedure for patent grant.[1363] With respect to, notably, Hungary, Krka however marketed perindopril under the Licence Agreement to avoid costs for a new marketing authorisation and costs for revocation). According to Krka, the Licence Agreement thus remains in force where national counterparts of the '947 patent are still valid.[1364]

(973) According to Servier,[1365] the exact dates of termination of Servier's settlement agreements correspond with the end of validity of the respective patents. With respect to Krka, the respective dates were 9 July 2007 for the UK, 11 June 2008 for the Netherlands, 6 May 2009 for the Member States in which the '947 patent was only invalidated on that day, and June 2010 for the Czech Republic.[1366] In Bulgaria, Estonia, Hungary, Poland and Slovakia national patents were still in force at the time and therefore no agreement termination took place.[1367]

4.3.4 Lupin

(974) This section describes the patent settlement concluded between Servier and Lupin Limited (the "Lupin Settlement Agreement"). Lupin Limited is an Indian generic producer with manufacturing plants for API and final dose products located in India. In the EEA, Lupin has a subsidiary called Lupin (Europe) Limited (both companies will be jointly referred hereinafter as "Lupin").

(975) On 30 January 2007, Servier and Lupin concluded a patent settlement covering all countries except [non-EEA jurisdiction]*. In return for a payment by Servier of EUR 40 million for the purchase of Lupin's three patent applications for perindopril, Lupin agreed to refrain from selling generic perindopril (until generic perindopril from third parties or Servier had entered the market or until expiry/invalidation of Servier's patents), and from challenging a number of Servier's patents. These applications were licenced back to Lupin. The settlement agreement furthermore

1359 ID0117, p. 160 - 164.
1360 ID1307, p. 111.
1361 Servier appealed to the EPO Enlarged Board of Appeal, which subsequently confirmed the invalidity of the '947 patent. Source: EPO.
1362 Reply to the Commission's RFI of 29 April 2010, ID2301, p. 2.
1363 ID4968, p. 3 - 4.
1364 Reply to the Commission's RFI of 29 April 2010, ID2301, p. 2.
1365 Reply to the Commission's RFI of 9 April 2010, ID2365, p. 29.
1366 ID3842, p. 3.
1367 ID2365, p. 29.

foresaw the parties to use "all reasonable endeavours" to enter into a distribution agreement, whereby Servier would start supplying perindopril to Lupin once generic perindopril from third parties or Servier had entered the market. No such agreement was subsequently reached and Lupin never entered the market with perindopril. In the course of the investigation, Servier did not provide substantiated information how it had made use of the patents acquired from Lupin.

4.3.4.1 Efforts by Lupin to enter the perindopril market

4.3.4.1.1 Initial product development

(976) Around 2002, Lupin started developing a generic version of perindopril.[1368] The development work involved the usual phases in the production of a generic product, namely the synthesis of perindopril API in the laboratory, the completion of stability and validation studies for both the API and finished dosage form (formulation), the production on exhibit batch scale, and bioequivalence studies against Servier's product.[1369]

(977) It can be inferred from the various development phases that Lupin's strategy for perindopril was to produce internally both the API and the formulation. For this purpose, Lupin developed its own processes for the manufacture of perindopril for which it filed three patent applications between February 2003 and June 2005:

- a novel process for the preparation of perindopril and salts thereof (EP 1603558, filed on 28 February 2003, published on 10 September 2004);
- a novel process for the preparation of crystalline perindopril erbumine (EP 1675827, filed on 21 October 2003, published on 28 April 2005);
- an improved process for the purification of perindopril (EP 1861367, filed on 9 June 2005, published on 21 September 2006).

(978) As will be elaborated below, these three patent applications were later assigned to Servier in the framework of the patent settlement agreement concluded on 30 January 2007.

(979) Initial contacts with Servier relating to perindopril took place through Biogaran, the generic division of Servier. On 17 September 2003, Lupin held a meeting with Biogaran. According to the minutes,[1370] signed by [employee name of Lupin]* (Lupin's [employee function]*) a number of products, including perindopril, were discussed as being in Lupin's pipeline. Servier was thus aware of Lupin's perindopril project already as of 2003.

4.3.4.1.2 Lupin's patent position

(980) Like any other API/generic manufacturer, Lupin was seeking to develop a product that would not infringe existing patent rights and could not be copied by third parties. To this end, Lupin developed a production process, which it protected by the three above mentioned process patents.

(981) Lupin sought external advice, analysed the patent situation around perindopril, and came to the conclusion that its product, when using its production process, was not

[1368] ID1039, p. 19, Lupin's reply to the Commission's RFI of 5 August 2009.
[1369] ID1039, p. 19 – 22.
[1370] ID0526, p. 10.

covered by Servier's patents. This is evidenced by a statement by one of Lupin's technical advisors, dated 8 September 2004: *"To the best of our knowledge the process employed by Lupin Ltd for manufacture of Perindopril Erbumine would not constitute an act of infringement of any of the subsisting Patents in the EU countries, a list of which is attached herewith as Annexure"*.[1371] That "Annexure" sets out three Servier patents on crystalline polymorphic forms of perindopril erbumine (alpha, beta, and gamma) and 28 process patents on perindopril. It should be noted that Servier's process patents '339, '340 and '341 do not appear in the list of patents analysed by Lupin. However, in relation to process patent '341, another email[1372] from Lupin's technical advisor to [employee name]* dated 24 February 2005 explains that the '341 patent does not claim the crystal structure, but claims the process for the preparation of perindopril, and that this process *"is entirely different from the chemistry practiced by Lupin"*. Regarding the three process patents applications, Servier itself admitted in its reply to the Statement of Objections that "**Lupin owned patents for its own process which apparently did not put it in a position of violation of Servier's process patents* ".[1373]

(982) Despite being listed in the document mentioned above, the opinions obtained from European patent attorneys between 2004 and 2006[1374] generally concurred on the potential infringement of the '947 patent by Lupin's product. An opinion of 25 September 2005 examined the majority of Servier's perindopril patents without finding a potential infringement with the exception of the '947 patent, concluding that *"the α form of Perindopril Erbumine seems to be the closest to the form produced by Lupin Ltd […]"*.[1375] Lupin claimed that *"[b]ased on this advice, it was Lupin's view that the major obstacle to entering the European markets was Servier patent 1 296 947"*.[1376] Lupin on the other hand considered that Servier's '947 patent was invalid and in November 2004 launched opposition proceedings (see further below, section 4.3.4.5.1.).

4.3.4.2 Further development of perindopril and commercial strategy

(983) By September 2004, Lupin considered itself to be at an advanced stage of the development of perindopril. This is confirmed in Lupin's correspondence[1377] with Ratiopharm for the potential supply of Lupin's product which explains with regard to perindopril "*We have a formulation at advanced stage of development. We have a NI*[1378] *statement for the API and successful pilot bio-study. We have completed API*

1371 ID5012, p. 48 – 49.

1372 ID0055, p. 78.

1373 Servier's reply to the Statement of Objections, paragraph 1253, ID10114, p. 400. Servier pointed nonetheless in paragraph 1189 of the same reply, and in its reply to the Letter of Facts (paragraph 701, ID10324, p. 188 – 189), that one document from Lupin dated January 2006 contains the sentence "*Lupin product is prima facie infringing of process patent in certain countries*" (ID6638, p. 21). This choice of wording seemingly indicates that Lupin product could at first view appear as infringing. It is however unclear to what patent and to what countries reference is made in this statement. Moreover, it remained possible to contest the validity of the process patent. For example, Lupin contested the validity of Servier's '947 patent before the EPO in 2004 and then, on appeal, in September 2006, following a favourable opinion of a patent attorney (see section 4.3.4.5.1.).

1374 ID1657, p. 1 – 8 (p. 5 – 8 further disclosed in ID10036, p. 1 – 4); ID1080, p. 1 – 2; ID1081, p. 1 – 14.

1375 ID1081, p. 13.

1376 ID1039, p. 51, reply to question 34 of the Commission's RFI of 5 August 2009.

1377 ID1487, p. 142 – 143.

1378 Non-infringement.

scale up and will take our pivotal bio-study in December. Our plan is to have a full CTD[1379] *format dossier available by May 2005".*

(984) In parallel to the development process, Lupin started to identify potential customers for the supply of perindopril.

(985) An undated presentation[1380] entitled "*Lupin (Europe) Limited – Strategic Plan 2005/06*" offers some useful insights into Lupin's commercial strategy. The document describes two options for entry to the EU generic market: direct to market or partnerships with generic companies.[1381]

(986) With regard to direct to market, this strategy was envisaged for the UK as can be seen in a presentation from [employee name of Lupin]* from January 2006 entitled "*Lupin Europe – Securing 2008/09 & Vision Plan to 2010/11*".[1382] The presentation highlights the advantages of the direct to market model and provides estimates of incremental sales forecasts for various products, including perindopril.

(987) With regard to partnerships, Lupin's Strategic Plan 2005/06 specifies that "*within Europe generic companies usually purchase a dossier and then enter a 5 year formulation supply agreement*", and further that "*the pricing for the formulation can be calculated in a number of ways (revenue share, transfer price, etc.), but the generic company usually expects 60-70% margin*".[1383]

(988) To this end, a succession of meetings took place with various generic companies, notably towards the end of 2004. Lupin's preferred option was to supply finished dose perindopril with the transfer of the dossier[1384] rather than just the API alone. On 1-2 December 2004, Lupin held a number of meetings with various generic companies concerning business opportunities including perindopril.[1385]

(989) [Name of Lupin business partner]* was one of the generic companies with whom Lupin explored possible collaboration. As of January 2005, Lupin was in negotiations with [name of Lupin business partner]* for a European deal covering perindopril. Perindopril forecasts and a draft commercial proposal were transmitted to [name of Lupin business partner]*.[1386] Those forecasts concerned the UK, Italy and Poland, but left open an option that "*other countries may be added*".

(990) On 8 February 2005, in the middle of the negotiations with [name of Lupin business partner]* and other generic companies, Lupin learned that Niche/Unichem had concluded a patent settlement agreement with Servier.[1387] A few days later, an internal communication[1388] from [employee name of Lupin]* dated 22 February 2005 questioned whether to continue with filing and launching perindopril in view of Niche's settlement and pending litigation: *"Given the position with Niche (Unichem) settling with Servier, we need to evaluate any risk in*

1379 DMF, used to apply for MA, must be prepared according to the Common Technical Document ("CTD") format.

1380 ID0522, p. 1 – 75.

1381 ID0522, p. 5.

1382 ID6638, p. 13.

1383 ID0522, p. 5.

1384 The MA dossier can be transferred to another company with the aim to change the MA holder.

1385 ID0494, p. 35; ID0527, p. 25 – 26, 30, 35 – 36, and 38.

1386 ID0494, p. 57.

1387 ID0119, p, 136 – 145.

1388 ID0055, p. 80.

proceeding with our plan to file and launch whilst not waiting for our patent challenge to be heard". [Employee name of Lupin]* assumed that if Lupin filed in France *"Servier will most likely litigate and also their chance of winning in France may be better than in the UK"*.

(991) Shortly thereafter, on 11 May 2005, Lupin received a perindopril API purchase order[1389] from [name of Lupin business partner]*. The purchase order was invoiced by Lupin to [name of Lupin business partner]* on 26 June 2005.[1390] [Name of Lupin business partner]* wanted [3.800-8.000] kg API of perindopril erbumine for exhibit batches and MAs in the EU. The order form specified: *"manufactured using a non-patent infringing process*". According to the email, [name of Lupin business partner]* had already tested three perindopril API erbumine batches from Lupin which they had found acceptable. Lupin explained it only had a small quantity in stock, so supply would have to be scheduled after receipt of order.[1391] Therefore, although it would appear that Lupin's production of perindopril API was limited, commercial collaboration with other generic companies can be observed already in 2005. As indicated, Lupin generally claimed to have a non-infringing product in its commercial contacts.

(992) Further negotiations with generic companies were held during the second half of 2005 for the EEA territory. In particular, negotiations with [name of Lupin business partner]* were resumed in July 2005. According to the minutes of a meeting that took place on 5 October 2006,[1392] [employee name of Lupin]* informed [name of Lupin business partner]* of "*Lupin's intent to initiate litigation in UK either by issuing a letter of intent to the UK courts, or by receiving national MA in UK and launching"*. This statement indicates that Lupin was considering a launch at risk[1393] in the UK.

(993) A number of forecasts of sales and gross margins prepared during 2005 placed perindopril as Lupin's expected top selling product from 2006 to 2011.[1394] In an internal Lupin communication of December 2005, perindopril-based products were included among the four products representing Lupin's best product development opportunities.[1395] This was also confirmed by subsequent documents, e.g. business plans for 2008/09 from July 2006, which show perindopril amongst Lupin's most important products.[1396] As for the envisaged geographic scope, a presentation by [employee name of Lupin]* from January 2006[1397] includes the following 14 countries for perindopril launch: "*Germany, France, Italy, UK, Spain, Hungary, Belgium, Czech Rep, Ireland, Slovenia, Slovakia,* [non-EU country], *Portugal, Poland*". Moreover, the forecast "*assumes launching at risk*".

(994) Discussions with [name of Lupin business partner]* continued during 2006. Correspondence[1398] from [name of Lupin business partner]* to Lupin on 30 March 2006 reflects negotiations on indemnity or compensation and concerns on

1389 ID0495, p. 48.
1390 Lupin is a vertically integrated company.
1391 ID0050, p. 29 – 31.
1392 ID0054, p. 136.
1393 See paragraph (75).
1394 ID0522, p. 29.
1395 ID0052, p. 39.
1396 ID0055, p. 17 – 25.
1397 ID6638, p. 19.
1398 ID0055, p. 160.

potential litigation if [name of Lupin business partner]* launched perindopril supplied from Lupin: "*The problem here is we are dealing with a lot of unknowns, particularly whether Lupin launches first in UK, whether Servier sues, whether an injunction is granted and how your invalidity application goes. At the end of the day in terms of risk, if neither party indemnifies the other, [name of Lupin business partner]* still bears the risk that its $400k + investment may lead to various MA's, but we could be taken off the market, with only termination as an option".*

(995) Despite these concerns, [name of Lupin business partner]* UK and Lupin entered into an agreement for the licence and supply by Lupin of perindopril for distribution and sale in the UK (the "UK Agreement") on 24 April 2006.[1399]

(996) Another agreement was concluded with [name of Lupin business partner]* on 27 July 2006 for the licence and supply by Lupin of perindopril for distribution and sale in the following Member States: Italy, Poland, Slovenia, Czech Republic, Hungary, Slovakia, Lithuania, Latvia, and Estonia (the "European Agreement").[1400]

(997) Discussions with [name of Lupin business partner]* also continued in the second half of 2006. In an email from 13 December 2006 to [employee name of Lupin]*, [name of Lupin business partner]* sent an updated Letter of Access request to Lupin's DMF for the following countries: "*Belgium, Czech Republic, Denmark, France, Hungry* [sic], *Ireland, Italy, Malta, Netherlands, Poland, Portugal, Slovenia, Slovak Republic, Spain, UK*".[1401]

(998) Despite numerous contacts, Lupin had, with the exception of the [name of Lupin business partner]* agreement, not concluded any other API/finished dose product supply agreements in the period up to the signature of the Settlement Agreement with Servier[1402]. It had however, as indicated, already supplied commercial quantities of perindopril API to various companies such as [name of Lupin business partner]*, and was actively searching for additional clients.

(999) In an email from 5 January 2007, [name of Lupin business partner]* announced its intention to end its perindopril partnership with Lupin.[1403] The reasons mentioned by [name of Lupin business partner]* were mostly linked to the terms offered to [name of Lupin business partner]* and the perceived risk of Lupin's regulatory approval not being ready in time for a first-mover entry by [name of Lupin business partner]*.[1404] This communication took place when the negotiations between Servier and Lupin had already started (see below paragraphs (1025) and (1026)). [Name of Lupin

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1399 ID0797, p. 84 – 114.

1400 ID0797, p. 116 – 146.

1401 ID6682, p. 48 – 55.

1402 For detailed information about Lupin's contacts regarding perindopril with API or finished dose products producers, reference is made to the list submitted by Lupin in Annex 42 of its submissions to the Commission's RFI of 5 August 2009 (ID1100, p. 1 – 18).

1403 ID8873.

1404 "*Given the current situation, this product is unlikely to be commercially viable for [name of Lupin business partner]*. In the UK there will be at least 5 other competitors which are likely to reach the market before [name of Lupin business partner]* under the current terms being offered to [name of Lupin business partner]*. As a result the price that could potentially be achieved is extremely low given the price competition which will occur. Other markets are likely to encounter the same issue*"; and "*[t]he regulatory position is still unclear and we still do not have a sufficient level of comfort that approvals will be available by the time of launch of the other competitors. As timing is absolutely critical in the generics industry being late to the market can mean that any business opportunity is lost*" (ID8873).

business partner]* in fact raised the question of an influence of the parallel negotiations with Servier on Lupin's behaviour towards [name of Lupin business partner]* (see below paragraph (1079)). The relationship between Lupin and [name of Lupin business partner]* was eventually terminated in March 2007, after the Lupin Settlement Agreement had been officially announced (see below paragraphs (1076) and (1080)).

4.3.4.3 Registration of Lupin's perindopril (up to the conclusion of the Lupin Settlement Agreement)

(1000) Lupin applied for a marketing authorisation in the UK on 17 January 2006, a year before the conclusion of the settlement agreement with Servier.[1405] At the time of filing, Lupin *"believed that its application might be expedited due to the earlier applications of other generic companies"*.[1406] In parallel, Lupin's French agent Venipharm/Hepartex prepared the application for a marketing authorisation for perindopril 2 mg and 4 mg in France.[1407] An internal presentation from January 2006 made the following assessment "*Lupin dossier complete and submitted in an equal first position*".[1408]

(1001) Following the application to the MHRA (UK marketing authorisation body), Lupin received a number of clinical and pharmaceutical questions on the bioequivalence study and the dossier. Based on Lupin's reply to the Commission's requests for information of 12 April 2013,[1409] and of 5 August 2009,[1410] the following overview of the progress of Lupin's MHRA application towards the granting of the marketing authorisation, including developments postdating the settlement agreement with Servier, can be drawn:

- Application on 17 January 2006;
- Letter of 30 March 2006, to which Lupin replied on 23 May 2006;
- Letter of 7 June 2006, to which Lupin replied on 19 September 2006;
- Letter of 22 September 2006, to which Lupin replied on 27 October 2006;
- Letter of 13 November 2006, to which Lupin replied on 28 March 2007;
- Referral to the Commission on Human Medicines on 3 July 2007;
- Submission of the results of a new bioequivalence study on 28 February 2008;
- Obtaining of marketing authorisation on 22 July 2008.

(1002) During this investigation, Lupin claimed that: "*The deficiencies cited by the MHRA [confidential] and, it was clear from approximately November 2006, that there would be a significant delay in Lupin obtaining its marketing authorisation, if it*

1405 ID1039, p. 26.

1406 ID1039, p. 26; MHRA granted the marketing authorisations for perindopril 2mg, 4mg, and 8mg on 22 July 2008. See paragraph (1089).

1407 ID1039, p. 48.

1408 ID6697, p. 19.

1409 ID9699, p. 1 – 9. The purpose of this RFI was to clarify the status of a seemingly incorrectly dated piece of evidence submitted by Lupin (see paragraph (1882)).

1410 ID1039, p. 26.

obtained a marketing authorisation at all. There were three separate stages to the delay in obtaining a marketing authorisation: clinical questions, pharmaceutical questions and referral to the Commission on Human Medicines".[1411]

(1003) Contemporaneous evidence nevertheless suggests that even after receipt of the latest request for clarification from the MHRA on 13 November 2006, Lupin internally estimated that it could be on the market in April 2007.[1412] Testing was conducted by Lupin's bioequivalence contractor Anapharm in January 2007 in order to reply to the 13 November 2006 MHRA deficiency letter.[1413] Hence, Lupin did not consider this setback insurmountable.

4.3.4.4 Servier's follow up of Lupin's activities

(1004) Inspection documents indicate that Servier had started to observe Lupin's development of perindopril early on in the process. An internal communication from [employee name]* ([employee function]* - Servier) to [employee name]* ([employee function]* - Servier) dated 21 December 2004 refers among others to Lupin as being in the process of developing generic perindopril. It is stated:[1414] *"*Note that LUPIN, an Indian company listed among the top 10 in India, possesses the Perindopril file (finished product)".*

(1005) Furthermore, internal documentation[1415] from 2006 indicates that Servier followed Lupin's patent applications, most prominently Lupin's patent application WO 2004/075889 A1 (EP 1603558 B1) as early as 2004.[1416] In the context of Servier's patent monitoring exercise, Servier took note that the EPO objected to patent EP 1603558 B1 for lack of inventive step, as the '341 patent was identified as the "*closest state of the art*". However, it is reported in September 2006 that some modifications were later introduced which made the application acceptable to the EPO. An internal Servier email[1417] dated 13 October 2004, raised doubts as to the viability of the patent application: *"*Of course nothing is being done at the moment but […] offers to make some manipulations on this coupling which seem risky to him".*[1418]

(1006) As for Lupin's patent application WO 2005/037788 A1, Servier provided with its reply to the Statement of Objections evidence of tests conducted in 2005 to check the crystalline form.[1419] The existence of this patent application was also known in an

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1411 ID1039, p. 26.

1412 ID0054, p. 144 – 148. In its reply to the Statement of Objections (paragraph 160, ID8752, p. 43), Lupin claimed that [employee name of Lupin]* had had no knowledge of the 13 November 2006 letter when drafting its note. However, given the importance of perindopril for Lupin UK, it appears implausible that such information would be withheld from the Lupin's [employee function]*. Furthermore, [employee name]*'s email makes reference to deficiencies and states "*I have made every effort to validate all of this again today*" (ID0054, p. 144). Lupin had already processed internally the letter by 14 November morning and contacted its bioequivalence study contractor Anapharm (ID9743, p. 4).

1413 ID9699, p. 7.

1414 ID0104, p. 55 – 56.

1415 ID0113, p. 65 – 71.

1416 Patent application assigned later to Servier.

1417 Oril Industrie SAS is a subsidiary of the Servier Group specialised in the manufacture of API.

1418 ID0113, p. 65.

1419 Exhibits AR – 11 and AR – 12 to the statement of the head of the Oril plant (Annex 00 – 04), ID10082 (Exhibit AR – 11), and ID10112 (Exhibit AR – 12).

expert report prepared for Servier in 2006 in the context of Servier's litigation with Krka.[1420]

(1007) Despite these critical comments (which ultimately did not prevent Servier from acquiring the patent applications allegedly with the aim of improving its own production process), Servier viewed Lupin as a potential API source to generic operators as can be inferred from a presentation by [employee name of Servier]* on 19 June 2006 during a sector management meeting entitled *"Coversyl: Defence against Generics"*. In this internal presentation dedicated to measures devised to combat generic entry (see section 4.1.2, for example, paragraph (141)) Lupin is listed as one of the potential perindopril API suppliers/developers.[1421]

(1008) Servier also followed Lupin's MA process. For example, in September 2005, Servier sent a letter to Lupin noting that it was aware of Lupin's registration plans for the UK and other countries.[1422] Also, on 4 April 2007, [employee name]* of Lupin received an email from Lupin's French agents, Venipharm/Hepartex, forwarding a letter in which Servier notified Venipharm/Hepartex that the perindopril on which it based its application for MA in France allegedly infringed Servier's patents.[1423]

4.3.4.5 Disputes and litigation with Servier

4.3.4.5.1 The EPO proceedings

(1009) Following the grant of the '947 patent to Servier on 4 February 2004 Lupin filed - together with nine other companies - a notice of opposition before the EPO on 4 November 2004[1424] demonstrating the shared conviction of the generic industry at the time that the '947 patent did not meet the patentability criteria. A patent attorney from Mewburn Ellis LLP representing Lupin proposed that the opponents "*coordinate their arguments and present a coherent case to the EPO*".[1425]

(1010) Oral proceedings were held by the EPO Opposition Division on 27 July 2006, at the end of which the patent was upheld with slightly amended claims.

(1011) With respect to the chances to appeal the decision of the EPO Opposition Division the following summary of Lupin's patent attorney opinion was sent to [employee name of Lupin]* in September 2006 referring to earlier opinions:[1426] *"(i) Letter of 20 October 2004: the opposition filed against this patent raises many points that I believe we would have made in opposition, including prior sale of perindopril erbumine in the alpha form. The arguments may succeed, but this is not certain. (ii) Letter dated 18 November 2004: The declarations (that are submitted in respect of opposition to EP 1296947) seem to present a strong case for invalidity of the opposed patent"*. In the light of this, Lupin appealed the EPO decision on 21 November 2006 together with the other opponents against the '947 patent (with the exception of Niche, which had withdrawn from the opposition procedure on 9 February 2005).

1420 Servier's reply to the Statement of Objections, Annex 10 – 04, paragraphs 23 -30, ID9063, p. 10 – 12.
1421 ID0105, p. 173.
1422 ID0104, p. 73.
1423 ID1039, p. 36.
1424 For more details, see section 4.1.2.4.2.1.
1425 ID0043, p. 197.
1426 ID5012, p. 198.

(1012) It should be noted that following the settlement between Lupin and Servier in January 2007 Lupin formally withdrew from the procedure on 5 February 2007. It is recalled that the '947 patent was revoked by the EPO Technical Board of Appeal in May 2009, which was confirmed before the EPO Enlarged Board of Appeal.[1427]

4.3.4.5.2 Litigation before the Courts in the UK

(1013) On 8 September 2005, a letter[1428] from Servier addressed to Lupin noted that Lupin was planning to obtain registration for generic perindopril in the UK and "*other European countries*", and informed that Servier was "*[…] determined to oppose any attempt to launch a generic of our drug in violation of our patent rights by all legal means*". A list of 17 patents is mentioned in this letter including patents '339, '340 and '341. It should be noted that six out of the 17 listed patents[1429] were internally classified by Servier as *"*blocking"* patents (see section 4.1.2.1.1). In this respect, Lupin contends that it had not filed any MA applications at this point in time and that *"[t]o the best of Lupin's recollection, Lupin did not respond to Servier's letter until October 2006*".[1430]

(1014) On 12 October 2006, Lupin wrote to Servier to advise that Lupin would start proceedings against Servier before the Courts in the UK for revocation of Servier's patent '947 and/or for a declaration of non-infringement.[1431]

(1015) Subsequently, on 18 October 2006, Lupin initiated patent litigation in the High Court claiming that Servier's '947 patent was invalid and seeking a declaration that the perindopril product that Lupin intended to commercialise in the UK did not infringe the UK '947 patent.[1432]

(1016) During November 2006, Lupin sent several letters to Servier informing that Lupin was confident that its method for the manufacture of generic perindopril did not fall within any claims of Servier's process patents. It required from Servier the confirmation of this view, but did not receive any reply.[1433]

4.3.4.6 Negotiations with Servier leading to the conclusion of a patent settlement agreement

(1017) The settlement negotiations between Lupin and Servier started in December 2006 and continued through January 2007, when the settlement was concluded.

(1018) An internal contemporaneous document[1434] providing an update as of August 2006 on Lupin's main products and projects observes in relation to perindopril that a few companies had developed generic versions but either had settled or were in a legal battle with Servier. It is mentioned that some companies had developed novel polymorphs but were late in developing a formulation. It was considered that Lupin *"[…] should in parallel with litigation plans add a second API source to make our offering more attractive*".

1427 Source: EPO.
1428 ID0104, p. 73.
1429 EP 1 319 668, EP 1 323 729, EP 1 354 874, EP 1 354 876, EP 1 371 659, and EP 1 403 277.
1430 ID1039, p. 35, reply to the Commission's RFI of 5 August 2009.
1431 ID1039, p. 35.
1432 ID0053, p. 89.
1433 ID0551, p. 10.
1434 ID0052, p. 32 – 35.

(1019) According to Lupin's explanations during the investigations,[1435] the perindopril project was discussed by Lupin's senior management team in November 2006. Lupin reported that the meeting raised *"the issue of Lupin's high levels of expenditure on patent litigation in relation to Perindopril and the fact that there was a strong possibility that Lupin would not have a UK marketing authorisation approved in time to be ready for launch in the event of a successful outcome in the UK proceeding. Following this meeting, [employee name of Lupin]* requested that [employee name of Lupin]* prepare a position paper setting out his thoughts on the UK market and what options Lupin had for proceeding".*

(1020) This document,[1436] collected at Lupin's premises during the inspections, is entitled *'Perindopril UK competitive Scenario'* and refers for the first time to a potential settlement with Servier. It notes the following options available to Lupin at the time (i.e., 14 November 2006):

"• Actively seek settlement with Servier:

1. Lever potential approval of Cefpodoxime Proxetil in France with Biogaran

2. File Perindopril in France ASAP

3. Advise Servier of intention to litigate in France?

• Continue litigation and seek to launch at earliest opportunity - a proposed forecast / gross margin assessment is attached assuming different scenarios

• Pull litigation and wait for market to open and ensure readiness for launch

• Seek partners for litigation cost sharing - this is considered to be remote possibility".

(1021) The document[1437] also contains an overview of the competitive scenario for perindopril in the UK, which demonstrates that Lupin followed the developments of other generic operators in the UK market closely and, in particular, the settlements concluded by Servier. Lupin takes stock of the regulatory situation (marketing authorisation granted to Apotex, Krka, and Ratiopharm; Sandoz (Apotex dossier) expected by April/May 2007; Glenmark unknown, but filed after Lupin). It transpires from the document that Lupin expected market entry for its own product in April 2007:

"The following competitors are expected to be in the market based upon different litigation outcomes:

• Non-Infringement:

Apotex, Lupin, [name of Lupin business partner] (Lupin label then switch to [name of Lupin business partner]* label) target April 1st and Sandoz (Apotex product) from July / August 07.*

Teva / GUK with Servier authorised generic.

This would result in Apotex / Lupin supplying the Chain stores (multiple retailers) as Teva /GUK would have too high cost of goods.

• Revocation:

[1435] ID1039, p. 43, reply to the Commission's RFI of 5 August 2009.
[1436] ID0054, p. 144 – 148.
[1437] ID0054, p. 146 – 147.

Krka (and Krka partners: Teva, Ratiopham, GUK), Apotex, Lupin, [name of Lupin business partner] (Lupin label then switch to [name of Lupin business partner]* label) target April 1st [emphasis added] and Sandoz (Apotex product) from July /August 07.*

Theoretically Matrix / Niche, but it is not considered they will have a license available.

Likely scenario is that Apotex / Lupin / Krka would supply Chain / Multiple pharmacies".

(1022) Only eight scenarios are presented in the document, of which four assume non-infringement and four assume revocation of relevant Servier's patents. No other outcome is mentioned. If the '947 patent was revoked, Lupin expected to have a total gross margin of EUR [3.7-10.5] million over the first three years from entry, depending on the cost of API.[1438]

(1023) Lupin also appears to be well informed of Servier's settlements with Krka, Niche, and Teva, as well as the pending MAs of its generic competitors:

"Settlements:

• Krka: agreed to withdraw litigation in English courts and not enter Western Europe markets for grant of a license to allow them to launch in CEE. It would seem the rationale for this settlement from Servier's view is that it protects the key markets where high level substitution and / or INN prescribing is prevalent (UK / France).

It seems that continuance of Servier´s GP sales force depends upon promotion of Perindopril and if the product goes generic then the probable outcome is that Servier cannot afford to maintain their sales force at present levels. By allowing Krka to enter branded generic markets of CEE it creates 'brand' competition and more controlled erosion, but does not lead to a 'land-slide' switch to generics.

Matrix / Niche: all pending regulatory activity and applications were stopped after their settlement. Licences were granted to Stada and Merck Generics in the Netherlands. There[1439] [sic: they] were switched to Krka with stability data and BE study, but are now blocked due to Krka settlement.

GUK, Ivax / Teva: settled with Servier and agreed to an authorised generic from Servier, to launch as soon as first generic enters the market. It seems early entry had been agreed and stock is held in the UK warehouses, but Servier has pulled back from allowing early entry since Krka has settled. I have learnt from within Teva that the terms are not very attractive, the transfer price and restriction on number of packs they can sell significantly reduces their competitiveness.

Ratiopharm: gave a court undertaking not to launch Perindopril until after the ruling in the Krka trial. Their approvals are based upon the Krka dossier. Now Krka have reached a settlement with Servier it leaves Ratiopharm with no clear strategy".

(1024) According to internal Servier correspondence from 29 November 2006, Discovery Pharmaceuticals (a UK health service provider for Primary Care Trusts) was

1438 ID0054, p. 144, see also p. 146-161. In another Lupin profit forecast, from July 2006, Lupin planned to achieve a gross margin of USD [4.02-6.8] million (EUR [3.18-5.38] million) on its perindopril worldwide sales in the financial year 2007/08, and USD [3.45-7.03] million (EUR [2.77-5.65] million) in the financial year 2008/09.

1439 Original wording.

contemplating cooperation with either Lupin or Apotex for the supply of perindopril following the court ruling (possibly in the Apotex case) instead of cooperation with Servier.[1440] Internal Servier correspondence reveals that, after settlements with Krka and Teva, Servier considered that there remained only two "*hostile players*", Apotex and Lupin.[1441]

(1025) During the investigation, Servier and Lupin provided inconsistent accounts as to who took the initiative of the settlement discussions.[1442] Lupin provided the following report on the negotiations with Servier leading to the conclusion of the settlement agreement: two months after the start of the patent litigation, on 18 December 2006, a Servier and a Lupin representative discussed the subject of perindopril during a dinner. As a consequence of this meeting, Lupin reported that *"A dialogue was set up between Lupin and Servier involving [employee name and function with Lupin]*, for Lupin, and [employee name]* for Servier".* A first meeting with Servier took place on 19 December 2006 to discuss the possibility of a settlement.[1443] Although not corroborated by Lupin, Servier reported that the aim of the meeting was to set up "**a commercial partnership*" and that settling was "**a necessity*" in view of this commercial partnership.[1444]

(1026) [Employee name of Lupin]* met with [employee name of Servier]* again on 9 January 2007. At this lunch meeting, [employee name of Servier]* reportedly expressed an interest in Lupin's Patent Applications.[1445] According to Servier, the question of the acquisitions was raised for the first time at this meeting.[1446]

(1027) In an email of 10 January 2007, [employee name of Lupin]* forwarded [employee name of Servier]* the details of Lupin's three patents applications.[1447] The email merely stated: *"It was a pleasure to meet you yesterday - thank you for a delightful lunch. Please see below the patent applications that may interest you*". The email additionally contained on each patent application a succinct summary encompassing title, dates of publication, filing and priority, and status of the applications. In addition, details of patentability reports were included (positive for two applications, non-existing for the third one).

(1028) During the investigation, when confronted with the question whether Servier carried out any detailed technical or commercial analysis of these three Lupin patent applications, Lupin could not point to any such analysis, but pointed out that "*Servier would have had sight of the relevant know-how associated with Lupin's patent applications/manufacturing process"* on the basis of the litigation procedure.[1448]

(1029) Servier submitted[1449] in its reply to the Commission's RFI of 7 February 2011 that the evaluation of patents or patent applications that Servier might acquire is done in an informal way, and *"*by trusting the knowledge and the expertise of key people in*

1440 ID0033, p. 56.
1441 ID0119, p. 56.
1442 Lupin's reply to the Statement of Objections, paragraph 30, ID8752, p. 14. Servier's reply to the Statement of Objections, paragraph 1144 and 1200, ID10114, p. 377 and 391.
1443 ID1039, p. 36, reply to the Commission's RFI of 5 August 2009.
1444 Servier's reply to the Statement of Objections, paragraph 1199, ID10114, p. 390.
1445 ID1039, p. 37.
1446 Servier's reply to the Statement of Objections, paragraph 1201, ID10114, p. 391.
1447 ID0055, p. 77; ID0113, p. 64.
1448 ID3592, p. 11; ID2448, p. 22.
1449 ID3842, p. 10 – 11.

the company, who are subject to the pressure induced by the negotiations, particularly in terms of deadlines, imposed by the companies holding industrial property rights. The Management has entrusted the decision to purchase patents to a small group of internal experts, belonging essentially to the Department of Technology and the Department of Patents, which are in the best position to determine the quality of the patents in question, as well as the potential interest of the invention in the context of the complex process of manufacturing perindopril".

(1030) Not only did Servier not provide any documents this group would produce, its statement is also difficult to reconcile with the oral declaration[1450] of [employee name of Servier]* made during the inspection in Servier's premises regarding the parallel acquisition of Krka's patents. *"[Commission]: [Employee name of Servier]*, do you think it is likely that an agreement with Krka has already been reached even though the feasibility studies are still ongoing? [[Employee name of Servier]*]: I find it hard to imagine that there is no clause, if indeed the case is as you describe it, which specifies that any contract signed takes effect without such analyses having been made".*

(1031) In its submission of 11 September 2009, Lupin states that "*There will have been further contact between Lupin and Servier after 10 January 2007 and prior to 26 January 2007 in respect of the broad commercial terms of the proposed settlement. However, [employee name of Lupin]* has been unable to locate any further records of such contact*". [1451]

(1032) On 26 January 2007, [employee name of Servier]* sent a draft Heads of Agreement[1452] to Lupin (dated 24 January 2006 and with the indication *"draft 1").* [employee name of Servier]* prefaced the document with the comment: "*I am not totally satisfied with it. It looks as if our lawyers have made it very complicated. In particularly [sic] the supply obligations will need to be rediscussed*".[1453] The Heads of Agreement foresaw, as regards Lupin's key obligations, to refrain from selling generic perindopril unless certain circumstances occurred, and from challenging a number of Servier's patents (allegedly) protecting perindopril.

(1033) In its submission of 11 September 2009, Lupin points that: "*One particular discrepancy between [employee name of Lupin]*'s understanding of the agreed settlement terms and the Heads of Agreement was the assignment to Servier of Lupin's three process patent applications. [Employee name of Lupin]* believed that the parties had agreed to a sole licensing arrangement*".[1454]

(1034) Handwritten notes (dated 26 January 2007) of a follow up conversation show that Servier proposed to buy the patent applications, and give Lupin a royalty free licence back.[1455] The notes also show discussion on payment by Servier and how to stagger the money transfers ("*Heads - € 10; Agreement - € 10; October - € 20*") and stresses that: "*What if the third patent is not granted - payment needs to be firm and not contingent upon approval of a patent*". It appears that there was a further discussion

1450 ID3443, p. 13.
1451 ID1039, p. 37.
1452 ID0055, p. 83 – 91.
1453 ID0055, p. 83.
1454 ID1039, p. 37.
1455 ID0052, p. 13.

on how to structure the payments, as Lupin proposed to revise the transfer dates and the payments attached to each of the patent applications:[1456]

"We realised that in the late drafting of the Agreement that the order of patent applications is not structured in the best way for either company as we are transferring the asset with the shortest life first. We would like to make a short amendment today as follows:

Currently in agreement:

First sale – WO2006: Euro 20m

Second and third sale: WO2004 and WO2005 @ EURO 10m each

Revision sought:

First sale- WO2004: Euro 20m

Second and third sale: WO2005: Euro 18m, WO2004 [sic] Euro 2m"

(1035) On 28-30 January 2007, there was an intense exchange between Servier and Lupin concerning the text of draft settlement,[1457] and the settlement agreement was signed on 30 January 2007. In the course of the Oral Hearing, Lupin mentioned that the rush in drafting the agreement was due to "*litigation being commenced in [non-EEA jurisdiction]*".[1458]

(1036) A number of differences can be observed between the Heads of Agreement and the final version of the Lupin Settlement Agreement, as described below. The Heads of Agreement contained an obligation on Lupin to destroy within 30 days all Lupin perindopril products,[1459] which disappeared in the final version of the contract (see section 4.3.4.7.1.). Clause 1.6, concerning the prohibition of Lupin's selling or offering for sale, was redrafted both as to the acts falling within such prohibition, and the temporal scope thereof.[1460] In relation to the distribution agreement, whilst the Heads foresaw a *'Purchasing Agreement'* with supply obligations requiring that *"For the duration of the Purchasing Agreement, Lupin shall not purchase any Product world wide other than Servier Product";*[1461] the signed agreement contained no reference to exclusivity (once the conditions for Lupin's launch are fulfilled), and the compromise to conclude the agreement four weeks later.

4.3.4.7 Description of the Patent Settlement Agreement (30 January 2007) and Parties' considerations for entering into the agreement

4.3.4.7.1 Terms of the agreement

(1037) The Lupin Settlement Agreement was concluded on 30 January 2007.[1462] The agreement comprised the settlement of the patent dispute (complemented by different commitments), the sale of Lupin's process patent applications to Servier, and a distribution contract for Servier's product to be signed at a later date.

(1038) The key settlement obligations for Lupin can be summarised as follows:

1456 ID0115, p. 267.
1457 ID1039, p. 37.
1458 Oral Hearing, recording of 18 April 2013, Lupin's intervention, at 01:21:10 (ID9654).
1459 Products containing as an active ingredient perindopril erbumine.
1460 ID0055, p. 85.
1461 ID0055, p. 86.
1462 ID0053, p. 89 – 94.

- Lupin and Servier settle their litigation on the '947 patent. Both parties agree to withdraw all claims in the UK and the EPO against the other party worldwide except for one non-EEA jurisdiction (Clauses 1.1, 1.2, 1.4, and 1.5).
- According to Clause 1.3, Lupin agrees not to *"directly or indirectly seek or assist or procure any third party to revoke, invalidate or otherwise challenge the Patents or any patent owned by Servier or its affiliates covering the Products in any country other than [a non-EEA jurisdiction] (the "Servier Patents")* (clauses 1.1 - 1.5 are subsequently referred to as non-challenge clause).
- According to the preamble of the Lupin Settlement, *"The Products"* are *"Pharmaceutical products containing, as an active ingredient, perindopril terbutylamine (also known as perindopril erbumine) and any salt thereof"*.
- Furthermore, according to the preamble *"the Patents"* are to be understood as the EPO Patent 1 296 947 B1, and its UK and [non-EEA jurisdiction] equivalents.
- According to Clause 1.6: *"Neither Lupin nor any of its affiliates shall directly or indirectly sell or offer for sale any Products in any country (excluding [non-EEA jurisdiction]) (a "Relevant Jurisdiction"), either by themselves or in collaboration with any third party, always provided that with effect from the date that the conditions set out in Clause 4.1(a) or (b) or (c) (or any of them) apply in respect of any Relevant Jurisdiction Lupin may sell and/or offer to sell Servier supplied Products and/or Products manufactured by Lupin or its affiliates in such Relevant Jurisdiction"*.
- Clause 4.1 sets out the conditions which need to be fulfilled so that Lupin is "*entitled to launch its own perindopril product. The (alternative) conditions are:*

  "(a) Products supplied by Servier (other than a non generic perindopril (such as Coversyl) or a generic in Servier's own name and marketed by Servier in its livery) are offered for supply or sale by a third party (other than a Servier affiliate) in that Relevant Jurisdiction; or

  (b) Servier's patent applications do not proceed to grant or any granted patents expire or are declared invalid or revoked for any reason; or

  (c) generic Products not produced by Servier are sold in a Relevant Jurisdiction other than (i) where Servier has applied for an injunction to prevent such sale and such application has not been rejected by the relevant courts; and (ii) such generic Product is not being sold in breach of any injunction applying in such Relevant Jurisdiction".

(1039) In other words, Lupin could start marketing its own perindopril in the respective jurisdiction if and when (1) an authorised generic is on the market, (2) all relevant patents expire, or (3) an independent third party sells perindopril and Servier does not request interim injunctions against such a sale.

(1040) The Lupin Settlement Agreement also contained the acquisition of Lupin's IPRs as follows:

- Servier purchases Lupin's three process patent applications[1463] for EUR 40 million:
  - WO 2004/075889 (EP 1603558 B1 – "*A Novel Process for the Preparation of perindopril and salts thereof*") for EUR 20 million,
  - WO 2006/097941 (EP 1861367 A – "*An improved process for the purification of perindopril"*) for EUR 10 million, and;
  - WO 2005/037788 (EP 1675827 A1 – "*A Novel Process for the Preparation of Crystalline Perindopril Erbumine*") for EUR 10 million.
- Lupin explicitly gives no assurance on the status (i.e., whether the patents are non-infringing), and validity of those patent applications (i.e., whether the patent applications will ultimately be granted) (Clause 3.1).
- Servier licences those three patent applications back to Lupin on a non-exclusive, non-transferable, non-sublicensable, royalty free, perpetual and irrevocable licence for the manufacture of perindopril under those patents applications (Clause 3.1).

(1041) The payment for and assignment of the three patent applications is staggered in time: first application by 2 February 2007, second and third applications by 1 October 2007. In inspection materials, two invoices of payments to Lupin have been found.[1464] The Lupin Settlement Agreement also foresees that Lupin and Servier conclude a distribution arrangement within four weeks following the conclusion of the settlement agreement. The key clause relating to the supply/distribution arrangements to be concluded can be summarised in the following way:

- "*Servier also irrevocably agrees to sell Products to Lupin for marketing, sale and distribution in any Relevant Jurisdiction if the following circumstances apply in such Relevant Jurisdiction (but not otherwise)*" (Clause 4.1). The circumstances are equal to those referred to in clause 1.6 explained above and which would trigger the possibility for Lupin to sell its own product.
- "*The parties agree to use all reasonable endeavours within 4 weeks of the date of signing of this Agreement to enter into a supply agreement to reflect the terms of Clause 4.1*". Servier will apply its standard conditions of sale (Clause 4.2).
- Lupin agrees not to actively sell or promote Servier's products to (Clause 4.3):

  "(a) customers located outside a Relevant Jurisdiction in so far as they are located in any territory exclusively reserved to Servier or allocated by Servier on an exclusive basis to another distributor; or

  (b) to a customer group in so far as they are reserved to Servier or allocated by Servier on an exclusive basis to another distributor, and for

1463 Additional source: EPO.

1464 ID0103, p. 131, ID0055, p. 159.

the avoidance of doubt Servier's distributors in a Relevant Jurisdiction comprise a customer group".

(1042) The Lupin Settlement Agreement contains a number of common clauses. The following are the most significant for the analysis of the settlement.

- Lupin is not restricted from seeking in its own name marketing authorisations for the manufacture and sale of perindopril anywhere in the world including countries in which Servier has applied or secured the grant of patents (Clause 5).
- Clause 7 establishes that the different parts of the agreement constitute an entire agreement.
- Clause 13 lays down that *"Unless expressly specified otherwise, each party agrees to bear its own costs in relation to the Dispute, including the drawing up of this Agreement".*

4.3.4.7.2 Parties clarifications of certain terms of the Lupin Settlement Agreement

(1043) The definition of the notions of "*Servier Patents*" and "*The Products*" as contained in the Lupin Settlement Agreement has led to diverging interpretations by the parties. Both parties argue ambiguity in the wording.[1465] A clear understanding of these terms is necessary to determine the scope of the non-challenge provision, and the obligation to abstain from selling its product.

(1044) As to the definition of "The Products", Lupin clarifies that this notion covers not only perindopril erbumine, but also "*any alternative salt of Perindopril*" including Servier's arginine salt.[1466] This would mean that Lupin could not sell perindopril erbumine and/or arginine for as long as their patent protection was valid (expiry date for perindopril arginine: 17 February 2023, unless annulled earlier), or an independent/authorised generic entered the market with that product. This interpretation is not necessarily in line with Servier's explanation which refers to "**any tert-butylamine salt*".[1467] As pointed out by Servier,[1468] the Heads of Agreement actually left less scope for ambiguity than the final Lupin Settlement Agreement, as they referred to "*perindopril erbumine and any combination containing perindopril erbumine (howsoever manufactured)*".[1469] What motivated this change is not substantiated. Servier clarified during the investigation that "**it was undoubtedly a drafting error*" due to the "**extreme conditions*" of the short timeframe for drafting between the Heads of Agreement and the Agreement itself.[1470]

(1045) As to the definition of patents covered by the agreement, when the parties were asked to explain their interpretation of the concept of "*Servier Patents*", Servier specified that the term would not cover the '873 patent for the arginine salt. Only patents related to perindopril erbumine would be covered, according to this *ex post*

1465 See, for instance, Servier's reply to the Statement of Objections, paragraph 1372, ID10114, p. 425; and Lupin's reply to the Statement of Objections, paragraph 264, ID8752, p. 67.

1466 ID2448, p. 18. Lupin's interpretation is confirmed by evidence from 2008 submitted at a later stage by Servier (Annex 10 – 01 to Servier's reply to the Statement of Objections, ID9063).

1467 ID3842, p. 11; and ID2365, p. 35.

1468 Servier's reply to the Statement of Objections, paragraph 1228, ID10114, p. 395.

1469 ID0055, p. 85.

1470 Servier's reply to the Statement of Objections, paragraph 1218, footnote 1304, ID10114, p. 393.

clarification by Servier.[1471] Similarly, the Heads of Agreement left less scope for ambiguity than the final wording, as they referred to "*the UK Patent and its foreign equivalents*".[1472]

(1046) Lupin seems to take a broader view and considers that the concept of "*Servier Patents*" includes, in addition to the '947 patent, Servier process patents '339, '340 and '341, and the patent '873 on the arginine salt. [1473]

(1047) As regards the notion of "*Servier's patent applications*" and "*any granted patent*" contained in clause 4.1(b), and directly referred to in clause 1.4., Servier clarified: "**the use in clause 4.1(b) of the undefined 'Servier's patent applications' and 'any granted patents' is imprecise. Instead of these terms, the clause should have referred to 'Servier Patents' in the specific jurisdiction ('Relevant Jurisdiction') – see the first sentence of clause 4.1*".[1474]

(1048) Lupin on the other hand focuses on the non-infringing nature of its own perindopril products and states[1475] that it could enter the market *"[…] immediately following the expiry, revocation, declaration of invalidity or non-grant of any patent or patent application owned by Servier that affected the way that Lupin manufactured and sold its own Perindopril product".*

4.3.4.8 Parties' considerations for entering into the Lupin Settlement Agreement

4.3.4.8.1 Ex post explanations concerning the Lupin Settlement Agreement

(1049) Contemporaneous evidence, including evidence *in tempore non suspectu*, on Lupin's and Servier's considerations to enter the Lupin Settlement Agreement was not submitted by the parties, nor was it found during the inspections.

(1050) Lupin described during the investigation its considerations to conclude the Lupin Settlement Agreement as follows:[1476]

"By the time Servier and Lupin met in late 2006, it had become clear that Lupin would not have its marketing authorisation and/or any finished product ready to launch pending the outcome of the UK Proceedings. […] Lupin had received a further deficiency letter from the MHRA in November following the commencement of the UK proceedings. Given the need to conduct retesting, which Lupin had diligently commenced as soon as it was aware of the deficiencies in its original methodology, Lupin felt that its chances of obtaining a marketing authorisation before the conclusion of the UK proceedings were virtually non-existent. Lupin felt that the arguments regarding the validity of Servier's patents were more than adequately covered by Apotex in the UK and the other parties before the EPO. These factors made continuing with the proceedings an unattractive proposition for Lupin.

Meanwhile, the UK Proceedings were proceeding at a rapid pace with the trial scheduled for 12 March 2007. This is largely due to the UK High Court Rules regarding the quick and efficient resolution of cases in the Court. Separately, there were non-extendable deadlines for filing the Appeal Brief in the EPO on 1 February 2007. Lupin did not wish to be put to the effort and expense of preparing

1471 ID5064, p. 2.
1472 ID0055, p. 85.
1473 ID3592, p. 14.
1474 ID2365, p. 36.
1475 ID2448, p. 19.
1476 ID1039, p. 42 – 43.

and filing these documents if it became unnecessary. For these reasons, Lupin was interested in coming to an early resolution of the issues.

Lupin considered the settlement with Servier because the conditions for entry allowed Lupin to enter the market sooner than it was then entitled to under the prevailing patent situation (see, for example, Clauses 4.1(c) and 1.6 of the Settlement Agreement)".

(1051) In its reply to the Statement of Objections, Lupin further explained that "*it became increasingly apparent that there was no possibility of Lupin entering as a first-mover generic (or even as one of the first few generic suppliers on the perindopril market). The fact that Lupin knew that it would not be able to compete with Servier on the perindopril market, even if successful in the litigation, inevitably affected Lupin's view of the benefits of proceeding with the litigation and of its perindopril project more generally"*.[1477] Lupin also stated that Apotex would "*have certainly entered the market first*", and would have benefited "*from "free-riding" on Lupin's litigation. It would have been Apotex, therefore, that would have gained the first-mover advantage, at Lupin's expense*".[1478]

(1052) In its reply to the Commission's RFI of 5 August 2009, Lupin concludes that due to the problems in obtaining MA and in the production of generic perindopril, the Lupin Settlement Agreement has had no practical or commercial consequences for Lupin's ability to develop, manufacture or market perindopril in the EEA.[1479] Lupin also explained that the reason for the staggered transfer "*was to assist Servier by splitting the consideration to be paid in respect of the three patent applications, pursuant to the terms of the Settlement Agreement, over two financial years*".[1480]

(1053) Lupin acknowledged that "*[t]he assignment of Lupin's three process patent applications was an integral part of the settlement discussions*".[1481] Lupin moreover described the payments received from Servier as "settlement monies" or "settlement sums".[1482] Servier, on the contrary, denied that any of the settlements would depend on the assignment of the IPRs.[1483]

(1054) Servier explained to the Commission that *"*[i]n the case of Lupin, we thought it was worthwhile acquiring certain patent applications held by Lupin, given the potential usefulness of the processes concerned in the context of improving our manufacturing processes […]*"; and it made the following claims for specific applications:[1484]

*"** Lupin - WO 2004 075889: method of coupling the two key intermediates to allow access to the Perindopril base. This method relates to a stage in the process that preceeds the salification.*

Desired objective: optimisation of the synthesis of perindopril base to ultimately gain both the tert-butylamine salt and the arginine salt.

1477 Lupin's reply to the Statement of Objections, paragraph 26, ID8752, p. 13.

1478 Lupin's reply to the Statement of Objections, paragraph 32, ID8752, p. 14.

1479 ID1039, p. 44.

1480 ID3592, p. 10 (Lupin's reply to the Commission's RFI of 14 February 2011).

1481 ID1039, p. 58.

1482 ID1039, p. 37, 39, 58.

1483 *"*None of the settlement discussions in which Servier participated depended on the allocation of intellectual property rights by the other party. Servier decided whether to settle or not in the light of a comprehensive analysis […]".* ID1151, p. 17 – 18.

1484 ID1151, p. 24.

** Lupin - WO 2005 037788: method for the preparation of a crystalline form of perindopril tert-butylamine.*

Desired objective: optimisation of the purification process and possible reduction of the time of crystallisation of perindopril tertubutylamine.

** Lupin - WO 2006 097941: purification process of perindopril through a new salt, which then makes it possible to isolate the Perindopril base and to subsequently access the tertbutylamine salt or the arginine salt.*

Desired objective: optimisation of the perindopril purification process".

(1055) Additionally, in its reply to the Commission's RFI of 16 January 2009, Servier explains[1485] that "**Alternative purification methods, in particular recrystallisation in Dimethoxyethane (Lupin WO 2005/037788A1), would be of great help for the success of this future optimisation*". However, in the same document Servier states[1486] that "*[it] *could not identify within the time requested documents on the value of the LUPIN patent applications acquired* ". As of March 2011, Servier has not been able to provide concrete evidence of the use given to Lupin's patent applications. Servier has reported that its industrial manufacturing processes do not currently use Lupin's patent applications, which are used for research and development purposes.[1487]

(1056) With respect to the licence back to Lupin of the IPRs, Servier explains that "**it is not the result of a "reasoning" of our company but a requirement of LUPIN"*.[1488] Servier also explained that it did not request any transfer of know-how for the patent applications from Lupin, as it had sufficient internal competences to test the acquired rights.[1489]

(1057) In Servier's views the court proceedings on-going prior to the conclusion of the Lupin Settlement Agreement (i.e., the grant of the interim injunctions against Krka, and the EPO decision maintaining the '947 patent) could have influenced Lupin's decision to settle ("**the court decisions against Krka could have prompted Lupin to settle*")*.*[1490]

4.3.4.8.2 Costs reported by the parties (perindopril development and litigation)

(1058) In terms of costs, as at 30 January 2007, Lupin reports to have incurred the following external costs in the development of perindopril:[1491]

1) S Majumdar & Co. fees for preparing Lupin's patent applications: Rs.[875,000-1,600,000]

2) Mewburn Ellis LLP fees for opposition of third party patent applications: €[7,200-13,300]

3) Bioequivalency studies:

a) Anapharm: US $[335,000 – 615,000]

1485 ID0376, p. 7.
1486 ID0376, p. 8.
1487 ID3842, p. 10.
1488 ID1151, p. 27.
1489 ID5064, p. 3.
1490 ID1151, p. 17.
1491 ID1039, p. 49 - 50.

b) World Courier fees: Rs. [21,000 – 38,000]

c) BA Research USA Study: US £ [sic] *[80,000 – 145,000]*

d) BA Research Indian Study: Rs. [1,340,000 – 2,475,000]

e) Lotus Labs: Rs. [755,000 – 1,395,000]

4) Regulatory costs in the UK including:

a) MHRA Filing Fees: £[28,000 – 50,000]

b) JKE Solutions Readability Testing: £[3,860 – 7,130]

(1059) Lupin explains in the same document that "*itself had spent Rs. [5,470,000 – 10,110,000] on materials required in the production of exhibit batches […]. At the time this work was undertaken, Lupin did not have a system for recording its time spent per project. Therefore, Lupin is unable to provide cost information relating to its own internal costs of developing Perindopril*".

(1060) For litigation related to perindopril, Lupin reports the following: for the UK litigation GBP [310 000 – 570 000] of external costs and for the EPO Opposition EUR [25 000 – 46 000].[1492]

(1061) In its reply to the Commission's RFI of 6 August 2009, Servier identified the cost of UK litigations[1493] in the proceedings with Lupin (settled before the hearing in the main proceeding), which amounted to EUR 224,080.

4.3.4.9 Developments after the Lupin Settlement Agreement

(1062) The first consequence of the Lupin Settlement was the discontinuation of the pending litigation/EPO proceedings. On the day of the signature of the Lupin Settlement, Bristows faxed to SJ Berwin a letter enclosing a consent order to be filed in the High Court discontinuing Lupin's claim and Servier's counterclaim in the UK litigation.[1494] Furthermore, on 5 February 2007 Lupin withdrew formally from the opposition procedure against the '947 patent before the EPO.

4.3.4.9.1 Failure to conclude the supply agreement foreseen in the Lupin Settlement Agreement

(1063) According to the Lupin Settlement Agreement, the companies agreed to use all reasonable endeavours to enter into a supply agreement within 4 weeks following the settlement agreement of 30 January 2007. A draft of a (non-exclusive) purchasing agreement for the UK was prepared by Servier and sent to [employee name of Lupin]* on 27 July 2007, i.e. 21 days after the judgement annulling the '947 patent by the Court of Appeal in the Apotex case.

(1064) As to why discussions were not held within the four weeks as envisaged, "**Servier did not find any evidence explaining why the distribution agreement was not negotiated within four weeks following the settlement agreement, as provided for therein. Lupin does not seem to have contacted Servier about this matter"*.[1495] Servier puts forward two explanations: Lupin's focus on its own regulatory application, and the shifting timing of the Apotex litigation. Servier speculates that discussions started

1492 ID1039, p. 51.

1493 ID1144.

1494 ID1039, p. 38.

1495 Servier's reply to the Statement of Objections, paragraphs 1297 – 1298, ID10114, p. 408 – 409.

again at the end of June 2007, "*possibly owing to the imminent conclusion of the dispute between Apotex and Servier and to the fact that the Lupin's regulatory difficulties seemed to worsen at this time*".

(1065) According to the draft agreement, Servier would appoint Lupin as its distributor for perindopril in the UK under Lupin's own livery and trade name following the "*First Distribution Date"*. It also stipulates payment from Lupin to Servier for the purchase of products (Reconciled Price).[1496] The "Floor Price" was 2 GBP (two pounds) per pack. The First Distribution Date is defined as the earliest of the following three dates:

"1.3.1 The date on which the patent EP 1 296 947 ceases to be in force as a result of revocation;

1.3.2 the date on which a third party commence distribution of a Product (as defined below) in the United-Kingdom with the consent of SERVIER;

1.3.3 the first date on which all of the following events have occurred:

- 1.3.3.1 a final determination has been made of the proceedings, including any appeal, brought by SERVIER and SERVIER Laboratories Limited against Apotex Inc […]in the UK High Court (Case No HC06C03050) (the "Judgment");

- 1.3.3.2 the Judgment lifts any orders previously imposed by the UK Courts injuncting the disposal of generic perindopril by Apotex in the UK; and

- 1.3.3.3 following the Judgment, Apotex has commenced distribution of generic perindopril in the UK; and

- 1.3.3.4 LUPIN is authorized by the competent authorities to market the Product in the Territory using its own livery and has Products with LUPIN own livery ready to be commercialised in the Territory".

(1066) The preamble and clauses 2.4 and 4.7 of the draft agreement stipulate that Lupin will purchase all requirements for perindopril and formulations containing perindopril API from Servier, and will not enter the market with any other perindopril formulation.

(1067) According to the documents collected at Lupin's premises during the inspection,[1497] Lupin considered that the company was free to launch their own product if the conditions of clause 4.1 (triggering the distribution rights) were fulfilled. Lupin explained to the Commission that "*Clause 4.1(b) allowed Lupin to launch its Perindopril product immediately following the expiry, revocation, declaration of invalidity or non-grant of any patent or patent application owned by Servier that affected the way that Lupin manufactured and sold its own Perindopril product…*"[1498]

(1068) This is in keeping with [employee name]* (Lupin) reply to Servier[1499] in August 2007: "*I notice that the preamble, Clauses 2.4, 4.7 etc propose that Lupin will purchase all requirements from Perindopril and formulations containing Perindopril API from yourselves and that we will not enter the market with any other*

1496 ID0055, p. 138 – 155.
1497 ID0055, p. 136 – 137.
1498 ID4977, p. 15.
1499 ID0033, p. 66 – 67.

Perindopril formulation. I believe this is contrary to our present agreement as Lupin has not given up the right to market our own product".

(1069) In its reply of 28 August 2007, [employee name of Servier]* informed Lupin that having discussed with its lawyers, Servier did not observe any contradiction with the Lupin Settlement Agreement.[1500]

(1070) There is no further contemporaneous explanation available from any party on the issue. However, during the investigation, Servier explained that [employee name of Servier]*'s letter merely meant that the parties are contractually free to agree upon an exclusive distribution arrangement, whilst Lupin's interpretation of the Lupin Settlement Agreement is that a UK revocation of the '947 patent in July 2007 would trigger at the same time Lupin's rights to distribute a product supplied from Servier (clause 4.1 of the Lupin Settlement Agreement) and its own product (clause 1.6 of the Lupin Settlement Agreement).[1501]

(1071) From a presentation[1502] by [employee name of Lupin]* in the internal strategy meeting of 5 October 2007, it can be inferred that Lupin was uncertain about when and how its own generic version of perindopril would be launched. In the presentation, all sales forecasts are provided with and without perindopril launch. Lupin retained the two options: to launch its own perindopril product or to sell perindopril as Servier's authorised generic. Lupin's strategy was to conduct negotiations with Servier while in parallel pursuing its efforts for its own applications ("*We are discussing authorised generic with Servier for Perindopril. This in no way however detracts from the need to expedite our own approval*").[1503]

(1072) Lupin continued discussions with Servier for the distribution of the authorised generic until June 2008.[1504] By that time it became clear that the supply agreement would finally not be concluded, and the discussions on the distribution agreement ended without result.

(1073) As to the reasons, Lupin explains: "*However, by early 2008, Lupin perceived that it was close to being able to enter the UK market with its own product in the light of the revocation of the UK patent and the fact that Lupin considered that it was close to obtaining a marketing authorisation for its own product. Therefore, the negotiations between Lupin and Servier ended without the conclusion of a supply agreement after Lupin received its marketing authorisation*".[1505] Another reason for the failure to conclude an agreement was, according to Lupin, Servier's insistence that Lupin should take exclusive supply of Servier's products "*to the exclusion of Lupin's own product*".[1506]

(1074) Servier presented the following as the reasons for the failed negotiations: "**However, after weeks of negotiations, the parties could not reach agreement on the economic*

1500 ID0055, p. 136.

1501 ID2448, p. 19.

1502 ID0055, p. 62 – 75.

1503 ID0503, p. 31. This email contrasts with the email, sent on the same day also by [employee name of Lupin]* (ID0051, p. 10) stating that: "*[t]his is high priority*", on which Servier relies to argue that: "**the achievement of the supply agreement had apparently even become a priority within Lupin*" (Servier's reply to the Statement of Objections, paragraph 1300, ID10114, p. 409).

1504 Servier's reply to the Statement of Objections, Annex 10 – 03, ID9063.

1505 ID1039, p. 59.

1506 ID1039, p. 45.

conditions of this supply (price, etc.) and Lupin launched its own perindopril generic".[1507]

(1075) Lupin did not conclude a distribution agreement with Servier for any of the other markets in which it would – by now – be entitled to market perindopril on the basis of a distribution agreement.

4.3.4.9.2 Public announcement of sale of Lupin's IPRs and reactions by customers

(1076) Lupin publicly announced the sale of its IPRs to Servier on 20 February 2007.[1508]

(1077) Following the announcement of the IPRs sale to Servier, a number of generic companies contacted Lupin with concerns about access to Lupin's perindopril API. For example, Mr Allen from [name of Lupin business partner]* stated in internal communication[1509] dated 23 February 2007: *"Servier buying up the alternative source of perindopril-INCLUDING OURS!"*. Subsequently, [name of Lupin business partner]* asked to [employee name of Lupin]* to *"[…] please confirm by return that this will in no way affect Lupin's undertakings to supply [name of Lupin business partner]* with this API for its European […] markets"*.[1510] [Employee name]* replied that Lupin's sale of IPRs to Servier had no impact on Lupin's commercialisation plans for perindopril, and that "*we remain ready to supply you API for […] Europe […], taking cognisance of existing patent rights"*.[1511]

(1078) [Name of Lupin business partner]* explained that although Lupin had indicated that it would be able to deliver [30-60] kg of API in December 2007, it only received [15-45] kg in September 2008.[1512] According to [name of Lupin business partner]*, [0-10] kg of the delivered API failed quality testing of the product. The quantity received was substantially below what [name of Lupin business partner]* had forecasted for the UK and French markets. Lupin's API price was USD [15 000-25 000] per kg. As a result, [name of Lupin business partner]* *"[…] used the API purchased from Lupin for supply into France during July, August and September 2009 and negotiated an alternative arrangement for supply from [company name]* on more economic terms for ongoing supply"*. Nevertheless, as explained below (see paragraphs (1099) and (1100)), Lupin indicated in March 2011 that it had a commercial collaboration with [name of Lupin business partner]* whereby Lupin supplied perindopril API to [name of Lupin business partner]* for their European finished product needs.

(1079) Similarly to [name of Lupin business partner]*, a communication[1513] from [name of Lupin business partner]* of 27 February 2007 states "*I can only assume (and hope) that this is a very recent decision by Lupin and is motivated by a) another positive hearing for Servier in the UK courts […] b) failure to secure other partners to participate in litigation - and that their previous reticence over IP disclosure was not being influenced by parallel discussions with Servier??*".

(1080) Shortly thereafter, in April 2007, a settlement agreement was concluded between [name of Lupin business partner]* and Lupin which terminated the two 2006

1507 ID2365, p. 36.
1508 ID0085, p. 39.
1509 ID0055, p. 26.
1510 ID0055, p. 26.
1511 ID0055, p. 26.
1512 ID1571, p. 21, reply to the Commission's RFI of 5 August 2009.
1513 ID0050, p. 81.

distribution agreements described in section 4.3.4.2. (in particular, paragraphs (995) and (996)).[1514] As a settlement payment, [name of Lupin business partner]*, which wanted to terminate the contracts, agreed to pay a sum. This sum was in addition to what [name of Lupin business partner]* had already paid under the UK agreement, which it was agreed Lupin was entitled to retain and not refund as a result of a termination clause.[1515] As to the reasons for the termination of the agreements Lupin explained that: "*In early January 2007, [name of Lupin business partner]* advised that it no longer wished to continue with the partnership as it did not view it as a commercially viable arrangement based on when it would be able to enter the market"*.[1516]

(1081) On 18 April 2007, an Indian newspaper, The Economic Times, reported about the acquisition of Lupin's patent applications by Servier. The press article reads:[1517] "*Grappling with escalating research and development costs and ever-rising generic competition, pharma companies are adopting increasingly innovative strategies to protect their turf in the market. In yet another attempt by big pharma to delay the entrance of generic players in the market, France's Servier Laboratories has acquired IP-related rights on Perindopril, better known in Europe under its brand name Coversyl, from domestic pharma company, Lupin"*.

(1082) In the same article [employee name and function with Lupin]*, is quoted to have said: "*Although Servier's original patent on Perindopril has expired in most European countries, this move will allow the French company to prevent generic players from entering the market and continue to enjoy exclusivity*".

(1083) The article also mentioned that Lupin expected to enter the market with Lupin's version of perindopril before the end of 2007, and that "*as Servier Laboratories and Lupin will be sharing exclusivity in the market, pricing pressure should remain limited*".

(1084) Lupin explained that a letter was sent to the newspaper to clarify the misunderstanding created by [employee name of Lupin]'s* declarations, and provided an unsigned copy thereof, bearing no company headers, address, dates, reference numbers, or other distinctive features.[1518] In a later reply,[1519] Lupin submitted that it had been unable to locate the original signed letter and does not believe it received any response from The Economic Times. Lupin reports that the letter was hand-delivered by an employee of Lupin's (then) Public Relations advisers, to The Economic Times on 19 April 2007. Lupin has been in contact with its former adviser, who has provided[1520] a statement confirming that the letter was hand-delivered and that the text of the letter (signed by [employee function with Lupin]*) was as provided[1521] to the Commission.

1514 ID0053, p. 24 – 26.
1515 ID0053, p. 25.
1516 ID1100, p. 12, its reply to the Commission's RFI of 5 August 2009. See also paragraph (999).
1517 ID5007, also accessible at http://articles.economictimes.indiatimes.com/2007-04-18/news/28476199_1_coversyl-desh-bandhu-gupta-domestic-pharma.
1518 ID1681, p. 1, Annex 44 of Lupin's reply to the Commission's RFI of 5 August 2009.
1519 ID2448, p. 11, reply to the Commission's RFI of 14 July 2010.
1520 ID2461, p. 1 – 2.
1521 ID2461, p. 3.

(1085) However, the article in an unchanged form was still available online on the website of The Economic Times in 2011.[1522]

(1086) In relation to patent application WO 2004/072889 – which was transferred on 30 January 2007; by August 2007, Servier had not taken any steps to register it in various jurisdictions to show Servier as the proprietor, and Lupin complained by letter regarding Servier's inaction.[1523]

(1087) In a general email communication[1524] of 12 October 2007 to Lupin's personnel, [employee name and function with Lupin]* commented in relation to the Press Release: 'Lupin sells additional Perindopril patents to Servier' that: "*It gives me great pleasure to announce that we have received an additional 20mn euros from Servier for sale of additional patents. Will make for this year being stellar also'.* This attitude is fully consistent with the performance review of [employee name of Lupin]* who personally negotiated the agreement with Servier. The review drafted by [employee name and function with Lupin]*, states: "*[i]n Q3'07[cit] we decided to pursue a transaction with Servier to sell our IP. [Employee name of Lupin]* pursued Servier, presented the IP and Lupin's position and negotiated what turned out to be the largest deal for the company".*[1525]

4.3.4.9.3 Own product launch and Dossier/API supply to others

4.3.4.9.3.1 Own product launch

(1088) After the conclusion of the Lupin Settlement Agreement, Lupin was actively seeking to complete the MA procedure in the UK which underwent, according to Lupin's submissions, several additional delays. Lupin explained that the most significant delay arose out of a referral from the Pharmaceutical Assessor to the Commission on Human Medicines.[1526] The referral took place on 3 July 2007, i.e. approximately five months after the conclusion of the settlement.

(1089) After additional requests regarding the summary of product characteristics and patient information leaflet, marketing authorisation was finally granted on 22 July 2008 for perindopril 2 mg, 4 mg, and 8 mg.[1527] In addition, on 4 March 2008, Lupin applied in the UK for marketing authorisation for perindopril 4 mg + Indapamide 1.25 mg, which was granted on 30 March 2010.[1528]

(1090) In France, following analysis due to deficiencies in the bioequivalence study, the AFSSAPS, the French MA body, granted Venipharm/Hepartex (Lupin's agent in France) a MA for perindopril 2 mg and 4 mg on 9 July 2008,[1529] and for perindopril 8 mg on 2 September 2009.[1530] Lupin informed Servier in a letter dated 17 March 2009[1531] of its intention to launch in France, as Sandoz had already launched a generic on the market. Lupin "*did not believe there is any proper reason for Servier to object*" but asked "*if Servier disagrees, please provide a full*

1522 ID5007.
1523 ID5016, p. 1 – 2.
1524 ID0055, p. 156.
1525 ID1688, p. 3.
1526 ID1039, p. 26 – 27.
1527 ID1039, p. 28.
1528 ID2448, p. 16.
1529 ID1039, p. 25.
1530 ID2448, p. 16.
1531 ID1076, p. 1.

explanation of its position within 14 days". [Employee name]* from Servier replied by letter dated 31 March 2009 that "*the perindopril product Sandoz has placed on the market in France does not contain the alpha polymorphic form of perindopril erbumine and does not infringe any of our patents*".[1532]

(1091) Subsequent to the grant of the MAs, Lupin reported that it became aware of problems in the manufacturing process, which would require an amendment to Lupin's MAs in France and the UK:[1533]

"Lupin had three batches of plain Perindopril manufactured for a January 2009 launch in the UK. […] The UK regulatory requirements demand that this change in process be cleared with the MHRA which requires the filing of a variation of Lupin's marketing authorisation".

(1092) It appears that the problems concerned Lupin's manufacture of formulations and not the API.[1534]

(1093) Lupin reports that the launch of its generic perindopril was further complicated by difficulties in producing enough perindopril to successfully launch the product in Europe. Capacity problems in the Indian manufacturing plants for different "prils"[1535] resulted in changes in production plans, which delayed perindopril launch. However, it appears that the company intended to expand the production of perindopril, and that the development of "prils" was an important strategic goal.[1536]

(1094) Internal correspondence[1537] in June 2008 shows that, at the time, the perindopril production capacities were concentrated on fulfilling a long standing order by [name of Lupin business partner]* of perindopril API. The mail of [employee name of Lupin]* reads: *"There will be none for the UK DTM* [Direct To Market] *and no more plans for extra API till 2009*".[1538]

(1095) Lupin finally explained in March 2011[1539] that "*the work required to finalise the variation application has been pushed out in lieu of other more important projects which Lupin considers to be of higher commercial importance. Lupin believes there are very limited commercial opportunities for its Perindopril final product in the UK and elsewhere in Europe […] hence why applying to vary the Marketing Authorisation in the UK is not a commercial priority*". Consequently, Lupin is not on the market in the EU with generic perindopril as a finished dose product.

4.3.4.9.3.2 Dossier/API supply to others

(1096) Apart from preparing its own launch, from 2007 Lupin continued to look for commercial partners mainly through negotiations with other generic companies for the supply of perindopril. For example, a few days after the signature of the Lupin Settlement Agreement, on 12 February 2007, Lupin made a commercial proposal[1540] to a generic company for a licensing and supply agreement regarding perindopril

1532 ID1077, p. 1.
1533 ID1039, p. 25, 29, reply to the Commission's RFI of 5 August 2009.
1534 ID4977, p. 15.
1535 The word "prils" is used by Lupin to refer to perindopril and other products whose names also end in "pril", see ID0524, p. 111 and 171.
1536 ID0524, p. 111 and 171.
1537 ID0524, p. 287 – 291.
1538 ID0524, p. 291.
1539 ID3592, p. 9.
1540 ID0502, p. 70 – 71.

(4 mg and 8 mg tablets) for Hungary. The proposal included the transfer of the product dossier for submission to the marketing authorities and the supply of perindopril API.

(1097) Most of Lupin's contacts did not result in the conclusion of contracts. However, Lupin reported to have concluded two agreements on product dossier licensing and the supply of finished Lupin's formulations for perindopril.[1541]

(1098) Lupin explains[1542] that a generic company filed its own application for a marketing authorisation under the national procedure in Bulgaria based on the same Lupin dossier. Regarding the sale of its finished dose product, Lupin states that "*Lupin does not require approval of its UK or French variations in order to sell its finished dosages in other Member States. These require marketing authorisations in the relevant Member State*".

(1099) With respect to API supply, Lupin reported to have provided commercial quantities only to [name of Lupin business partner]* for its European needs, and development or lab quantities to various EU companies.[1543]

(1100) In relation to [name of Lupin business partner]*, Lupin has clarified[1544] that [name of Lupin business partner]* can use Lupin's API and sell the final product produced by [name of Lupin business partner]* (utilising Lupin's API) in other Member States without the approval of the variations required by the UK and French marketing authorisation bodies. Lupin explains that *"[t]his is because the variations relate to Lupin's finished product not [name of Lupin business partner]'*s finished product"*.

(1101) [Name of Lupin business partner]* requested Letters of Access to Lupin's DMF for several Member States.[1545] However Lupin does not know with certainty if [name of Lupin business partner]* is present on those markets. According to [name of Lupin business partner]*, as the perindopril prices in the UK fell due to generic competition, it was no longer economical to launch in the UK with Lupin API. It used Lupin API for supply into France in July-September 2009.[1546]

1541 ID3592, p. 15, reply to a Commission's RFI of 14 February 2011.
1542 ID4977, p. 17.
1543 ID3592, p. 15.
1544 ID4977, p. 18.
1545 See paragraph (997).
1546 ID1571, p. 21.

5 ASSESSMENT OF PATENT SETTLEMENT AGREEMENTS BETWEEN SERVIER AND ITS COUNTERPARTIES UNDER ARTICLE 101 OF THE TREATY

(1102) As a matter of principle, patent holders are free to rely on their patents to exclude competitors from practising the patent invention. Companies are generally entitled to settle litigation, including patent litigation. Patent settlements often benefit both the parties to the dispute and, more generally, society, by allowing for a more efficient allocation of resources than if litigation were to be pursued to judgement. The vast majority of patent settlement agreements between competitors do not raise antitrust concerns. There is no presumption that patent settlements between competitors are antitrust infringements. Where such patent settlements comprise a value transfer from the originator to the generic company, this value transfer must be carefully analysed pursuant to the test set out below in paragraph (1154). An infringement of Article 101 can be envisaged only where the transfer of value represents a significant inducement which substantially reduced the incentives of the generic undertaking to pursue its independent efforts to enter the market. Any finding of an antitrust infringement by a patent settlement depends on the specific circumstances of the case.

(1103) This part will first set out a general assessment of reverse payment patent settlements, and outline the relevant legal framework for such agreements. Second, the common part will be complemented by a specific analysis of each of these agreements in relation to Article 101 of the Treaty, based on the above description of relevant facts.

5.1 General competition law assessment of patent settlement agreements

5.1.1 Restrictions of competition by object under Article 101(1) of the Treaty

(1104) Article 101(1) of the Treaty prohibits all agreements between undertakings "*which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market*". Agreements explicitly prohibited by Article 101(1) include those which "*limit or control production, markets, technical development, or investment" or "share markets or sources of supply*".

(1105) In order for there to be an agreement within the meaning of Article 101(1) of the Treaty it is sufficient that the undertakings in question should have expressed their joint intention to conduct themselves on the market in a specific way.[1547] An agreement within the meaning of Article 101(1) of the Treaty can be regarded as having been concluded where there is a concurrence of wills on the very principle of a restriction of competition, even if the specific features of the restriction envisaged are still under negotiation.[1548] The concept of a concerted practice refers to a form of coordination between undertakings which, without being taken to the stage where an

[1547] Judgment of 17 December 1991, *Hercules Chemicals* v *Commission* T-7/89, ECR, EU:T:1991:75, paragraph 256; and Judgment of 20 March 2002, *HFB and Others* v *Commission*, T-9/99, ECR, EU:T:2002:70, paragraph 199.

[1548] See, to that effect, Judgment of 20 March 2002, *HFB and Others* v *Commission*, T-9/99, ECR, EU:T:2002:70, paragraphs 151 to 157 and 206.

agreement properly so called has been concluded, knowingly substitutes for the risks of competition practical cooperation between them.[1549]

(1106) In this respect, Article 101(1) of the Treaty precludes any direct or indirect contact between economic operators of such a kind as either to influence the conduct on the market of an actual or potential competitor or to reveal to such a competitor the conduct which an operator has decided to follow itself or contemplates adopting on the market, where the object or effect of those contacts is to restrict competition.[1550]

(1107) As the Commission's Guidelines on the application of Article 81(3) [now Article 101(3)] of the Treaty state: *"A general principle underlying Article 81(1)* [now Article 101(1) of the Treaty] *which is expressed in the case law of the Community Courts is that each economic operator must determine independently the policy which he intends to adopt on the market".*[1551] *"The type of co-ordination of behaviour or collusion between undertakings falling within the scope of Article 81(1) is that where at least one undertaking vis-à-vis another undertaking undertakes to adopt a certain conduct on the market or that as a result of contacts between them uncertainty as to their conduct on the market is eliminated or at least substantially reduced. It follows that co-ordination can take the form of obligations that regulate the market conduct of at least one of the parties as well as of arrangements that influence the market conduct of at least one of the parties by causing a change in its incentives".* [1552]

(1108) The agreements that are subject to this Decision clearly constitute agreements in the sense of Article 101(1) of the Treaty and they contain a concurrence of wills with respect to the future commercial behaviour of the generic undertaking in question. As the analysis of each of the agreements will show, the obligations which the generic undertaking accepted in each of the agreements restricted their ability to enter the market and thereby their autonomy of decision-making, and eliminated or substantially reduced commercial uncertainty for Servier with respect to the future competitive behaviour of the generic undertaking for the duration of the agreement in question.

(1109) The anti-competitive object and effect of an agreement are not cumulative but alternative conditions for assessing whether such an agreement comes within the scope of the prohibition laid down in Article 101(1) of the Treaty.[1553]

(1110) Restrictions "*by object*" are those which, "*by their very nature*", can be regarded as being injurious to the proper functioning of normal competition.[1554]

(1111) In order for an agreement to be regarded as having an anti-competitive object, it is sufficient that it has the potential to have a negative impact on competition. In other

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1549 Judgment in *Commission* v *Anic Partecipazioni*, C-49/92 P, EU:C:1999:356, paragraph 115; and Judgment in *Hüls* v *Commission*, C-199/92 P, EU:C:1999:358, paragraph 158.

1550 See, to that effect, Judgment in *Commission* v *Anic Partecipazioni*, C-49/92 P, EU:C:1999:356, paragraphs 116 and 117.

1551 *Commission Notice: Guidelines on the application of Article 81(3) of the Treaty*, OJ C 101, 27.4.2004, page 97, point 14.

1552 *Commission Notice: Guidelines on the application of Article 81(3) of the Treaty*, OJ C 101, 27.4.2004, page 97, point 15.

1553 Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 55.

1554 Judgment in *Miller v Commission* 19/77, EU:C:1978:19, paragraph 7; and Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 17.

words, the agreement must simply be capable in an individual case, having regard to the specific legal and economic context, of resulting in the prevention, restriction or distortion of competition within the internal market.[1555]

(1112) It is settled case-law that, for the purpose of the application of Article 101 of the of the Treaty, there is no need to take into account the actual effects of an agreement which has as its object the prevention, restriction or distortion of competition within the internal market. Consequently, it is not necessary to show actual anti-competitive effects where the anti-competitive object of the conduct in question is proved.[1556] According to the Court of Justice in *Expedia*, "*an agreement that may affect trade between Member States and that has an anti-competitive object constitutes, by its nature and independently of any concrete effect that it may have, an appreciable restriction on competition*".[1557]

(1113) The assessment of the specific settlement agreements in this Decision will be structured in keeping with settled case-law. In order to assess if an agreement involves a restriction by object, regard must be had *inter alia* to the content of its provisions, the objectives it seeks to attain and the economic and legal context of which it forms a part.[1558] When determining that context, it is also appropriate to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question.[1559] In addition, although the parties' intention is not a necessary factor in determining whether an agreement involves a restriction of competition by object, there is nothing prohibiting the Commission or the Courts of the Union from taking that aspect into account.[1560] Thus the anti-competitive object of an agreement may be deduced not only from the content of its clauses but also from the intention of the parties as it arises from the "*genesis*" of the agreement and/or manifests itself in the "*circumstances in which it was implemented*" and in the "*conduct*" of the companies concerned.[1561]

1555 Judgment in *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, paragraph 31; and Judgment in *Allianz Hungária Biztosító and Others*, C-32/11, EU:C:2013:160, paragraphs 35-38.

1556 Judgment in *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, paragraph 31; Judgment in *Allianz Hungária Biztosító and Others*, C-32/11, EU:C:2013:160, paragraphs 28-30; and Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 55.

1557 Judgment in *Expedia*, C‑226/11, EU:C:2012:795, paragraph 37.

1558 See, to that effect, Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 25; and Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraphs 16 and 21.

1559 Judgment in *Allianz Hungária Biztosító and Others*, C-32/11, EU:C:2013:160, paragraph 36 and the case-law cited there.

1560 See, to that effect, Joined Judgments in *IAZ v Commission*, 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82, EU:C:1983:310, paragraphs 23-25. See also Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 58.

1561 See Joined Judgments in *IAZ v Commission*, 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82, EU:C:1983:310, paragraphs 23-25. See also, Judgment in *Société Technique Minière v Maschinenbau Ulm*, 56/65, EU:C:1966:38; Joined judgments in *CRAM v Commission*, 29/83 and 30/83, EU:C:1984:130, paragraph 26; and Opinion of Advocate General Tizzano delivered on 25 October 2005 in Judgment in *General Motors*, C-551/03 P, EU:C:2006:229, paragraphs 77-78, and case-law cited there.

(1114) The parties argue that the objective aim of the settlement agreements was merely to resolve disputes between the parties, to set up a supply relationship, safeguard access to markets etc.[1562] However, the fact that an agreement may also have had other, entirely legitimate objectives does not bar the possibility of finding a restriction by object. In *Irish Beef*, the Court of Justice confirmed that:

"an agreement may be regarded as having a restrictive object even if it does not have the restriction of competition as its sole aim but also pursues other legitimate objectives".[1563]

(1115) Likewise, in the BAT judgment, the ECJ considered the application of Article 101 of the Treaty to delimitation agreements, which generally serve to amicably resolve disputes on the scope of the parties' trade mark rights. The ECJ held that "*such agreements are [not] excluded from the application of Article [101] of the Treaty if they also have the aim of dividing up the market or restricting competition in other ways. As the court has already stated [in the Consten and Grundig case], the Community system of competition does not allow the improper use of rights under any national trade mark law in order to frustrate the Community's law on cartels"*[1564]

(1116) In addition, a restriction by object is not necessarily obvious[1565] because there is no restriction by object without individual and specific examination of the content and objective of the agreement and the legal and economic context of which it forms a part.[1566]

(1117) As Advocate General Trstenjak stated in the *Irish Beef* case: "*…it is clear that the category of restrictions of competition by object cannot be reduced to agreements which obviously restrict competition.[…] In my view, the notion of restriction of competition by object cannot be reduced to an exhaustive list either. The words 'in particular' in Article 81(1) EC [now Article 101(1) of the Treaty] make clear that the restrictions of competition covered by Article 81(1) EC are not limited to the restrictions of competition mentioned in Article 81(1) (a) to (e) EC. Therefore, the*

1562 For example, Lupin's reply to the Statement of Objections, paragraphs 236-241, ID8752, p. 61-62, Niche's Statement of Objections, ID8524, p. 51, Servier's reply to the Statement of Objections, paragraph 733, ID10114, p. 280, Krka's reply to the Statement of Objections, paragraph 146, ID8742, p. 74. These arguments are further addressed in sections 5.1.5 and 5.7.

1563 Judgment in *Beef Industry Development and Barry* Brothers, C-209/07, EU:C:2008:643, paragraph 21. See also Joined Judgments in *IAZ v Commission*, 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82, EU:C:1983:310, paragraph 25.

1564 Judgment in *BAT v Commission*, 35/83, EU:C:1985:32, paragraph 33.

1565 The parties suggest that agreements qualified as restrictive by its very object typically contain obvious restrictions of competition, for which extensive experience shows that they invariably produce anticompetitive effects. (for example, Teva's reply to the Statement of Objections, paragraph 487, ID8495, p. 104, Niche's reply to the Statement of Objections, ID8524, p. 46, Matrix's reply to the Statement of Objections, paragraph 4.10, 4.11, ID8835, p. 42). Concerning Teva's claim that such agreements should have no material prospect of enhancing competition, the Commission considers that it does not accurately reflect the structure of Article 101 of the Treaty, according to which even restrictions by object can be exempted under Article 101(3) of the Treaty. (see, for example, Judgment of 15 July 1994, *Matra Hachette v Commission*, T-17/93, ECR, EU:T:1994:89, paragraph 85).

1566 See the judgment of 29 November 2012, *CB v Commission*, T-491/07, ECR, EU:T:2012:633, paragraph 146, no official English translation available yet. Informal translation: *"*With respect, firstly, to the applicant's argument that the measures in question do not contain any obvious restriction of competition, it must be recalled that Article 81(1) EC does not refer to the notion of obvious restriction".*

notion of restriction of competition by object cannot be limited to the examples cited in Article 81(1) (a) to (c) EC either".[1567]

Patent settlement agreements fall under the purview of Article 101 of the Treaty

(1118) Patent holders are free to rely on their patents to exclude competitors from practising the patented invention.[1568] Undertakings are also generally entitled to settle litigation including patent litigation. Patent settlements may benefit both the parties to the dispute and, more generally, society, by allowing for a more efficient allocation of resources than if all litigation were to be pursued to judgment.[1569]

(1119) However, the case-law shows that holders of IPRs, including patent rights, are not immune from the application of competition law. From early on the Court of Justice has pointed out that "*[a]lthough the existence of rights recognized under the industrial property legislation of a Member State is not affected by Article 85 of the Treaty [now Article 101 of the Treaty], the conditions under which those rights may be exercised may nevertheless fall within the prohibitions contained in that Article. This may be the case whenever the exercise of such a right appears to be the object, the means or the consequence of an agreement".*[1570] More recently the Court has instead referred to the concept of the subject-matter of the intellectual or industrial property right in question.

(1120) The subject matter of a patent has been defined in the following way: "*In relation to patents, the specific subject matter of the industrial property is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third*

1567 Opinion of Advocate-General Trstenjak delivered on 4 September 2008 in Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraphs 47-48. An example of a restriction by object that was not obvious can be found in *Judgment Pierre Fabre Dermo-Cosmétique*, C-439/09, *EU:C:2011:649*, in which the Court of Justice held: *"In the light of the foregoing considerations, the answer to the first part of the question referred for a preliminary ruling is that Article 101(1) of the Treaty must be interpreted as meaning that, in the context of a selective distribution system, a contractual clause requiring sales of cosmetics and personal care products to be made in a physical space where a qualified pharmacist must be present, resulting in a ban on the use of the internet for those sales, amounts to a restriction by object within the meaning of that provision where, following an individual and specific examination of the content and objective of that contractual clause and the legal and economic context of which it forms a part, it is apparent that, having regard to the properties of the products at issue, that clause is not objectively justified".* Judgment in *Pierre Fabre Dermo-Cosmétique*, C-439/09, EU:C:2011:649, paragraph 47.

1568 Save for vexatious litigation (see Judgment of 17 July 1998, *ITT Promedia v Commission*, T-111/96, ECR, EU:T:1998:183, paragraph 60, and Judgment of 13 September 2012, *Protégé International v Commission*, T-119/09, ECR, EU:T:2012:421, paragraph 49). It is emphasised that, contrary to what Servier argues in its reply to the Statement of Objections (paragraphs 196-197, ID10114, p. 101), the Commission never contested the legitimacy of Servier's infringement suits in the Statement of Objections or this Decision.

1569 See for example, European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, paragraph 707; Servier's reply to the Statement of Objections, paragraph 182, ID10114, p. 117-118.

1570 See, for example, Windsurfing, para 45. Notwithstanding this, the distinction between existence and exercise of rights and the application of the concept of subject-matter are expressions of the same conceptual approach. The concept of subject-matter is an expression of the reasoning that for each intellectual property right it is possible to identify a number of core rights which the owner of that right enjoys under national law and whose exercise is not affected by the Treaty rules. See the Opinion of Advocate General Gulmann of 1 June 1994 in joined Judgments in *RTE and ITP v Commission*, C-241/91 P and C-242/91 P, EU:C:1994:210, paragraph 31.

parties, as well as the right to oppose infringements". [1571] In Windsurfing International case, in the context of a contractual obligation on a licensee not to challenge the validity of licensed patents, the Court of Justice found that such a non-challenge clause *"clearly does not fall within the specific subject-matter of the patent, which cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity".*[1572] The Court of Justice thus prohibited as unlawful a non-challenge clause in a license agreement, because that clause eliminated the possibility that legal actions could be brought against the licensed patent, which in turn represented a possibility of competition unrestrained by a given patent.[1573] There are various other examples of cases in which the Courts of the European Union considered that agreements concerning intellectual or industrial property rights are subject to Union competition law and may infringe Article 101(1) of the Treaty.[1574]

(1121) The 'right to oppose infringements' is a unilateral right of the patent holder which flows directly from the intellectual property in question. It covers the right to warn other undertakings who risk infringing one's patent of the existence of such patent and the exclusionary rights it entails. It also includes, based on the procedural instruments provided for in the applicable national legal framework, the right to initiate infringement proceedings before national courts, including requests for interim injunctions to avert imminent infringements of a granted patent, and requests for damages to repair the injury caused to the patent holder by an infringement of a patent or patent application. However, a patent's validity can be challenged and the competent court or as the case may be, the competent patent office, may find it invalid. Similarly, it is for the competent courts to determine if a patent has been infringed.

(1122) The Court of Justice has also recognised that agreements to settle patent litigation can fall within the prohibition of Article 101(1) of the Treaty: *"In its prohibition of certain 'agreements' between undertakings, Article 85(1) makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind".*[1575] Even if they may be encouraged as a matter of public

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1571 Judgment in *Centrafarm BV and Others v Sterling Drug*, 15/74, EU:C:1974:114, paragraphs 7 to 9. Reference for a preliminary ruling.

1572 Judgment in *Windsurfing International v Commission*, 193/83, EU:C:1986:75, paragraph 92. This was reiterated by Advocate General Darmon in Judgment in *Bayer v Süllhöfer*, 65/86, EU:C:1988:448, paragraph 7 ("*the [non-challenge clause] has the concrete effect, erga omnes, of reducing the chances that a 'doubtful' patent will be revoked*").

1573 The Court of Justice did not examine whether such challenge would have actually happened and would have been successful.

1574 See, for example Joined Judgments in *Grundig v Commission of the EEC*, 56/64 and 58/64, EU:C:1965:60, paragraph 346; Judgment in *Keurkoop v Nancy Kean Gifts*, 144/81, EU:C:1982:289, paragraphs 24, 26; Judgment in *Ottung v Klee & Weilbach and Others*, 320/87, EU:C:1989:195, paragraphs 13 and 18; Judgment in *Deutsche Grammophon v Metro SB*, 78/70,EU:C:1971:59, paragraph 6; Judgment in *Sirena v. Eda*, 40/70, EU:C:1971:18, paragraph 5; and Judgment in *BAT v Commission*, 35/83, EU:C:1985:32, paragraph 33.

1575 Judgment in *Bayer v Süllhöfer*, 65/86, EU:C:1988:448, paragraph 15. See also Judgment in *BAT v Commission*, 35/83, EU:C:1985:32, paragraph 33. In the latter case, the ECJ acknowledged that so-called *delimitation* agreements resolving trade-mark related disputes may be *"lawful and useful"* as they are *"intended to avoid confusion or conflict between [the parties]"*. However, the Court concluded that *"such agreements are [not] excluded from the application of Article [101] of the Treaty if they also have the aim of dividing up the market or restricting competition in other ways. As the court has already stated [the Consten and Grundig case], the Community system of competition does not allow*

policy and the vast majority do not raise competition law issues, patent settlement agreements between actual or potential competitors can fall within the prohibition of Article 101(1) of the Treaty, and there is no presumption of validity of settlements for this reason.[1576] Thus, such agreements do not provide immunity from competition law because they concern a patent or the settlement of a dispute.

(1123) It follows that while undertakings who are actual or potential competitors may reach agreement on their patent disputes just as they may conclude other kinds of agreements, in doing so they must respect Union competition law.

(1124) Prior to examining the specific facts of each of the settlement agreements pursuant to the elements identified in paragraph (1113), the Commission will first make some general observations concerning the competitive process in the pharmaceutical industry, particularly as concerns competition between originator and generic undertakings, and the legal and economic context relevant for the assessment of patent settlements (section 5.1.2), followed by a framework for assessing whether the parties were actual or potential competitors in view of the nature and functioning of pharmaceutical markets (section 5.1.3), the content of the agreement, including the specific restrictions on the generic companies' behaviour and the nature of the benefit they received in return (section 5.1.4), as well as the allegations made by the parties to the proceedings regarding the qualification of the agreements as restrictions by object in accordance with Article 101(1) of the Treaty (section 5.1.5).

5.1.2 Patent settlement agreements can be restrictions of competition by object

Generic competition and patents in the pharmaceutical industry

(1125) In the pharmaceutical sector, potential generic competition starts when generic companies that want to launch a generic medicine upon expiry of the exclusivity on the compound patent begin developing commercially viable technologies for production of the API and the finished product. The agreement-specific assessments in sections 5.2 - 5.6 will show that the investigated generic companies had invariably put in place strategies to enter the market with generic perindopril. They had invested several years of time and extensive resources in product development, including resolving regulatory and patent barriers. While, as the parties claim, entry into the market for perindopril was difficult as a result of the number of patents protecting Servier's product, it was by no means impossible. Servier itself acknowledged, in relation to the UK, that "**a key element of the economic context was that in 2006 Servier considered the entry of generic perindopril on the market to be eventually possible' and that such entry 'could take place in three ways, by way of generic companies launching a product infringing Servier's patents 'at risk' […] (without Servier being able to procure an injunction), following the revocation of the '947 patent by the EPO, or, lastly, through the development by certain generic companies of a version of perindopril which would not infringe Servier's IPRs.*"[1577]

(1126) Thus, the generics were perceived as a source of competitive pressure by Servier. At the same time, once the compound patent and data exclusivity had expired and generics could obtain MA through the abbreviated procedure, generics were a source of competitive pressure on their generic rivals, as they compete to be the first to

the improper use of rights under any national trade mark law in order to frustrate the Community's law on cartels".

1576 See Servier's reply to the Statement of Objections, ID10114, paragraph 43.

1577 Servier's reply to the Statement of Objections, para 657 and footnote 759, ID10114, p. 258.

bring to the market a generic version of the originator's product. The status of first generic entrant is often associated with high profit margins, until such time as other generics also enter the market and generic competition intensifies. This "first mover advantage" explains the willingness of API producers and generic undertakings to make certain investments and accept certain risks (including the risk of infringing patents held by the originator firm).

(1127) The originator has a strong incentive to protect its product exclusivity from generic entry, as its market position can otherwise erode rapidly. To confront generics upon expiry of the compound patent, originators often put in place strategies to create and enforce a comprehensive set of additional patents protecting other aspects of the product (production process, forms, formulations etc.).

(1128) The onset of first projects to develop generic perindopril can be traced back to 1999, or 4 years before the compound patent expired in the majority of Member States.[1578] In the very same year, Servier recognised the threat that generic entry could not be averted with the then existing patent portfolio, and devised a manifold strategy to confront generic entry. This strategy also comprised reinforcing Servier's patent portfolio by over 30 patents protecting certain manufacturing processes and crystalline forms. But in principle, perindopril could be commercialised if the generic companies respected the existing patents, and received marketing authorisation.

(1129) Competitive pressure is obviously stronger after the expiry of the compound patent, even if the originator company still enjoys some protection by a number of other patents. Such patents offer more limited protection than the compound patent as their scope only extends to the specific form or formulation, or to the manufacturing process covered by the patent (including any products directly obtained from them). As the General Court stated for a formulation patent in *AstraZeneca*: *"the ability of a formulation patent to confer exclusivity on a product is not equivalent, in any event, to that of a substance patent, since an active substance can be incorporated into different formulations"*.[1579] Servier also acknowledged this: "**The compound patent (including the Supplementary Protection Certificate) expired in 2003-2005 in most countries of the European Union. Although Servier's turnover was up, it was obvious for Servier that the entry of generics in one or more European markets was inevitable in the short or medium term, given the many possible synthesis routes of perindopril. Thus, it was obvious for Servier that sooner or later the relative protection – albeit legitimate – conferred by the patents would no longer provide Servier exclusivity with regard to sales of perindopril"*.[1580]

(1130) During product development, generic companies typically examine options to increase the likelihood that the product would overcome the entry barriers, notably patent barriers, by reducing, to the extent possible, the risk that a given product infringes a known patent. In addition, by complying with regulatory requirements needed to obtain an MA, generics try to overcome that barrier, too. Generic

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1578 As was the case with [company name]* (see paragraph (247) and Niche/Unichem and Matrix (see paragraph (423)).

1579 Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 607 The same reasoning applies to patents for manufacturing processes, specific forms of API etc. Servier itself acknowledges that patents for new chemical entities confer stronger protection than other product patents (for example for new pharmaceutical formulations) or process patents, which only offer limited protection. See ID0114, p. 130.

1580 Servier's reply to the Statement of Objections, paragraph 1366, ID10114, p. 424.

companies developing perindopril were confronted with the remaining Servier patents, in particular the '947 patent and some of the process patents, as a possible obstacle to their entry. But, the investigated generic companies sought to overcome these entry barriers by challenging the infringement and/or validity of these patents (by way of EPO opposition or court actions/counterclaims for annulment), and/or were facing patent enforcement by Servier.

(1131) In the pharmaceutical sector, patent challenges are an essential, and at times unavoidable, part of the competitive process both for generic companies seeking market entry for their essentially similar medicines and for originator companies that invoke process patents or other patents against such market entry. The Commission's 2009 inquiry into the pharmaceutical sector found that generic companies won 62% of all patent litigation cases that resulted in a ruling.[1581] In such a situation, competition – actual or potential – from generic undertakings trying to enter the market by inventing around the outstanding process and other patents, having to defend themselves against alleged infringement, seeking declarations of non-infringement or trying to invalidate process patents or other patents still held by the originator undertaking, or indeed by generic entry at risk, is the essence of competition in this sector. Denying that in such situations potential competition exists would amount to denying the existence and thriving of the generic pharmaceutical industry and of the competitive pressure it exerts on the originator industry when expiry of exclusivity looms.

(1132) Preventing patent challenges, whether in the form of pre-litigation disputes, court litigation, or opposition procedures may therefore seriously impact the competitive process as they are frequently the very expression of competition to enter the market with a cheaper, generic product.[1582] In *Windsurfing International*, the Court of Justice confirmed that "*it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error*".[1583] For example, when confirming the annulment of Servier's '947 patent, the Court of Appeal (Civil Division) felt the need to stress the importance of an effective legal review of patents: "*[The '947 patent] is the sort of patent which can give the patent*

1581 For secondary patents (defined as patents protecting all other aspects relating to a pharmaceutical product but the active ingredient), the corresponding figure was 74%. Out of all litigation cases (comprising both compound and secondary patents) in which a final judgment was given on the issue of the validity of a given patent, the court revoked the patent in 55% of cases and upheld it in the remaining 45%. For litigation initiated by originator undertakings, 32% of the judgments found the invoked patent not to be infringed, and in an additional 12% of cases the court annulled the invoked patent. (European Commission, DG Competition: *Report on the pharmaceutical sector inquiry*, 8 July 2009, pages 11, 237-240). Servier notes that, concerning process patents, they were more often upheld as valid than revoked (in 22% compared to 18% of all litigation). This is correct but the difference is not very significant and it says little about generic companies' chances to prevail in litigation concerning process patents, where they were successful in 69% of cases (patent not infringed in 49%, upheld yet non-infringed in 2%, and revoked in 18% of all litigation cases).

1582 Servier's reply to the Statement of Objections is inconsistent in criticising the Commission for considering litigation as a normal component of pharmaceutical companies activities, and of competition. According to one statement by Servier, litigation should be seen as a pathologic dimension of company life (paragraph 947, ID10114, p. 331). This however contradicts Servier's description of generic companies as the "**patent dispute professionals*" (paragraph 1900, ID10114, p. 544), which in the Commission's view correctly acknowledges that patent challenges belong to core activities of generic companies. Resorting to legal mechanisms provided by the patent system, both to assert patent rights, and to defend itself against such assertions, is not pathological.

1583 Judgment in *Windsurfing International / Commission*, 193/83, EU:C:1986:75, paragraph 92.

system a bad name. I am not sure that much could have been done about this at the examination stage. There are other sorts of case where the Patent Office examination is seen to be too lenient. But this is not one of them. …The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest"[1584] (emphasis added).

Patent settlements with a payment or other significant value transfer may affect generic companies' incentives to compete

(1133) Where parties can reasonably disagree on the validity of a particular patent or whether that patent has been infringed and there is genuine uncertainty as to the outcome of litigation, it can be reasonable to reach a patent settlement, notwithstanding the utility of having judicial decisions.

(1134) However, the Commission considers that, depending on the specific circumstances of the case, a patent settlement agreement by which a generic company accepts restrictions on its ability and incentives to compete in return for a value transfer (either in the form of significant sums of money or another significant inducement) can be a restriction of competition by object contrary to Article 101 of the Treaty.

(1135) The parties claim that the restrictions in the investigated settlement agreements in no way deviate from non-compete and non-challenge clauses inherent to any settlement agreement.[1585] While similar obligations may indeed be used both in settlements with and without a value transfer, one cannot draw any inferences from this fact without examining the actual context in which such a settlement came about, including the relationship between the parties, the manner in which the restrictions were obtained, and the overall balance of contractual rights and obligations.

(1136) When in a patent dispute or patent litigation, a settlement is reached on the basis of each party's assessment of the patent case before them, such a patent settlement is unlikely to infringe competition law even though it may contain an obligation on the generic undertaking not to use the invention covered by the patent during the period of patent protection (e.g. a non-compete clause) and/or an obligation not to challenge the patent concerned in court (e.g. a non-challenge clause).[1586] Although in such a

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1584 See paragraph (187). The judgment adds that the enforcement of the '947 patent by Servier was in principle not unlawful, except possibly under competition law: "*It is right to observe that nothing Servier did was unlawful. It is the court's job to see that try-ons such as the present patent get nowhere. The only sanction (apart, perhaps, from competition law which thus far has had nothing or virtually nothing to say about unmeritorious patents) lie in an award of costs on the higher (indemnity) scale if the patent is defended unreasonably*".

1585 See, for example, Servier's reply to the Statement of Objections, paragraphs 43 and 44, 980-983, ID10114, p. 78, 339-340, Lupin's reply to the Statement of Objections, paragraphs 253-260, 265-270, ID8752, p. 64-68, Niche's reply to the Statement of Objections, ID8524, p. 84, Krka's reply to the Statement of Objections, paragraph 104, ID8742, p. 54-55.

1586 Compare in this respect, point 209 of the *Commission Notice: Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*, OJ C 101 of 27.4.2004, which states: *"In the context of a settlement and non-assertion agreement, non-challenge clauses are generally considered to fall outside of Article 81(1). It is inherent in such agreements that the parties agree not to challenge ex post the intellectual property rights covered by the agreement. Indeed, the very purpose of the agreement is to settle existing disputes and/or to avoid future disputes"*. The parties argue that the Technology Transfer Guidelines apply to the assessment of agreements in the present case (for example, Lupin's reply to the Statement of Objections, paragraph 239, 265-266, ID8752, p. 61, 67-68, Servier's reply to the Statement of Objections, paragraph 387, ID10114, p. 181, Matrix' reply to the Statement of Objections, paragraph 3.18, ID8835, p. 33, Krka's reply to the Statement of Objections,

case certain limitations on the commercial behaviour of the generic undertaking are agreed between the parties to the patent dispute, they directly and exclusively result from the strength of the patent litigation case, as perceived by each party and are not the result of an additional transfer of value from the originator to the generic.

(1137) The situation is very different when such a result is achieved where the generic parties' incentives to independently compete have been affected by elements extraneous to the dispute/litigation. This is notably the case where the originator pays significant sums of money, or offers other compensation (for example, a market sharing arrangement), to the generic company as consideration for a significant restriction of the generic company's commercial behaviour, limiting its independent efforts to enter one or more EU markets with a generic product (a "reverse payment" situation).[1587] This is not foreseen by the patent system. While a patent holder has the right to oppose possible infringement of its patent, patent law does not provide for a right to pay actual or potential competitors to stay out of the market or to refrain from challenging a patent prior to entering the market.[1588] The means used by patent holders to defend their rights matter. It is not because the patent, if valid and infringed, grants the patent holder certain rights to exclude that any means used to obtain the exclusionary result would necessarily be compatible with competition law.[1589] In particular, payments made by patent holders to generic challengers aimed

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paragraph 124, ID8742, p. 62-63). On the contrary, these Guidelines only apply to agreements that transfer technology, such as agreements licensing patent rights, as the provisions they contain are based on a specific balance between the pro-competitive effects of licensing and possible restrictive effects (see point 9 of the Guidelines). The agreements covered by this Statement of Objections did not include any enabling transfer of Servier's technology to the generic undertakings concerned for the restricted markets. Moreover, the Guidelines analyse non-challenge obligations on a stand-alone basis, and not in combination with other elements, such as the existence of a payment in consideration for the obligation. The Commission clarifies that the Commission Notice: *Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*, OJ C 101 of 27.4.2004, point 32, has been superseded by *Communication from the Commission — Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements*, Official Journal of the European Union, C 089, 28 March 2014, p.3. However, in this Decision, all references to the *Guidelines on application of Article 101 of the Treaty* (previously Article 81) to technology transfer agreements (also referred to as Technology Transfer Guidelines) are to be understood as referring to the 2004 Guidelines, which were applicable during the investigated period.

1587 Servier argues that the Commission overlooked the fact that, for some settlements, negotiations came on the initiative of the generic company (Servier's reply to the Statement of Objections, paragraph 961, ID10114, p. 334). Similarly, Teva claims that some of the restrictions were imposed on it by Servier against its interests (Teva's reply, section 6.2.3, ID8495, p. 73-79). The Commission is indeed of the view that, for an agreement to be qualified as restrictive of competition, it is not important which of the parties proposed the agreed solution (Judgment in *Courage v Crehan*, C-453/99, EU:C:2001:465). What matters is that they agreed to restrict competition between them based on an inducement to the generic party.

1588 Krka argues that the settlement did not in any manner extend the exclusionary rights as afforded to Servier by law and arising from its patents, and did not grant to Servier any right that Servier was not enjoying on account of its patents. Krka's reply to the Statement of Objections, paragraph 114, ID8742, p. 58-59.

1589 According to Servier, "*from an economic point of view, there is nothing abnormal about a situation in which the party in litigation that gives up its claims in a settlement receives compensation for the expected value of those claims and hence there is nothing "reverse" about this type of payment*" (Servier's reply to the Statement of Objections, paragraph 50, ID10114, p. 78 and Annex 00-01B to Servier's reply to the Statement of Objections, ID9054, p.10-11). However, in disputes alleging patent infringement by a generic company, payments to the putative infringers indeed flow in the reverse direction of the expected one. Such payments may be economically rational for the companies involved,

at persuading them to stop or delay their independent efforts to enter the market may well, in certain specific circumstances, fall afoul of Union competition law. Indeed, even if the limitations in the agreement on the generic undertaking's commercial autonomy do not go beyond the material scope of the patent, they constitute a breach of Article 101 of the Treaty when those limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market.

(1138) In other words, in the absence of the agreed inducement and hence based purely on its assessment of its chances to succeed in the patent dispute, i.e. on the merits of the patent case, the generic company as a reasonable economic operator would not accept the commercial limitations which are accepted in the settlement and instead act independently in keeping with its own specific competitive incentives and resort to more pro-competitive solutions (for example, continued litigation, acceptance of an early entry settlement).[1590]

(1139) The protection of rivalry, including through patent law challenges, relates to an important general principle underlying Article 101 of the Treaty, which is that each economic operator must determine independently the policy which it intends to adopt on the market.[1591] In this respect, *Irish Beef* is of particular interest to the facts examined in this Decision. This case dealt with a mechanism, the so-called BIDS arrangements, to reduce perceived overcapacity in the Irish beef sector. As part of the BIDS arrangements, the undertakings that stayed in the market paid financial compensation to those who agreed to leave the market. The Court of Justice found that:

"That type of arrangement conflicts patently with the concept inherent in the EC Treaty provisions relating to competition, according to which each economic operator must determine independently the policy which it intends to adopt on the common market. Article 81(1) EC [now 101(1) of the Treaty] is intended to prohibit any form of coordination which deliberately substitutes practical cooperation between undertakings for the risks of competition.

In the context of competition, the undertakings which signed the BIDS arrangements would have, without such arrangements, no means of improving their profitability other than by intensifying their commercial rivalry or resorting to concentrations. With the BIDS arrangements it would be possible for them to avoid such a process and to share a large part of the costs involved in increasing the degree of market concentration…".[1592]

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as Servier suggests, but may be anti-competitive if made in return for limiting competitor's ability and incentives to compete.

1590 Lupin claims that the Commission's logic is incoherent as a settlement without the inducement with exactly the same restrictions as a restrictive settlement with an inducement would not be found to restrict competition (Lupin's reply to the Statement of Objections, paragraphs 246-251, ID8752, p. 63-64). The Commission considers that this premise fails to explain why, in the identical economic and legal context (all other things being equal), the generic party would accept the same restrictions without the inducement. A proper analysis will not only compare the type of restrictions agreed, but also the respective contexts in which the agreements under comparison came about.

1591 *Commission Notice: Guidelines on the application of Article 81(3) of the Treaty*, OJ C 101, 27.4.2004, page 97, point 14.

1592 Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraphs 33-34. A comparison may also be made with COMP Case 38.543 – *International Removal Services,*

(1140) The European Court of Justice in *Irish Beef* concluded that the arrangements in question, premised on exclusionary payments, were a restriction by object. Advocate General Trstenjak characterised the arrangement as *"the 'buying off' of competition"*[1593]. This is close to how one of the settlements had been described internally, as well as by a third party, as the generic company "*taking the money in exchange for being bought out*" by Servier.[1594]

(1141) Yet, patent holders are not entitled to pay generic companies to keep them off the market and reduce the risks of competition, whether in the context of a patent settlement agreement or otherwise.[1595] In essence, settlement agreements rewarding a competitor for staying out of the market distinctly pursue the object to restrict competition.[1596]

(1142) From an ex ante perspective, alternatives to reverse payment settlements assessed in this Decision would have led to more pro-competitive results in various scenarios in which the generic companies incentives to compete would have remained undistorted by the value transfer. For example, without the payment, litigation between the parties may have continued, or the generic could have insisted on less restrictive settlement conditions. In both cases, the degree of competition (actual or potential) would have been superior compared to the situation where the restrictions are leveraged by a reverse payment, or another value transfer to the generic company.

(1143) The parties contend that the existence of a value transfer is in itself not an indication that the settlement is collusive,[1597] as it provides the incentives to settle.[1598] This is not disputed, as the Commission examines value transfers on a case by case basis, to establish whether such transfers amount to a significant inducement for the generic to withdraw from competition. In particular, the assessment of an individual settlement agreement will examine the claimed purposes of a value transfer, and evaluate its quantum in particular against the earnings generics were expecting from perindopril

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Decision (2008) 926, in which the Commission considered that the payment of commissions by international removal companies to competitors in exchange for the latter issuing artificially high quotes for removal services amounted to a restriction by object. This legal assessment was confirmed by the General Court, for instance in Joined Judgments of 16 June 2011, *Gosselin Group NV and Stichting Administratiekantoor Portielje v Commission*, T-208/08 and T-209/08, ECR, EU:T:2011:287, paragraphs 67-71. The parallel in this case to the facts at hand is that competitors paid each other not to compete and that as a result all undertakings fared better, at the expense, however, of higher consumer prices. Cartel arrangements where customers are allocated between competitors would be another example. The difference with these kinds of cases is, again, that in the case at hand the agreements were concluded against the background of patent disputes.

1593 Opinion of Advocate General Trstenjak delivered on 4 September 2008 in Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 77.

1594 See paragraphs (413)-(414), and (544).

1595 If such a naked payment was made from an originator to a generic company in return for generic's commitment to exit the market, then Article 101 of the Treaty would also apply. The fact that the payment is made as part of a patent settlement agreement does not shelter it from the application of Article 101 of the Treaty.

1596 The parties argue that, as there is no EU precedent on reverse payment patent settlements, they could not be qualified as a restriction by object (for example, Matrix' reply to the Statement of Objections, paragraph 1.23, ID8835, p. 9). The existence of a precedent is not a pre-requisite for finding a restriction by object. As discussed, these agreements are quite similar, in their essence, to market sharing agreements which are specifically mentioned in Article 101(1) of the Treaty as being prohibited.

1597 Servier's reply to the Statement of Objections, paragraphs 72-75, ID10114, p. 86-87.

1598 Matrix' reply to the Statement of Objections, paragraphs 1.7-1.8, 1.32, 1.37, 3.1-3.4, ID8835, p. 5-6, 11-12, 28-29.

sales. Servier also claims that a mutually beneficial settlement will in all likelihood imply a value transfer to the generic company (lump sum, licence, distribution and/or early entry agreements), and that settlements without a value transfer to the generic are improbable.[1599] Value transfers may, in specific legal and commercial circumstances, be instrumental to the finding of an acceptable and legitimate solution for both parties. This is the case in particular, but not exclusively, where, for example, the generic undertaking had already entered the market and if each party in the course of litigation comes to consider that the likelihood that a court would consider the patent valid and infringed is high. There, a patent settlement may legitimately include not only a withdrawal from the market of the generic product but also a payment from the generic undertaking to the originator undertaking to settle the damage suffered by the latter. Likewise, a patent settlement could include a payment from the originator undertaking to the generic undertaking if originally, through legal threats or court action of the originator undertaking, the generic undertaking had refrained from entering the market or had been legally prevented from marketing its product pursuant to an injunction and both parties come to consider later on, for instance in the course of on-going litigation, that there is in fact a high likelihood either that a court would find the patent invalid or not infringed. If in that case a patent settlement is concluded that allows for immediate market entry by a generic undertaking, such a settlement could legitimately include a payment by the originator company to the generic company to compensate the latter for the damage suffered. Similarly, a settlement where the parties only agree on an early entry date may be seen as constituting a value transfer to the generic company. But to the extent this transfer will limit exclusivity claims by the originator and thus, instead of extending, reduce restrictions for the generic, it will benefit consumers, contrary to an inducement to accept more restrictive settlement terms.

(1144) Patent settlements by definition avoid an authoritative, judicial decision on the merits. The outcome of litigation can thus not be established with certainty. On this basis, the parties claim that reverse payment patent settlements cannot constitute a restriction by object, as it is impossible to conclude whether the agreement will have anticompetitive effects.[1600] This is incorrect. If the generic company was an actual or potential competitor as it had a real concrete possibility to enter, or viably remain on, the market absent the settlement, the immediate and direct consequence of the reverse payment patent settlements as assessed in this Decision is to remove the possibility that the generic undertaking will enter or remain on the market. Obviously, a settlement prevents a patent dispute/litigation from reaching an authoritative judicial decision on the merits. The question of whether the agreement entailed actual effects thus belongs to the purely speculative sphere, and is not relevant for the purposes of competitive assessment (of restrictions by object). What matters is if a reverse payment patent settlement collusively removes a potential competitor and affects the structure of the market. In the *T-Mobile* case,[1601] the European Court of Justice confirmed that Article 101 of the Treaty was designed to "*protect not only the immediate interests of individual competitors or consumers, but also to protect the structure of the market and thus competition as such*". Therefore, in this case, it is not only inappropriate, but also unnecessary for the Commission to

1599 Servier's reply to the Statement of Objections, paragraphs 72-79, – ID10114, p. 86-89.

1600 Servier's reply to the Statement of Objections, paragraphs 85-92, ID9070, p. 90-92, Lupin's reply to the Statement of Objections, paragraph 228, ID8752, p. 58-59.

1601 Judgment in *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, paragraphs 38-39.

rely on posterior patent court decisions or perform an own assessment of the likely outcome of the patent dispute/litigation. A reverse payment settlement may remove a potential competitor and distort the market structure, resulting in reduced risks from competition[1602] and the resulting market uncertainty[1603], thus easing competitive pressure to the benefit of the originator. This may equally be the case where a settlement agreement does not block all avenues for a future challenge to the originator's product exclusivity. Even removing a single competitor may impact the market structure and change the course of justice if that competitor is particularly advanced (and thus any later decision implies a delay) compared to other potential entrants or has a relatively stronger patent case.

Economic context of patent settlement agreements with a reverse payment

(1145) In addition to their legal context, it is equally important to examine the economic context of these agreements in order to properly appreciate the incentives of the parties to a patent settlement agreement.

(1146) The economic context shows that it may be in the interest of the originator undertaking to induce, with a significant value transfer, the generic undertaking to stay out of the market for a period of time and in the interest of the generic undertaking to agree to stay out of the market in exchange for that payment. In fact, both parties may do better with such an agreement than if they had continued their own independent commercial course and rivalry.

(1147) The reason why both (potential) competitors can be better off at the same time is that the profits the generic undertaking could make from entering the market will be lower than the loss in profits that would likely result for the originator undertaking from generic entry. Therefore the originator can easily afford to pay-off one or several generics to prevent their entry.

(1148) Generic entrants price their product lower, and often considerably lower, than the originator's product, as otherwise distributors, pharmacies, prescribers, patients and health insurers would have little reason to choose their product, given that the generic product uses the same active ingredient as the original product. The only significant way for generic undertakings to compete with the originator's product and with each other's products is therefore on price. The more generic companies enter, the stronger the price competition will tend to become and the faster prices will tend to fall. Moreover, as discussed in section 6.4, pricing and/or reimbursement legislation exists in most Member States of the EEA to impose or stimulate price reductions for medicines for which generic alternatives exist. In general, therefore, generic entry will tend to be followed rather quickly by a significant reduction in market share and/or price level of the originator product, i.e. by a significant reduction in the originator undertaking's profits.

(1149) From the perspective of the originator company, it thus makes commercial sense to avert generic entry by making a payment to the generic company to induce it to accept restrictions on its commercial independence. Servier claims this should be justified by the asymmetry of risks between the parties, whereby the originator company would be exposed to much higher harm from possibly unlawful generic

1602 Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 33.

1603 See, for example, Judgment in *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, paragraph 35; Judgment in *Thyssen Stahl v Commission*, C-194/99 P, EU:C:2003:527, paragraph 81.

entry, as it is difficult for the originators to obtain an interim injunction.[1604] This is unfounded for a number of reasons. First, the patent holder can apply for injunctions to prevent unlawful generic entry. The loss of market exclusivity due to a refusal to grant an interim injunction is based on a judicial assessment of the opportunity and need of injunction, as well as the availability of redress to the patentee. As such, it is a risk inherent to competition. Servier made no claims that the relevant national patent systems could not grant effective interim relief. On the contrary, it claims success in using interim injunctions, averting such potential harm.[1605]. Second, even if Servier failed to obtain an injunction for a launch at risk which was confirmed as patent-infringing in court proceedings, Servier could still claim damages from the generic company. Third, none of the generic companies to which this Decision is addressed was supplying generic perindopril at risk in the markets covered by restrictions. Fourth, to avoid risk from a given litigation, Servier could structure a settlement differently, notably without resorting to value transfers affecting the generic companies' incentives to compete. Fifth, the loss of market exclusivity in homogeneous end products always an asymmetry of risks, provided one looks only at the incumbent originator company and the would-be generic entrants, and ignores the interests of consumers. As shown in Graph 1 and Graph 2 below, originator's losses from generic entry exceed generic company's expected gains from competing. The difference would accrue to the consumer. Therefore, if also consumers' interest in lower, off-patent prices is taken into account, the originator's interest in preserved product exclusivity is counterbalanced by both generics' and consumers' interest in generic competition. It can certainly make commercial sense for an originator company to simply pay the generic undertaking the money than it could hope to gain by entering the market, or more, on condition that the generic undertaking stays out of the market. The incentive to do so is even higher if the originator perceives an appreciable risk that its patent(s) will be held invalid and/or not infringed by a court. This does not imply that it is legitimate to avoid risks of competition by practical cooperation between the companies.[1606] To illustrate this in the present case, when generic entry did eventually take place in the UK, following the rejection by the Court of Appeal to continue the injunction which had been granted against Apotex at first instance, Servier's volumes eroded significantly as the average market price dropped by as much as 90%. As Servier had sales of more than EUR 0.8 billion from perindopril worldwide before generic entry,[1607] it clearly had the incentive to prevent such entry for as long as possible. Each month without generic entry meant considerably higher earnings for Servier[1608], at the expense of consumers.

(1150) From the perspective of the generic company, a patent settlement agreement with a significant reverse payment is normally also attractive, and will affect its incentives to compete. As a result of such a deal, the generic company can make a significant amount of money without even entering the market. It avoids the efforts and risks attached to market entry, including the risks of litigation with the originator undertaking, risks associated with obtaining the regulatory approval, and risks of

1604 Servier's reply to the Statement of Objections,, paragraphs 62-65, ID10114, p. 84.

1605 Servier's reply to the Statement of Objections, for example paragraphs 417, 905-939, ID10114, p. 189, 321-328.

1606 Judgment in *Beef Industry Development and Barry Brother,* C-209/07, EU:C:2008:643, paragraphs 33 to 35.

1607 See paragraph (103).

1608 As stated in one of Niche's documents, "*[…]**". See paragraph (544).

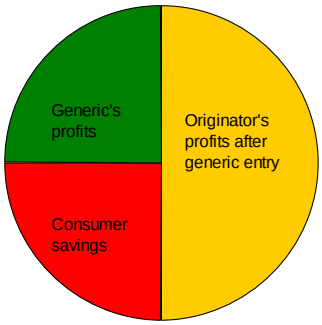
competition from other generic undertakings and/or the originator undertaking. Thus, the generic company is compensated handsomely for not entering, effectively through sharing part of the monopoly rents with the originator.[1609]

(1151) Consumers, however, will be considerably worse off in this situation, as they fail to benefit, whether through their health insurance premium or the public health budget, from the lower prices that would have followed generic entry. Such a patent settlement is the result of collusion between (potential) competitors at the expense of the consumer.

(1152) The following three graphs illustrate this situation:

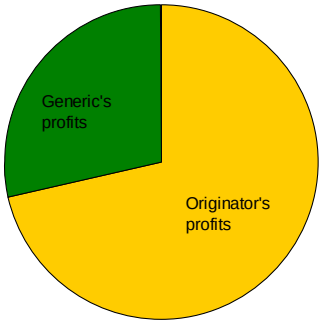
Graph 1: The profits of the originator undertaking before generic entry

Graph 2: Consumer savings after generic entry



1609 Part of the Commission's case in this Decision involves comparing these payments to the levels of revenues and profits which were *contemporaneously* expected upon market entry by the generic, which provides an indication of the value of these transfers to the generics and a strong sign that Servier was sharing its monopoly rents on the perindopril market with them.

Graph 3: Sharing of the consumer savings by the originator undertaking and the generic undertaking through a settlement with an exclusion payment



(1153) It follows that undertakings should not be entitled to enter into reverse payment settlement agreements which have the objective, if only in part, of blocking challenges to patents "*perhaps wrongly granted*"[1610] based on rent sharing, and delay the entry onto the market of the generic product. The patent systems in the EU offer no immunity against patent litigation and non-challenge clauses are not considered to fall within the subject-matter of the patent. The originator as the patent holder cannot buy certainty against the risks inherent in litigation as an expression of competition and still obtain immunity under competition law. Unduly averting patent litigation may effectively bar competition, as the competitor may be prevented from removing the patent barrier to entering or remaining in a market, and therefore from competing with the patent holder.

Elements for assessing patent settlements with a value transfer for the purpose of applying Article 101 of the Treaty in this Decision

(1154) The assessment of whether the patent settlement agreements at issue in this case are restrictions by object will depend on the facts relating to each agreement which will be examined in the relevant sections below on a case-by-case basis. In order to identify whether each agreement had the potential to restrict competition by its very nature, the analysis in sections 5.2 - 5.6 below will in particular take into account whether:

- the generic undertaking and the originator undertaking were at least potential competitors (see section 5.1.3);
- the generic undertaking committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter one or more EU markets with a generic product (see section 5.1.4.1), and
- the agreement was related to a transfer of value from the originator undertaking as a significant inducement which substantially reduced the incentives of the generic undertaking to independently pursue its efforts to enter one or more EU markets with the generic product. (see section 5.1.4.2)

(1155) In the present case other important factors will also be taken into consideration. First, the restrictions either lasted throughout the entire period of the patent term, or did not

[1610] Judgment in *Windsurfing International v Commission*, 193/83, EU:C:1986:75, paragraph 91.

contain any commitment by Servier to refrain from infringement proceedings in case of independent entry with the relevant generic products after the expiry of the agreement. Second, the value Servier transferred to generics took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market. Third, the obligations on certain generic undertaking in the respective agreements exceeded the scope of the underlying patent litigation/ dispute, in particular as the restrictions went beyond what Servier could have legally obtained through successful enforcement of its patents in the underlying disputes/litigation.

5.1.3 Settling parties as at least potential competitors

Applicable rules

(1156) The specific assessment of the context of each of these agreements will establish that the settlements were agreements between undertakings which were at the time of the events at least potential competitors. According to well-established case-law of the Courts of the European Union, the examination of conditions of competition on a given market must be *"based not only on existing competition between undertakings already present on the relevant market but also on potential competition, in order to ascertain whether, in the light of the structure of the market and the economic and legal context within which it functions, there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to penetrate the relevant market and compete with the undertakings already established"*.[1611]

(1157) In its judgment in *Visa*, the General Court stated that, to qualify a company as a potential competitor, the Commission is:

"required to determine whether, if the [restriction] had not been applied to Morgan Stanley [the excluded operator], there would have been real concrete possibilities for it to enter the United Kingdom acquiring market and to compete with established undertakings.

It is also clear from the case-law that such a demonstration must not be based on a mere hypothesis, but must be supported by evidence or an analysis of the structures of the relevant market (see, to that effect, European Night Services and Others v Commission, paragraph 67 above, paragraphs 142 to 145). Accordingly, an undertaking cannot be described as a potential competitor if its entry into a market is not an economically viable strategy (see, to that effect and by analogy, Case T-177/04 easyJet v Commission [2006] ECR II-1931, paragraphs 123 to 125).

It necessarily follows that, while the intention of an undertaking to enter a market may be of relevance in order to determine whether it can be considered to be a potential competitor in that market, nonetheless the essential factor on which such a description must be based is whether it has the ability to enter that market.

It should, in that regard, be recalled that whether potential competition – which may be no more than the existence of an undertaking outside that market – is restricted cannot depend on whether it can be demonstrated that that undertaking intends to enter that market in the near future. The mere fact of its existence may give rise to competitive pressure on the undertakings currently operating in that market, a

[1611] Joined Judgments of 15 September 1998, *European Night Services and Others v Commission,* T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198, paragraph 137. This case relates to the assessment of restrictions by effect.

pressure represented by the likelihood that a new competitor will enter the market if the market becomes more attractive".[1612]

(1158) With respect to the time-frame within which potential entry should take place, the General Court stated in *Visa*: *"…the essential factor is the need for the potential entry to take place with sufficient speed to form a constraint on market participants...*"[1613] The General Court held, in this respect, that a period of one year mentioned in the Commission's Guidelines on horizontal cooperation agreements was merely illustrative.[1614] The General Court also rejected the applicant's claim that the Commission had not used the correct test and that it should have instead applied the more stringent test used in *BaByliss*.[1615]

(1159) In the *BaByliss* case,[1616] the General Court examined whether a producer of small electrical appliances for personal care was a potential competitor of the merging parties in a number of electrical kitchenware markets where it was not yet present. The Court assessed the following elements for the existence of potential competition: (i) parent company was present in the target markets in the US, (ii) the EU entry strategy was based on the group's US experience,[1617] (iii) the fact that entry was actually postponed several times was not a decisive factor as "*the cost and time necessary for entering a new product market may be considerable, having regard to the characteristics of the market*". The Court concluded that "*its position in the market for personal care appliances and the business and experience of its parent […] provide it with a sufficient basis to justify the description of "potential" competitor and to facilitate its entry into the small electrical household appliances market*". Thus, a company's objective ability (based on experience and position in other related markets), corroborated by plans to enter the relevant market, can exercise competitive pressure on the incumbents and thus qualify as a potential competitor. Where delays occur which reflect complexities in development, this will not necessarily be an indication that there is no competitive pressure exercised, but can also suggest that the time-frame over which competitive pressure may be exercised by a potential entrant is longer.

(1160) In *Hitachi*[1618] the General Court dealt with the issue of whether a common understanding, between the European producers and the Japanese producers of gas-insulated switchgear had existed, whereby the Japanese undertakings would have agreed to stay out of EEA markets. The General Court had to deal with various

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1612 Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission,* T-461/07, ECR, EU:T:2011:181, paragraphs 166-169.

1613 Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission,* T-461/07, ECR, EU:T:2011:181, paragraph 189.

1614 The Commission's Guidelines on Technology Transfer Agreements state: *"Normally a period of one to two years is appropriate. However, in individual cases longer periods can be taken into account"*. This also is illustrative. See *Commission Notice: Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*, point 29.

1615 Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181, paragraphs 166-169.

1616 Judgment of 3 April 2003, *BaByliss v Commission*, T-114/02, ECR, EU:T:2003:100, paragraphs 96-106. The issue was raised concerning the question whether BabyLiss had legal standing to contest a merger decision.

1617 In paragraph 104 of the BaByliss decision, the Court also accepted that, although the business plan only envisaged entry in France, "*the group hoped to use successful penetration of the French market as a basis for expansion into other Member States later on"*.

1618 Judgment of 12 July 2011, *Hitachi v Commission* , T-112/07, ECR, EU:T:2011:342.

arguments that the common understanding would have been devoid of purpose because of the existence of barriers to entry, which made entry into the market 'difficult', that the Japanese producers faced other obstacles because they were not well accepted in the market and that they did not in any event have commercial interest in entering EEA markets. While rejecting those arguments, the Court based its conclusion that a common understanding existed on the fact that the Japanese producers of gas insulated switchgear were *"regarded"* and *"perceived"* as *"potential credible competitors"* by the incumbents in the EU despite the *"objective entry barriers"* (uncontested by the Commission).[1619] So the Court in that case deduced from the fact of the agreement and the conduct of the parties that the Japanese producers were regarded as potential competitors.[1620] Thus, the European producers' assessment as to the possibility of Japanese entry was taken into account and was considered valid evidence that the Japanese producers were potential competitors. Another key point in that judgment is that the Japanese producers were technically able to enter the European market.[1621] Key items of evidence *"did not state that it was impossible to enter that market, but merely that such entry was difficult"*.[1622] By contrast, whether the Japanese producers actually had a commercial interest in entering the European market was considered *"irrelevant"*.[1623] Furthermore, *"*[i]*f the European market was actually impenetrable for the Japanese producers because of the barriers to entry, the European producers would have no reason to* [engage in market-sharing arrangements with the Japanese producers]*"*.[1624]

(1161) It is only logical that the perception of the market incumbent should play a role in the assessment of whether potential competition existed. If a market incumbent, who is an experienced operator, perceives a competitive threat from generic undertakings, such a threat is likely to form a competitive constraint on its behaviour on the market, which is the relevance of potential competition. As referred to by the Court in *Visa*[1625], potential competition may be no more than the existence of an undertaking outside the market, and its mere existence may give rise to competitive pressure, which is represented by the likelihood of entry.

(1162) The position in Hitachi has more recently been confirmed in *Toshiba* concerning an agreement by which Japanese producers of power transformers committed not to compete in the EU with the European producers, which constituted a restriction by object of Article 101 of the Treaty. In this context, the General Court concluded that[1626]: "*Article 81 EC protects not only actual competition, but also potential*

1619 Judgment of 12 July 2011, *Hitachi v Commission*, T-112/07, ECR, EU:T:2011:342, paragraphs 90, 226 and 319.

1620 Otherwise the European producers will not have entered into an agreement that cost them market share outside the EEA.

1621 Judgment of 12 July 2011, *Hitachi v Commission*, T-112/07, ECR, EU:T:2011:342, paragraphs 157 and 160.

1622 Judgment of 12 July 2011, *Hitachi v Commission*, T-112/07, ECR, EU:T:2011:342, paragraph 111. This directly contradicts the claim that the Commission applied the wrong legal test by examining whether the respective generic companies encountered any insurmountable barriers to entry (see, for example, Lupin's reply to Statement of Objections, paragraphs 74-77, ID8752, p. 24). The latter element served to verify if, in spite of generic company's general ability and proven intention to enter, there were objective reasons rendering generic entry impossible.

1623 Judgment of 12 July 2011, *Hitachi v Commission*, T-112/07, ECR, EU:T:2011:342, paragraph 160.

1624 Judgment of 12 July 2011, *Hitachi v Commission*, T-112/07, ECR, EU:T:2011:342, paragraph 226.

1625 See paragraph (1157).

1626 Judgment of 21 May 2014, *Toshiba v Commission*, T-519/09, ECR, EU:T:2014:263, paragraph 230.

competition between undertakings. Consequently, an agreement such as the Gentlemen's Agreement, which is designed to protect the European producers in their home territories from actual or potential competition from Japanese producers, is capable of restricting competition, unless insurmountable barriers to entry to the European market exist which rule out any potential competition from Japanese producers. In the present case, the Commission could therefore restrict itself to showing that the barriers to entry to the European market were not insurmountable".

(1163) In view of the foregoing, the key question that needs to be answered is whether the generic companies exercised competitive pressure on the incumbent company, Servier.[1627] In the present case, such competitive pressure will be demonstrated by both the ability and the intention of the generic companies to enter the market. Account will be taken of the legal and economic context and the precise circumstances of the parties to a given agreement. While the intention to enter a market may also be relevant, the crucial aspect in demonstrating potential competition is the ability to enter a market. The perception of the incumbent, Servier, and of other generic competitors will also be taken into account.

(1164) The parties claim that no competition between Servier and the generic companies having perindopril products in the pipeline was possible. Servier's outstanding patents, in particular the '947 patent, were blocking patents which created "*an absolute bar to entry and so [preclude] all competition, both potential and actual.*[1628]

(1165) In the pharmaceutical sector, generic pressure on originator medicines may emerge several years before a branded medicine loses the broadest possible protection, the compound patent. In *AstraZeneca*, the Court of Justice recognised that SPCs can have significant exclusionary effects after the expiry of the compound patents, but that *"they are also liable to alter the structure of the market by adversely affecting potential competition even before that expiry"*.[1629] This suggests that the Court of Justice considers that in the pharmaceutical sector potential competition on the compound can and is likely to exist already well before the expiry of a basic, compound, patent, even if process or other patents may still be in force. In AstraZeneca, the applications for the SPCs in question had been filed between five and six years before the expiry of the basic patent.[1630]

(1166) The open nature in principle of perindopril markets in the EU at the time the agreements were concluded is a fundamental difference with the situation the *EON/GDF* case[1631] where the French and German markets were, for legal and factual reasons, respectively closed for competition at the time of the agreement. For the periods in which those two markets were closed, the General Court held there was no competition, even potential. Unlike in the present case, the legal barriers to entry were not readily challengeable. However, for the period after the German market opened up, the Court found that there was "*no evidence to permit the inference that, during that period,* [the structure of the German market] *was on its own capable of*

1627 See, for example, Servier's reply to the Letter of Facts, ID10324, p. 158-159.

1628 Lupin's reply to Statement of Objections, paragraph 40, ID8752, p. 16-17, see also Servier's reply to the Statement of Objections, paragraph 1374, ID10114, p. 426, Teva's reply to the Statement of Objections, paragraph 444, ID8495, p. 95, Matrix' reply to the Statement of Objections, paragraph 4.33-4.35, ID8835, p. 54-55.

1629 Judgment in *AstraZeneca v Commission,* C-457/10 P, EU:C:2012:770, paragraph 108.

1630 Judgment in *AstraZeneca v Commission,* C-457/10 P, EU:C:2012:770, paragraph 108.

1631 Judgment of 29 June 2012, *E.ON Ruhrgas and E.ON v Commission,* T-360/09, ECR, EU:T:2012:332.

totally precluding any potential competition".[1632] The same can be said for the marketing of generic perindopril, in particular following the expiry of the compound patent (including SPC).

(1167) Several parties mentioned[1633] that the General Court in *AstraZeneca* held that:

"When granted by a public authority, an intellectual property right is normally assumed to be valid and an undertaking's ownership of that right is assumed to be lawful. The mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right".[1634]

(1168) This however provides no basis for the parties' claims that the alleged assumed validity of patents precludes the scope for potential competition.[1635] The parties are, in the view of the Commission, wrong to claim that entry was impossible as the existence of a patent excludes any potential for competition,[1636] and to draw the conclusion[1637] that Servier's patents established a one-way blocking position, meaning that the generic products in question could not be produced without infringing Servier's patent.[1638]

1632 Judgment of 29 June 2012, *E.ON Ruhrgas and E.ON v Commission,* T-360/09, ECR, EU:T:2012:332, paragraph 123. For the German market, which remained closed until 24 April 1998, the General Court found that in the period before 24 April 1998, the Commission had failed to present evidence "*which permits the inference that GDF's entry to the market could have taken place, by those means, sufficiently quickly for the threat of potential entry to influence the conduct of the participants in the market, or on the basis of costs which would have been economically viable"* (paragraph 114). However, for the period between 24 April 1998 and 10 August 2000, when the German market became in principle open, the General Court found that *"the applicants do not adduce any evidence…in support of their claim"* that potential competition was still not possible (paragraphs 119-120). For this period, the General Court concluded that *"there is no evidence to permit the inference that, during that period,* [the structure of the German market] *was on its own capable of totally precluding any potential competition on the German market. In those circumstances, it is clear that there is no evidence to show that the Commission was wrong to find that there was potential competition on the German market for gas from 24 April 1998 to 10 August 2000"* (paragraph 123). For the French market, which became open as of August 2000, the General Court found that Ruhrgas "*was therefore able to penetrate the French market as of August 2000. Consequently, the Commission was right to find that Ruhrgas and GDF were potential competitors in the French market as from 10 August 2000 (emphasis added)*".

1633 See, for example, Teva's reply to the Statement of Objections, paragraphs 424-426, ID8495, p. 92.

1634 Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 362.

1635 The General Court did not find that the existence of a patent means that there can be no potential competition on a market and its statement needs to be read in the specific context of the issues raised in that judgment. The General Court was rejecting AstraZeneca's arguments that there could not be an abuse of a dominant position unless the exclusive right had been enforced or exercised through legal proceedings. The General Court found that the submission of misleading representations to public authorities which are liable to lead them to grant the exclusive right, and thus to wrongly create regulatory obstacles, may have significant adverse effects on competition (paragraphs 357, 377). However, this does not show that the (alleged) existence of patent protection necessarily results in there being no real and concrete possibility of entry: an alleged patent can deter entry without necessarily precluding entry. This was confirmed by the Court of Justice on appeal.

1636 See, for example, Krka's reply to the Statement of Objections, paragraph 3, ID8742, p. 8.

1637 See, for example, Teva's reply to the Statement of Objections, paragraphs 428-436, ID8495, p. 92-94.

1638 "*If the parties own technologies that are in a one-way or two-way blocking position, the parties are considered to be non-competitors on the technology market. A one-way blocking position exists when a technology cannot be exploited without infringing upon another technology".* Commission Notice: Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, OJ C 101 of 27.4.2004, point 32. It needs to be clarified from the outset that such reference to the Technology Transfer Guidelines is inappropriate, as they only apply to situations where technology was

(1169) In any event as amply shown by the number of oppositions, revocation actions and counterclaims of invalidity either launched or envisaged by the generics in this case, the validity of a patent may be challenged. In addition, the burden to prove infringement rests with the patent holder. There is no presumption that a particular product is manufactured with a particular process that infringes a given patent. In the Commission's view, nothing prevents the possibility that an invoked patent is found invalid or not infringed and thus incapable of blocking a generic product. Indeed, as the Court of Justice ruled in *Windsurfing*, the specific subject-matter of the patent *"cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error"*.[1639] The Court of Justice explicitly clarified that potential competition may exist even before the lapse of the compound patent.[1640] Furthermore, even in a situation in which a generic product is found to have infringed a valid process patent, this still does not mean that the generic will be unable to enter the market, if the generic can switch to another API, manufactured with a different process which does not infringe that patent, or to another, non-patented form. In this case, Servier acknowledged that it was possible for some generic competitors to develop a form of perindopril that did not infringe its patents.

(1170) In this case, it is common ground that a genuine patent dispute on the validity and/or infringement of one or more patents held by Servier was directly or indirectly at the source of each of the five settlements. The fact that Servier alleged or was expected to allege infringement of its patent rights is inconclusive for the determination whether the patents would in fact bar generic entry. In Servier's words, generic companies are "**patent dispute professionals*",[1641] and if patent rights are, rightfully or not, asserted by the originator, generics can either deny infringement and/or contest the validity of the patent. Indeed, Servier's infringement claims were countered by generic companies' claims of non-infringement and/or invalidity of the invoked patent rights both before and after the decision of the EPO Opposition Division, which upheld the '947 patent in July 2007.

(1171) The power to confirm that a patent is valid and has been infringed, or find it invalid and non-infringed lies exclusively with a court. In Case 193/83 *Windsurfing*

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transferred for the markets concerned. The investigated settlement agreements do not transfer technology and enhance competition for the markets concerned, but restrict competition there. The provisions of these Guidelines, including those governing the existence of competitive relationships between a licensor and a licensee, strike a careful balance between the positive effects of licensing and possible restrictions of competition (point 9). This balance is different from the assessment of a horizontal agreement whereby the incumbent transfers value for the rival to withdraw from competition. The Guidelines may, however, provide useful analogies on issues which are not specific to settlements containing a licence, such as market definition, definition of competitors, and situations in which even settlements involving a licence could be found to be anti-competitive.

1639 Judgment in *Windsurfing International v Commission*, 193/83, EU:C:1986:75, paragraph 92.

1640 The Court of Justice's judgment in AstraZeneca recognises that potential competition can exist even if the compound patent is still in place. AstraZeneca had argued that the mere fact of applying for SPCs could not constitute an abuse because those SPCs only came into force 5-6 years later and, until then, AstraZeneca's rights were totally protected by the compound patents. The Court of Justice rejected this, noting that, in addition to the exclusionary effect that the unlawful SPCs could have after the expiry of the basic patents, "*they are also liable to alter the structure of the market by adversely affecting potential competition even before that expiry*". Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 108.

1641 Servier's reply to the Statement of Objections, paragraph 1900, ID10114, p. 544.

International v Commission, the Court of Justice ruled in the context of a clause that enabled the licensor in a licensing agreement to intervene in disputes between licensees in order to detect and prevent slavish imitation of products, that a licensor cannot substitute "…[its] *discretion for the decisions of national courts, which were the proper forum for actions...*"[1642] Although Servier filed a number of actions for patent infringement in the UK (and elsewhere), no court decision established, throughout the investigated period, that any of the generic undertakings, addressees of this Decision, were infringing any of Servier's perindopril patents in force in the EU.[1643] The mere allegation of infringement, without a court decision on the merits, does therefore not allow to draw the conclusion that the product actually infringes a valid patent.[1644]

(1172) The Commission will, with respect to the perceived possibility of invalidity or of infringement of Servier's patents, rely on assessments by the parties themselves, as well as third parties, in particular as found in contemporaneous documents,[1645] and not on posterior developments.[1646] For the purpose of the present Decision, the Commission obviously did not seek to establish that a patent was invalid, or not infringed, and that generics were hence certain to win.[1647] But the evidence, as presented in the assessment of individual agreements, shows that there was a genuine doubt both on the side of Servier and the generic companies[1648] as to whether Servier could successfully enforce its patents.[1649]

1642 Judgment in *Windsurfing International v Commission*, 193/83, EU:C:1986:75, paragraph 52. As explained by the Commission in that case, the danger is that the licensor, if it sets itself as the sole arbiter in place of the courts, in any doubtful cases that may arise, may use that discretion in its own favour and restrict licensees in their competitive freedom (see paragraph 44). Such a danger is even more acute when it concerns the enforcement of one's own patent than in the situation in Windsurfing which concerned disputes between third parties.

1643 See Table 6.

1644 This position is consistent with the Technology Transfer Guidelines, even if they are not applicable for the reasons explained above. The Guidelines state that: *"Particularly convincing evidence of the existence of a blocking position is required where the parties may have a common interest in claiming the existence of a blocking position in order to be qualified as non-competitors*". Both Servier and the generic companies which are the addressees of this Decision had a common interest in arguing to the Commission that Servier's patents were infringed or were likely to be infringed, and argued that no potential competition existed between them.

1645 See the specific legal assessments of the existence of potential competition for each of the agreement analysed in sections 5.2 - 5.6.

1646 The Commission agrees with Krka's assertion "*that the mere finding of the invalidity of a patent does not render the patent irrelevant to the appropriate competition law analysis (i.e. it is always necessary to conduct ex ante analysis and not resort to the inappropriate ex post analysis)".* Krka's reply to the Statement of Objections, paragraph 13, ID8742, p. 12.

1647 See, for example, Servier's reply to the Statement of Objections, paragraph 195-198, 982, ID10114, p. 121, 339-340, Lupin's reply to the Statement of Objections, paragraph 135, ID8752, p. 36-37.

1648 In its reply to the Statement of Objections, Krka observed: "*Servier apparently also had certain doubts as to the strengths of its litigation cases, which presumably resulted in its decision to settle with Krka*" (paragraph 91, ID8742, p. 50).

1649 Servier claims that, applying the criterion of a general doubt, or a non-marginal possibility that a patent would be annulled, would mean that any settlement concerning that patent would be suspected as having an anticompetitive object (see, for example, Servier's reply to the Statement of Objections, paragraphs 60 and subs. and 1025, ID10114, p.82 and 350). This is incorrect. The parties' subjective views and intentions concerning patent enforcement, and, more broadly, commercial strategy to limit the impact of generic entry, are but one amongst the elements in assessing whether the parties were potential competitors. For a reverse payment settlement agreement to be found anticompetitive, it would moreover need to fulfil further conditions specified in paragraph (1154).

(1173) By way of an example – with reference to Teva's internal communication reporting that Servier believed that they have a 50:50 chance to prevail in the Apotex litigation, and commenting that this is less bullish than usual[1650], Servier argues this to show that *"Servier believed it had a reasonable chance to win the Apotex trial, that there was a reasonable possibility that we could win the case"*.[1651] Conversely, Servier's counsel explicitly confirmed that in such a scenario there was a real concrete possibility that a generic company, which would, but for the patent barrier, be fully prepared for launch, would enter the market.[1652]

(1174) In addition, in the absence of a European patent and single patent judiciary, generics remained free to devise and pursue product launch strategies as deemed most appropriate in each of the remaining geographic markets. Thus, they could initiate litigation to "clear the way" in other Member States, by way of declaratory actions for non-infringement or actions for invalidity. Teva, for example, launched an action for annulment of the '947 patent in the Netherlands.[1653]

(1175) In addition to litigating to a judgment in the on-going court procedures, generic companies could in principle resort to alternative routes to the markets where litigation was taking place.

(1176) First, once in possession of a marketing authorisation and to the extent that an interim injunction was not in force, generic companies would remain free to launch perindopril at risk and face Servier's action for patent infringement, and/or an application for interim injunction. The parties err in confounding launch at risk (that is to say sales in the market with the risk that the originator undertaking may start infringement action) with the infringement of patent rights.[1654] Generic medicines launched at risk are not as such 'illegal' or unlawful. Provided the generic obtains a marketing authorisation (and fulfils other national requirements such as price approval, where necessary) and unless there is a court order, nothing prevents the generic from launching the product 'at risk' if in its own assessment it believes that the patents are not valid or not infringed. It is the regulatory framework which enables those entries at risk, as the marketing authorisation approval does not depend on the patent status of the originator. In those situations it is for the originator to try to enforce whatever patents it may still have to try to prevent the generic coming

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1650 ID0346, p. 55.

1651 Servier's reply to the Statement of Objections, paragraph 677, 982, ID10114, p. 263-264, 339-340. As the test is not about the certainty, but real concrete possibility to enter, it is not necessary to exclude all chances that a generic would be blocked from entering.

1652 Recording of the Oral Hearing, 15 April 2013 afternoon, at 1:49:21, ID9641: "*If God tells the generic "you have a 50% chance of winning this legal battle tomorrow" and the UK public authority says "there is your marketing authorization" then yes indeed, the generic has a concrete chance of entering the market and selling its product*". This statement is obviously not considered to have any evidentiary value, but as a hypothetical comment which contrasts with the assertion that in view of the existence of the '947 patent, the entry was merely a theoretical, and not a real concrete possibility. (see, for example, Lupin's reply to the Statement of Objections, paragraphs 194-195, ID8752, p. 52). Servier claims that the Commission disregarded other Servier statements arguing that the percentages of probability do not provide certainty as to market entry, or may include a chance of judicial error (Servier's reply to the Letter of Facts, ID10289, p. 78-79. The Commission emphasises that the reference to specific percentages of probability of success/failure in patent litigation is merely for illustrative purposes. It is also noted that the quotes invoked by Servier essentialy claim that there is no certainty of either winning or losing in patent litigation, which is consistent with the Commission's assessment.

1653 See paragraphs (198)-(200).

1654 Lupin's reply to the Statement of Objections, paragraph s 44-46, 114, 188, Servier's reply to the Statement of Objections, paragraph 965, ID10114, p. 335).

onto the market. The Commission does not contend that in the circumstances of this case, there was no risk of patent infringement. But there was also no certainty that the generic product would be found by a court of law to infringe a valid patent. There is no presumption that any given product, manufactured with a given process, infringes a valid patent. It is for the courts to establish infringement.[1655] and it is for the patentee to prove the infringement.

(1177) Upon the expiry of the compound patent, situations where a generic product cannot be subject to any infringement action over the remaining patents are rare. Close to the expiry of the compound patent, originators typically apply for a number of patents protecting various production processes, formulations, etc. This situation is marked by reciprocal uncertainty – the originator lacks certainty that the remaining patent protection will be sufficient to keep generics legally at bay; generics run the risk that they may fail to circumvent valid patents, and/or fail in infringement or invalidity litigation and incur the risk of having to pay damages. In this sense, virtually all such sales after basic patent expiry are "at risk", and no generic company would qualify as a competitor. By way of example, it cannot be said that Apotex' entry at risk in the summer of 2006 violated Servier's patent rights, although Servier alleged patent infringement and even obtained an interim injunction. The ensuing patent litigation namely resulted in a judgment invalidating the '947 patent in the UK, and the corresponding award of damages to Apotex.[1656] In this case, the launch at risk violated no valid patent rights in the EU, and Servier was in principle liable to pay damages incurred by Apotex during the interim injunction.[1657]

(1178) Second, the generic company, or its suppliers, could adapt the process to avoid current infringement claims. While a change in the manufacturing process may engender some extra regulatory delays if it requires the filing of a variation to the marketing authorisation application, this may be a viable alternative route to the market.[1658] Evidence shows that Niche and Matrix, for example, changed the process to produce API in view of their internal concerns that their process could be infringing.[1659]

1655 The Court of Justice ruled that a licensor cannot substitute "…[its] *discretion for the decisions of national courts, which were the proper forum for actions*". Judgment in *Windsurfing International v Commission*, 193/83, EU:C:1986:75, paragraph 52.

1656 See paragraphs (176)-(190).

1657 Servier also claims that entry at risk is not a commercially attractive strategy in view of the risk of liability for damages to the originator, calculated based on branded and not generic prices, and entries at risk are thus few – in the case of Servier, nobody was willing to enter at risk (reply to the Statement of Objections, paragraph 69, 151, ID10114, p. 86, 106). The Commission finds that (1) several generic companies have considered entering at risk with generic perindopril and have actually entered on at least three occasions (for example, Apotex in the UK, Katwijk (Apotex) in the Netherlands, Krka in Hungary); (2) generic companies may manage the risks of liability in view of the perceived likelihood of success. Amongst others, it can decide to limit the exposure to damages by launching in limited quantities and/or at a limited price discount (see, for example, paragraph (883)).

1658 Generic companies could in principle also change the source of perindopril API or formulations and seek another supplier which would be more likely to avoid infringement claims. While, in the period of the settlements available sources offering an alternative route to market were scarce (see sections 7.3.3.1 and 5.1.7.3), generic companies did consider changing their supplier. Teva, which had an own source of generic perindopril, was also considering supplies from Krka (see section 4.3.2.3.1.). Another such example was Lupin which sought to include a second source of API in its regulatory file to make Lupin's *"offering more attractive"* (see paragraph (1018)).

1659 See paragraphs (465) and (467).

(1179) To conclude, the settlements were concluded in a situation where the perindopril compound patent had expired, and all of the generic parties were involved, directly or indirectly, in legal actions or disputes concerning one or more of Servier's remaining patents, whether in the form of a defence against claims of infringement or actions or counterclaims to invalidate such patents. Generics could also elect other patent related measures as potential avenues to the market. The Commission will examine in detail if generic undertakings seeking to overcome patent barriers and launch generic perindopril were a source of competitive pressure on Servier in spite of its patents. It may be recalled, in this respect, that all of the agreements covered by this Decision were concluded at a point in time where there was uncertainty whether any patent had been infringed and whether in particular the '947 patent could be invalidated.[1660] The mere existence, and enforcement, of Servier's patents thus did not bar all scope for potential or actual competition.[1661]

(1180) With the exception of Krka, generic companies settled with Servier before they received the marketing authorisations needed to market their product in one or more Member States. The parties essentially claim that the fact that the marketing authorisation was not obtained and the uncertainty as to whether at all, and when, this would happen, rule out the existence of potential competition.[1662] According to Servier, the fact that a generic company pursues regulatory approval does not give an indication about its capacity to obtain the authorisation, but merely reflects its intentions. To accept this argument would, in the Commission's view, actually mean that whenever there is uncertainty about whether a barrier to entry would be overcome, potential competition would be completely excluded. But the analysis of potential competition by definition looks at potential future developments, and not at the certainty that entry would in fact ensue.

(1181) The absence of a marketing authorisation does not suggest that the product was not capable of reaching the market,[1663] as long as the generic was pursuing its efforts to

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1660 In terms of the *Hitachi* judgment, concerning the patent rights in question, the facts of the case do *"not state that it was impossible to enter that market, but merely that such entry was difficult"* (Judgment of 12 July 2011, *Hitachi v Commission* , T-112/07, ECR, EU:T:2011:342, paragraph 111).

1661 Teva claims that the Commission's objections are based on contradictory statements, which, on the one hand, find, in the context of assessment of potential competition, that Servier's patents did not disable generic undertakings' ability to enter, and on the other hand, in the context of assessment of Servier's dominance, acknowledged that Servier's patent protection dissuaded generic companies from entering the relevant market (Teva's reply to the Statement of Objections, paragraph 449, ID8495, p. 96-97). There is no contradiction, The existence of potential competition does not bar a finding that the incumbent company which enforces its patents (even if not to Court judgment) may still be dominant, in particular where its own actions are aimed at averting actual competition by protecting the patent barriers. See also paragraph (1167). As recognised in the AstraZeneca judgment an asserted patent can deter entry without actually preventing entry.

1662 Servier's reply to the Statement of Objection, paragraph 150, ID10114, p. 105, Lupin's reply to the Statement of Objections, paragraph 152, ID8752, p. 40-41.

1663 In merger review, the Commission has considered that generic products in development generally constitute "pipeline" competition as a form of potential competition to an already marketed originator product, in particular in view of the high likelihood that such generic products would eventually be brought to the market (Commission Decisions M.3751 Novartis/Hexal, recital 106; M.5253 Sanofi-Aventis/Zentiva, recital 194). According to the parties, this decisional practice is irrelevant as it only concerned markets with no blocking patent (see, for example, Lupin's reply to the Statement of Objections, paragraph 89, ID8752, p. 26-27, Teva's reply to the Statement of Objections, paragraph 460-464, ID8495, p. 98-100). For the reasons set out in this section, the Commission considers that this practice is relevant for all markets for which a blocking position was not legally established, including the present case, where significant entry preparations, including patent challenges, were underway.

obtain regulatory approval and such attempts did not run into objectively insurmountable problems by the time of the settlement.[1664] This is consistently reflected in the case law of the General Court, which, in the language of the *Visa* case, speaks of "*real concrete possibilities"* (emphasis added) to enter, and not the "certainty of actual entry".[1665] It is also recalled that in the *Hitachi* case, evidence showing that entry may have been difficult, but not impossible, is insufficient for a finding that a party was not a potential competitor. Moreover, in the Toshiba case the General Court confirmed that the existence of barriers to entry do not preclude a finding of potential competition, unless such barriers are insurmountable.[1666] Obtaining MA was not an insurmountable barrier for any of the generics who concluded agreements with Servier, even if they had to submit further data and carry out further studies, partly as a result of interventions made by Servier before regulatory authorities (see section 4.1.2.2). It should be observed that in none of the cases the generics' application for MA was set to be rejected by the regulatory authorities.

(1182) Nor can such a conclusion be inferred from the fact that the company risked running into delays compared to its original timeline, either because of delayed regulatory approval or because of patent litigation, including injunctions. According to the *BaByliss* judgment, "[*t*]*he mere fact it takes longer than planned to enter the market does not mean that such entry will not take place*". While delays may reflect the difficulty of entering in terms of cost and time, they do not as such call into question the ability to enter.[1667] On this point, the General Court held that *"…the essential factor is the need for the potential entry to take place with sufficient speed to form a constraint on market participants...*"[1668] In view of the actual duration of court procedures in the UK, the prevailing litigation forum in this case, and of the actual length of the delays in obtaining MA, the claimed delays do not appear sufficiently long for the generic challenger not to form a constraint.[1669] The fact that, under

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1664 See, by analogy, Judgment of 21 May 2014, *Toshiba v Commission*, T-519/09, ECR, EU:T:2014:263, paragraph 230. See also judgment of 8 July 2004, *Dalmine SpA v Commission*, T-50/00, ECR, EU:T:2004:220, paragraph 186.

1665 Joined Judgments of 15 September 1998, *European Night Services and Others v Commission*, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198, paragraph 137.

1666 Judgment of 12 July 2011, *Hitachi v Commission* , T-112/07, ECR, EU:T:2011:342, paragraph 111; and Judgment of 21 May 2014, *Toshiba v Commission*, T-519/09, ECR, EU:T:2014:263, paragraph 230. This directly contradicts the claim that the Commission applied the wrong legal test by examining whether the respective generic companies encountered any insurmountable barriers to entry (see, for example, Lupin's reply to Statement of Objections, paragraphs 74-77, ID8752, p. 24). The latter element served to verify if, in spite of generic company's general ability and proven intention to enter, there were objective reasons rendering generic entry impossible.

1667 Judgment of 3 April 2003, *BaByliss v Commission*, T-114/02, ECR, EU:T:2003:100, paragraph 102.

1668 Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 189.

1669 The first instance procedure in the Apotex litigation, which lifted the interim injunction and allowed Apotex to enter, took eleven months. As to regulatory delays, the grant of the marketing authorisation to Lupin, took place eighteen months after the settlement agreement was concluded. While this does not correspond to the actual delay (as this would require speculating on the timing absent the delay), it is nonetheless used as a proxy. A period of not more than three years is considered to be a "*short period of time*" by the R&D and Specialisation Block Exemption Regulations, and Horizontal Guidelines. The facts of the present case show that that the development of perindopril API technology for commercial use took often around two to three years (as was the case with [company name]*, Azad, Sandoz, etc.), followed by an additional period of one to two years for regulatory approval of perindopril formulations

certain future scenarios, market entry may be less commercially attractive in view of the delay,[1670] does a priori not affect the company's ability to enter or the constraint it exercises on Servier, or other generics.

(1183) From the perspective of the *Hitachi* judgment, the question is whether Niche/Unichem, Matrix, Teva, Krka and Lupin were "*perceived*" as a source of competitive pressure, and thus "*potential credible competitors*",[1671] by both Servier and other generic companies.[1672] On the one hand, generic companies exerted competitive pressure on Servier in the form of impending generic penetration, which prompted Servier's actions to prevent or limit commercial losses. This is, amongst others, documented in Servier's strategy paper from June 2006 entitled "*Coversyl: Defense against generics*"[1673] which exclusively tackled the impending generic threat. It stated that the perindopril turnover was "at stake", identified the array of protective measures against generics, and discussed the specific situation of certain generics.[1674] Accordingly, Servier launched a second generation product, perindopril arginine, which it described as "**defense tool to extend the life cycle of Coversyl*",[1675] contracted authorised generics in the UK and elsewhere, but also transferred considerable value to a number of generic suppliers in exchange for their acceptance not to enter the market. On the other hand, generic companies also exercised pressure on their generic rivals in a race to be the first to enter the market and reap the higher profits which are normally expected from a "first mover" advantage. All this shows that generic companies were perceived as potential competitors by both Servier and their own generic rivals.

5.1.4 Content of patent settlement agreements with reverse payments between Servier and the respective generic companies

(1184) The patent settlement agreements with reverse payments at issue in the present case essentially contain the following two elements:

- contractual limitations imposed on the generic company as a patent challenger (typically in the form of non-challenge and non-compete obligations); and
- a "reverse payment" which may be in the form of an actual financial payment or another inducement (through a value transfer) from the originator (the patent holder) to the generic company.

(1185) Patent settlements may include other provisions (or be related to other parallel transactions) which deal with provision of services, transfer of assets, or constraints on behaviour. When this is the case, the assessment of the contractual limitations and of the inducement must take these into account. The Commission's approach is thus

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as the final product, The sections analysing individual settlement agreements will, where applicable, assess whether the expected delays were capable of removing the competitive pressure on Servier.

1670 Teva argues that the only commercially relevant timeframe for entry was entry by the summer of 2006, just a "few weeks" after the conclusion of the settlement agreement when competitive generic entry, if at all, were to occur. Teva's reply to the Statement of Objections, paragraphs 45 and 421 , ID8495, p. 15 and 91.

1671 Judgment of 12 July 2011, *Hitachi v Commission* , T-112/07, ECR, EU:T:2011:342.

1672 See paragraphs (1160)-(1163).

1673 See, for example, paragraph (886) and footnote 2386.

1674 For a more comprehensive overview of Servier's action to confront generic entry, reference is made to section 4.1.2.

1675 See paragraph (222).

fully consistent with Servier's remark that various parts of the settlement, including the inducement, should not be assessed in isolation, but as a part of the overall settlement balance. The Commission also agrees with Servier that the payment can be considered as a "**necessity inherent in the agreement*" – as *conditio sine qua non* for the conclusion of the investigated settlements.[1676]

5.1.4.1 Contractual limitations on the generic company

(1186) As noted above, there are two main types of contractual limitations included in all of the patent settlement agreements at issue which restrict the generic company's ability and incentives to compete. First, non-challenge obligations may hamper the generic company's right to challenge the validity, or, in cases of (non)infringement actions to establish the non-infringement of an asserted patent. Second, a non-compete obligation constitutes a general limitation on the generic company's ability to pursue commercial activities, including by seeking to enter the market with its generic version of the originator product in a viable and timely manner. To assess whether these limitations amounted to significant restrictions, regard needs to be had to the nature and content of the limitations, geographic and temporal coverage, as well as their actual implementation. Restrictions can be significant (and be found to infringe Article 101(1) of the Treaty) irrespective of whether non-challenge and/or non-compete obligations fall within the scope of the patent-in-suit and the settled litigation, or exceed it.

(1187) Thus, the Commission will also examine if the limitations on the generic undertaking in fact go beyond the scope of Servier's patents at issue and the related dispute/litigation. (what Servier could have legally obtained through successful enforcement of its patents in court in the underlying disputes/litigation). In this respect, guidance can by analogy also be drawn from the Technology Transfer Guidelines: *"where it was clear to the parties that no blocking [patent] position exists […] the settlement is merely a means to restrict competition that existed in the absence of the agreement"*.[1677] Such out-of-scope restrictions may entail an even broader impact on the generic company's ability and incentives to compete.

5.1.4.2 Value transfer as an inducement to the generic company

(1188) Investigated value transfers may simply consist of a one-way transfer of value from the originator company to the generic company (here a net value transfer is clear) or may consist of a series of two-way transactions within the settlement agreement and related agreements. In the latter case, a reverse payment to the generic company is represented by the difference between the value flowing from the originator to the generic company and the flow of value from the generic to originator. This may represent an inducement which affects the generic company's incentives to compete and its decision to instead accept restrictive settlement terms. In contrast to patent settlement agreements without significant value transfers, the settlement is no longer based only on the parties' assessment of (a) the validity of the patent, (b) whether there is an infringement of the patent by the generic company's product and (c) the corresponding strength of each party's litigation case. Accordingly, the restrictions on the generic company are not only the result of the individual assessment of the

1676 Servier's reply to the Statement of Objections, paragraph 104, ID10114, p. 95.

1677 *Commission Notice, Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*, O.J. C 101 (27 April 2004) p. 2-42, point 205.

strength of each party's patent litigation/dispute case but also of the payment or another value transfer by the originator undertaking.

(1189) To the extent that the parties claim that the settlement helped to save litigation costs,[1678] both in terms of resources and time, such savings by Servier cannot be considered as counter performance by the generic company for the reverse payment. The generic companies, too, saved litigation costs, and therefore did not need additional payment if avoiding litigation cost was genuinely the reason to settle. Such explanations are particularly difficult to understand when the originator company pays more than the costs of the litigation.

(1190) Inducement to the generic company may also result from different commercial arrangements. The inducement from the originator company to the generic company may consist in a "side deal" dependent on the generic company's acceptance of settlement terms. Such deal could be prima facie concluded at arms' length and therefore not necessarily result in a loss for the originator. In such cases an analysis of the link between the side deal and the settlement, and the commercial importance of such deal would be necessary to understand whether such an agreement constituted an inducement to accept the settlement terms.

(1191) At any rate, the significance of the inducement to the generic party will be examined, where possible, by comparison to the expected competitive scenarios absent the settlement, indicating the generic company's opportunity cost of settling. In particular, a value transfer which broadly corresponded to the profits associated with generic company's entry would in itself be an indication that it constituted a significant inducement, and affected the generic companies' incentives to accept the settlement terms. At the same time, this is not to say that value transfers inferior to the expected profits would not be considered as an inducement to enter into a given settlement, provided that such transfers would be of comparable magnitude, taking into account the generic company's incentives to compete.

5.1.5 Other general comments by the parties

(a) The legal test is flawed and curtails parties' fundamental right of access to courts

(1192) The parties claim that the Commission's legal test based on value transfer is flawed. In view of the presumption of legality of patent settlement agreements, agreements, even if accompanied by a value transfer, do not fall under the purview of Article 101 as long as they meet the following conditions.[1679] (a) the patent-in-suit has not been obtained by fraud; (b) the settled litigation was not fictitious or vexatious; and (c) settlement terms do not go beyond the exclusionary scope of the patents.[1680] Thus,

1678 See, for example, Matrix' reply to the Statement of Objections, paragraph 3.20, ID8835, p. 33.

1679 Servier's reply to the Statement of Objections, paragraphs 116-125, ID10114, p. 98-100. See also, for example, Teva's reply to the Statement of Objections, paragraphs 55-67, 619-621, ID8495, 18-19, Niche's reply to the Statement of Objections, ID8524, p. 57,

1680 These elements are presented as "objective" by Servier. On the contrary, the Commission notes that the finding of vexatious patenting or litigation would require an assessment of the parties' subjective intentions (Judgment of 17 July 1998, *ITT Promedia NV v Commission*, T-111/96, ECR, EU:T:1998:183, paragraph 117). This is not the case with the elements for assessment of patent settlements as set out in paragraph (1154).

settlements within the scope of the patent-in-suit simply reflect the exclusionary nature inherent in any patent right.[1681]

(1193) The Commission considers that the proposed "scope-of-the-patent" test is not supported by the case law of the Court of Justice and, in addition, is ill-suited.[1682] It would not be in the interest of competition in the pharmaceutical sector and would tend to perpetuate very high costs to consumers for medicine compounds whose patent protection has expired. First, the case law makes clear that the exercise of intellectual and industrial property rights may fall within the prohibition in Article 101(1) whenever it is the object, the means or the consequence of an agreement that restricts competition and not only in so far as the restrictions in the agreement are considered as being outside the scope of the patent.[1683] As explained in paragraph (1120), the Court has used a different concept of subject-matter of the patent.[1684] Furthermore, as explained in paragraph (1122), the Court has confirmed that patent settlement agreements are not excluded from the purview of competition law and may be found to infringe Article 101(1) of the Treaty, without restricting this only to settlement agreements that go beyond the scope of the patent.[1685]

(1194) Also the parties' other suggestion that there are restrictions of competition which are inherent in a patent cannot be accepted. The Court of Justice said in Parke, Davis v. Centrafarm that "[a] *patent, taken by itself and independently of any agreement of which it may be the subject […] is the expression of a legal status granted by a State to products meeting certain criteria, and thus exhibits none of the elements of contract or concerted practice required by Article 85(1)*".[1686] Thus, when a patent holder pays a potential competitor for the latter's commitment to stay out of the market or delay its entry, one cannot say that this restriction of competition reflects the exclusionary nature of patent rights, simply because paying or otherwise inducing potential competitors to stay out of the market is not part of any patent right, nor is it one of the means provided for under patent law to enforce the patent. The restriction of competition results from the agreement between competitors to delay entry in return for payments or other inducement, whereas a patent by itself and independently of any agreement does not imply such a restriction.

(1195) Second, the Commission's test is not akin to an automatic prohibition rule depending on the existence of any value transfer, as the parties wrongly suggest[1687], but

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1681 Matrix's reply to the Statement of Objections, paragraph 1.9, ID8835, p. 6.

1682 The Commission however agrees with the parties that settlements which failed to fulfil one of the criteria propose**d** by the parties could also restrict competition by their very object.

1683 See, e.g., Judgment in *Deutsche Grammophon v Metro SB*, 78/70, EU:C:1971:59, paragraph 6; Judgment in *Sirena v. Eda*, 40/70, EU:C:1971:18, paragraph 5. In addition, in other cases the Court has taken the view that competition rules only protect the legitimate exercise of intellectual or industrial property rights (see, Joined Judgments in *Grundig v Commission* of the EEC, 56/64 and 58/64, EU:C:1966:41, page 346; Judgment in *Keurkoop v Nancy Kean Gifts*, 144/81, EU:C:1982:289 paragraphs 24 and 26; and Judgment of 10 July 1991, RTE v. Commission, T-69/89, ECR, EU:T:1991:39, paragraph 67. See, also Opinion of Advocate General Jacobs in Judgment *CNL-SUCAL v. HAG*, C-10/89, EU:C:1990:112, paragraph 12).

1684 Judgment in *Centrafarm BV and Others v Sterling Drug*, 17/74, EU:C:1974:114, paragraphs 7 and 9.

1685 Judgment in *Bayer v Süllhöfer*, C -65/86, EU:C:1988:448, paragraph 15, Judgement in *Nungesser and Kurt Eisele v. Commission*, 258/78 , EU:C:1982:211, paragraph 28.

1686 Judgment in *Parke, Davis & Co. v Probel and Others*, 24/67, EU:C:1968:11, page 71.

1687 There is therefore no automatic, or per se, finding that a settlement agreement with a value transfer is restrictive under Article 101(1) of the Treaty, as the parties assert (see, for example, Matrix' reply to the Statement of Objections, paragraph 4.18, ID8835, p. 45-46). Moreover, the notion of per se

examines, on a case by case basis, the entire agreement and the relationship between the parties, in their legal and economic context.

(1196) Third, the "scope-of-the patent" test assumes[1688] that the generic's medicine infringes the originator's patent and allows the originator to exclude the generic from the market on that basis, without antitrust scrutiny, and even though the originator transfers a considerable sum of money to the generic as part of the deal. Such a one-sided view is unreliable and inconsistent with the substantial uncertainty which existed at the time Servier and its generic counterparts entered into the respective settlements. The Decision fully recognises and respects the right of patent holders to oppose infringements, including through access to the courts, which is part of the subject-matter of the patent. However, the fact that a generic competitor may be excluded from the market if it is found by a court to infringe a patent does not mean that patent holders are allowed to purchase the same goal of market exclusion through a restrictive agreement, notably by offering the generic a sum that roughly matches the profits the generic could expect to make if it entered the market in exchange for a commitment not to enter. The purchase of market exclusion that includes potentially non-infringing generic sales cannot be justified by the right to oppose infringements. Such market exclusion agreements are not immune from competition law.

(1197) If the patents had been enforced, *quod non*, the courts may or may not have sided with Servier. The relevant counterfactual[1689], to eliminating a potential competitor by a settlement akin to the investigated ones, is not that the patent would be invalidated, but that the competitive process consisting also in genuine patent challenges by potential competitors (as well as their legitimate interest in settling) would remain undistorted by inducements affecting the generic companies' incentives to compete. Paying potential competitors not to try to enter the market with their product is not based on any rights granted by patent law, nor on the strength of the patent, nor is it one of the legitimate means society has provided for the defence of patent rights.

(1198) Fourth, the test advocated by the parties would fail to capture any settlement based on an exclusionary payment or another significant inducement for the potential competitor to drop patent litigation and abandon planned entry, or otherwise limit its ability to compete within the scope of the patent-in-suit, even when there was a real concrete possibility that the challenger could overcome the patent barrier and lawfully enter before its lapse.

(1199) Fifth, in support of the proposed test, the parties repeatedly invoke that such an approach is consistent with the case-law of US courts.[1690] The Commission recalls that Union law is distinct from US law, and that therefore decisions by US bodies are without legal bearing for the application of Article 101 and 102 of the Treaty. The Commission is not obliged to accept arguments based on foreign law or to reason

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infringement derives from US case law and is not an equivalent to restriction by object, as set out in section 5.1.1 above.

1688 See, for example, Teva's reply to the Statement of Objections, paragraph 630, ID8495, p. 128, Matrix's reply to the Statement of Objections, paragraph 1.10, 1.34-1.35, ID8835, p. 6, 11.

1689 Parties consider that the Commission took "*a position on the outcome of litigation as a valid counterfactual*". See, for example, Matrix's reply to the Statement of Objections, paragraph 1.34-1.35, ID8835, p. 11.

1690 See, for example, Servier's reply to the Statement of Objections, paragraph 115, ID10114, p. 98, referring to decision in re FTC v Watson Pharmaceuticals, US Court of Appeals for the 11th Circuit, 25 April 2012.

their rejection.[1691] Moreover, there are significant differences in the legal and regulatory framework between the EU and the US, which would need to be carefully examined before any interpretational inferences are drawn. At any rate, the scope-of-the-patent test was rejected recently by the US Supreme Court, which held that reverse payment settlements with restrictions not exceeding the scope of the patent could infringe US anti-trust laws.[1692]

(1200) According to the parties, the prohibition of settlements agreements with a value transfer to generic companies is too broad and could affect incentives to litigate, or to settle.[1693] This would, according to Servier, also be in violation of Article 47 of the Charter of Fundamental Rights of the EU and Article 6(1) of the European Convention for the Protection of Human Rights and Fundamental Freedoms.[1694] This claim is unfounded. First, the parties' fundamental right of access to courts of law does not also encompass the entitlement to conclude agreements between the parties which restrict competition. Moreover, the Commission recalls that parties to litigation can resort to an array of legitimate settlement solutions, including those comprising a value transfer (for example, a settlement allowing for early generic entry in the contested market(s) before the lapse of the disputed patent). Section 5.1.2 clarifies that not all settlements with value transfer constitute a restriction by object, only those with a significant inducement which substantially reduced the incentives of the generic undertaking to independently pursue its efforts to enter one or more EU markets with a generic product instead of competing.[1695]

(1201) As the parties rightly claim, there is no obligation for competitors to pursue the annulment or revocation of a patent granted to another competitor.[1696] As in the present case, the incentives for such action will depend on the commercial opportunity of entering with a specific product and the perceived strength of the patent case. A company can decide to attempt to enter a market by challenging the validity of a patent, whether on its own initiative or as a counterclaim in a patent infringement action and it can also decide to abandon such endeavours. However, where the commercial freedom to decide whether or not to litigate, and thus to overcome patent barriers and secure a patent-compliant product launch, is restricted due to an inducement by the holder of IPRs to enter into a restrictive arrangement, this may fall within the prohibition of Article 101(1) of the Treaty.

(b) Observations on the economic studies on pro-competitiveness of patent settlements presented by the parties

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1691 Joined Judgment of 30 September 2003, Atlantic Container Line and Others v Commission, T-191/98, T-212/98 to T-214/98 ECR, EU:T:2003:245, §1407. See also, Judgment of 1 July 2010 AstraZeneca v Commission, T-321/05, ECR, EU:T:2010:266, cited above, §368. See, also Judgment in Eni v Commission, C-508/11 P, EU:C:2013:289, §78 and 81.

1692 In re FTC v Actavis, Inc., et al., Supreme Court of the United States, 17 June 2013.

1693 For example, Lupin's reply to the Statement of Objections, paragraphs 497-499, ID8752, p. 118-119. Niche's reply to the Statement of Objections, ID8524, p. 54.

1694 Servier's reply to the Statement of Objections, paragraphs 105-109, ID10114, p. 95-96; paragraphs 23 and 24 of Annex 00-02 of Servier's reply to the Statement of Objections, ID9054, p. 8-9.

1695 See, for example, Servier's claim that the Commission's characterisation of the investigated settlement agreements as avoiding competition on the merits would mean that no generic involved in a patent dispute could ever conclude a settlement agreement (Servier's reply to the Statement of Objections, paragraph 1351, ID10114, p. 421).

1696 See paragraph (917), Servier's reply to the Statement of Objections, paragraphs 95-96, ID10114, p. 93, Lupin's reply to the Statement of Objections, paragraph 464, ID8752, p. 111, Krka's reply to the Statement of Objections, paragraphs 14-16 and 182-185, ID8742, p. 12-13, 90-91.

(1202) A report entitled "*The consumer welfare effects of value transfer settlements*",[1697] which Servier submitted in reply to the Statement of Objections, alleges a number of shortcomings in the Commission's economic assessment of static and dynamic effects of patent settlements with a value transfer.

(1203) The report claims that the Commission's objections concerning the investigated settlements imply that intervention is needed because "*patent litigation fails too frequently to go all the way to a judicial decision*".[1698] This in unfounded. The Commission notes that the objections are strictly and specifically limited to situations where the reverse payment settlement was tantamount to "buying off" a competitor from the market. The Commission does not find that "*too few patent cases [are] going to trial*",[1699] but found that the investigated value transfers constituted an inducement which distorted the generic company's incentive to participate in the competitive process, including by litigation. Therefore, Servier's proposition that "*the objection should be to any form of settlement*"[1700] is groundless. All the more so, given that this Decision consistently finds that not only continued litigation, but agreements without a reverse payment (for example, early entry settlements) could constitute a legitimate alternative to the investigated settlements.

(1204) On this basis, Servier also contends that the Commission's approach is premised on the hypothesis that there is a market failure deriving from the patent grant system, which the Commission seeks to regulate by competition law intervention. Such an approach would lead to increased legal uncertainty, as "*the relatively strong part of the patent process in Europe is at the patent issuing stage, while the relatively weak part of the process is the system of adjudicating patent infringement and validity in national courts – a system that results in high costs and unpredictable and contradictory decisions*".[1701] First, although the existing patent system has certain shortcomings, as pointed out in the Commission's Sector Inquiry,[1702] which has as such already prompted legislative changes, the Commission does not accept that adjudicating patent issues is a 'weak' part of the patent process in the EU.[1703] While the current system of enforcement could in theory give rise to national court decisions which may appear contradictory, there is no evidence of any such contradictions arising in this case. Moreover, the fact that after grant, patents granted by the EPO become a bundle of national patents and that national courts are exclusively competent within their territory to adjudicate on issues of validity and infringement in accordance with their national law also played to Servier's advantage. Thus, even after the '947 patent had been found invalid in the UK and

1697 Report prepared by Charles Rivers Associates for Servier. Annex 00-01B to Servier's reply to the Statement of Objections, ID9054.

1698 Annex 00-01B to Servier's reply to the Statement of Objections, ID9054, p. 12-16.

1699 Annex 00-01B to Servier's reply to the Statement of Objections, ID9054, p. 17.

1700 Annex 00-01B to Servier's reply to the Statement of Objections, ID9054, p. 12.

1701 Servier's reply to the Statement of Objections, paragraph 60 and 101, ID10114, p. 83 and 94; Annex 00-01B to Servier's reply to the Statement of Objections, ID9054, p. 12-16. See also Lupin's reply to the Statement of Objections, paragraph 453-461, ID8752, p. 109-110.

1702 Servier points to the Commission's Pharmaceutical Sector Inquiry Final Report, which found that national patent judgments were contradicting in 11% of the cases. Therefore, even if the patentee were 100% certain on the merits of its case, it could still risk losing in 11% of cases (Servier's reply to the Statement of Objections, paragraph 67, ID10114, p. 85). Such discrepancies may not necessarily represent judicial errors, but divergences in national case law, for example concerning the doctrine of equivalence for the assessment of patent infringements. See, for example footnote 1815.

1703 Unified Patent Court agreement was signed on 19 February 2013.

until the decision of the Appeals Board of the EPO, Servier could continue to enforce that patent in other Member States, which in fact it did, for example in the Netherlands and Belgium. Servier thus failed to demonstrate that, in the specific circumstances of this case, the claimed deficiencies of the patent system would justify the use of settlements with reverse payment. On the contrary, Servier itself claimed to have had a number of successes before both patent offices and courts.[1704] Second, even though the Commission is entitled to assess patents under certain conditions,[1705] this is not necessary in the circumstances, and for the purpose of this Decision. Nor is the Commission, in applying Article 101 and/or 102 of the Treaty, called upon to second guess the authority or decisional practice of patent offices or patent courts.[1706]

(1205) The report posits that since patent holders are not obliged to consider effects on consumer welfare when determining the prices of a patented product, there is also no obligation to consider such effects when structuring an agreement with a generic company.[1707] This argument fails to acknowledge that unlike sales of a patented products, the possibility of settling legal challenges is not specific to patent disputes, but is the consequence of a public interest in the settlement of disputes, a recognition that, in general, settlements generate efficiencies and save court resources.[1708]. Nonetheless, such general public policy considerations do not exclude the application of competition law. The Commission recalls that "*Article 85(1) makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind*".[1709]

(1206) According to the report, the Commission's analysis focuses only on the short run effects of settlements with a value transfer on consumer welfare and ignores longer run effects of prohibiting such agreements on the incentives to innovate. It is claimed that this happens because expected earlier generic entry will reduce originators'

1704 Servier's reply to the Statement of Objections, paragraphs 905-939, ID10114, p. 321-328.

1705 In Windsurfing International, the Court of Justice concluded that "*[a]lthough the Commission is not competent to determine the scope of a patent , it is still the case that it may not refrain from all action when the scope of the patent is relevant for the purposes of determining whether there has been an infringement of Article 85 or 86 of the Treaty. Even in cases where the protection afforded by a patent is the subject of proceedings before the national courts, the commission must be able to exercise its powers in accordance with the provisions of Regulation No 17".* Judgment in *Windsurfing International v Commission,* 193/83, EU:C:1986:75, paragraph 26. Such assessment is without prejudice to the assessment which national courts may later make, must be based on the legal position in the Member State in which the patent was granted and is subject to review by the European courts as to whether it is 'reasonable' (see paragraphs 27 – 28).

1706 See also, for example, Matrix' reply to the Statement of Objections, paragraph 4.36, ID8835, p. 55.

1707 Annex 00-01B to Servier's reply to the Statement of Objections, ID9054, p. 18.

1708 Limitations may not only flow from substantive but also procedural rules. For example, the possibility for the parties to litigation to enter into a settlement will depend on the national court procedures, including the stage of procedure reached at a particular time.

1709 See, to that effect, Judgment in *Bayer v Süllhöfer*, C -65/86, EU:C:1988:448, paragraph 15. See also Judgment in *BAT v Commission*, 35/83, EU:C:1985:32, paragraph 33. In the latter case, the ECJ acknowledged that so-called *delimitation* agreements resolving trade-mark related disputes may be *"lawful and useful"* as they are *"intended to avoid confusion or conflict between [the parties]"*. However, the Court concluded that *"such agreements are [not] excluded from the application of Article [101] of the Treaty if they also have the aim of dividing up the market or restricting competition in other ways. As the court has already stated [the Consten and Grundig case], the Community system of competition does not allow the improper use of rights under any national trade mark law in order to frustrate the Community's law on cartels".*

expected profits.[1710] The Commission recognises the importance of preserving incentives to innovate, but disagrees with Servier that the findings of this decision would necessarily stifle dynamic competition.[1711] Averting the possibility of an earlier generic entry by reverse payment settlements bestows protection to the patent holder that goes beyond that provided by the patent system. The Court of Justice has clarified that a "*misuse of the patent system potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator"*.[1712] Although this conclusion concerns a unilateral abuse of the patent system, the logic that undue generic delay may decrease the originator's incentives to undertake R&D is inherent also to the reverse payment patent settlements. Servier's basic premise that extending originator profits necessarily leads to more innovation is incorrect. Moreover, the argument advanced in the report suffers from internal incoherence. On the one hand, Servier claims that a prohibition of payment settlements will "*raise the expected costs to patent holders of dealing with generic challenges and […] reduce patent holder profitability*".[1713] However, elsewhere in the same submission, Servier maintains that the prohibition of value transfer settlements would make generic challenge less attractive and could result in fewer generic patent challenges.[1714] This implies that the overall effect on the originator's expected profits (and thus incentives to innovate in the long-term) is ambiguous: on the one hand earlier generic entry would reduce originator's expected profits, on the other hand less generic challenge would push these profits up. Finally, this incoherence is accentuated by Servier's argument that "*generic companies might use 'at risk entry' as a strategy to 'blackmail' patent holders subject to judicial uncertainty rather than as a genuine attempt to launch a successful commercial venture"*.[1715] In addition to the arguments concerning alleged "asymmetry of risk" to Servier's disadvantage (see paragraph (1149)), Servier fails to consider that it may be the very prospect of a reverse payment that may be at the source of such hypothetical "hold-up" strategies. Contrary to Servier's claim, a prohibition of reverse payment patent settlement removes the incentives to engage in such conduct.[1716]

1710 Annex 00-01B to Servier's reply to the Statement of Objections, ID9054, p. 19-25 and 27. See also Lupin's reply to the Statement of Objections, paragraphs 498-499, ID8752, p. 118-119. These arguments could, by their very nature, also belong to the analysis of efficiencies under Article 101(3) of the Treaty. However, the parties neither claimed the benefits of Article 101(3) of the Treaty nor discharged their burden of proof pursuant to Article 2 of Council Regulation No 1/2003. Therefore, these arguments, which are very general and abstract in nature and as such do not allow a proper analysis under Article 101(3) of the Treaty, are not further assessed in section 5.7.

1711 As a preliminary point, the Commission recalls that the legal conditions identified in section 5.1.2 demonstrate that only certain, and not all, settlements with value transfer would be considered as restrictive of competition.

1712 Judgment of 1 July 2010 *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 367.

1713 Annex 00-01B to Servier's reply to the Statement of Objections, ID9054, p. 27.

1714 Annex 00-01B to Servier's reply to the Statement of Objections, ID9054, p. 16-17. See also Appendix 3 to Teva's reply to the Statement of Objections, ID8498, p. 17, Lupin's reply to the Statement of Objections, paragraph 497-499, ID8752, p. 118-119.

1715 Annex 00-01B to Servier's reply to the Statement of Objections, ID9054, p. 18.

1716 If what Servier means with this argument is that it was coerced into the agreements by the 'blackmail' it suffices to state that the EU courts have consistently rejected coercion or pressure brought to bear on an undertaking as a justification for entering into anticompetitive agreement (see, e.g. Judgment in *Dansk Rørindustri and Others v Commission*, C-189/02 P, EU:C:2005:408, paragraphs 369-370; Judgment of 6 April 1995, *Trefileurope v Commission*, T-141/89, ECR, EU:T:1995:62, paragraph 58; Judgment of 20 March 2002, *KE KELIT v Commission*, T-17/99, ECR, EU:T:2002:73, paragraph 50; Judgment of 29

(1207) An economic report entitled "*Should reverse payment patent settlements be treated as restrictions by object and prohibited per se?*" annexed to Teva's reply to the Statement of Objections[1717] claims that reverse payment patent settlements "*should not be treated as restrictions by object […] even when the reverse payment is substantial and exceeds the originator's expected litigation costs*".[1718] On a preliminary note, the Commission considers that the discussed economic models do not adequately reflect the facts of the present case. Notably the models in question define changes in consumer welfare in terms of the so-called early entry, where, as a part of the settlement, the parties unconditionally agree that the generic company will enter on the market at an earlier date than the expiry date of the patent(s) in dispute.[1719] As the Commission's analysis in the subsequent sections 5.2 - 5.6 shows, the agreements investigated in the present case do not include any provisions allowing for unconditional generic entry before the expiry or invalidation of the patents in dispute. For this reason, the models in question cannot offer any insights that could be potentially relevant for the present case.[1720]

(1208) Teva also claims that reverse payment patent settlements (referring to *"[e]ven those settlements that do result in delays in generic entry*") are necessary to manage the risks associated with litigation and investments into development of new products.[1721] The Commission reiterates that certain risks, like those related to competition on merits, cannot be eliminated through direct payments between competitors in return for commitments to restrict generic entry.[1722] There cannot be insurance against competition.

(1209) A report entitled "*An assessment of the competitive effects of the settlement agreement between Servier and Matrix*" has been submitted as an annex to Matrix' reply to the Statement of Objections.[1723] Matrix' claim that reverse payment settlements should not be considered as restrictions by object is based on a model which links the size of the reverse payment with the following factors: the originator and the entrant's view on their respective likelihood of success, litigation costs and lost/expected profits.[1724] In the Commission's view, this model is inadequate to support Matrix' position. First, it does not discuss consumer welfare, but merely explains why the originator and the generic are better off by settling. Therefore, it falls short of explaining why competition, and consumers, would benefit from such settlements. Second, linking the reverse payment to the lost/expected profits of the

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November 2005, *Union Pigments v Commission*, T-62/02, ECR, EU:T:2005:430, paragraph 63; and Judgment of 19 May 2010, *Chalkor v Commission*, T-21/05, ECR, EU:T:2010:205, paragraph 72).

1717 Report prepared by Compax Lexecon for Teva. Appendix 3 to Teva's reply to the Statement of Objections, ID8498.

1718 Appendix 3 to Teva's reply to the Statement of Objections, ID8498, p. 18,

1719 Appendix 3 to Teva's reply to the Statement of Objections, ID8498, p. 2, 9.

1720 Teva's models contain a further fundamental flaw, as they do not explain why the parties would decide to settle on the terms that would extend consumer welfare (save for compliance with competition law) as compared to the outcome of adjudicated court dispute, in a situation in which the parties can maximise their joint profits by delaying generic entry against the payment.

1721 Appendix 3 to Teva's reply to the Statement of Objections, ID8498, p. 10. These arguments could, by their very nature, also belong to the analysis of efficiencies under Article 101(3) of the Treaty. See section 5.7.

1722 See, for example, Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 33.

1723 Report prepared by RBB Economics for Matrix and annexed to its reply to the Statement of Objections, ID8831-8834.

1724 Annex to Matrix's reply to the Statement of Objections, ID8831, p. 4.

parties in the counterfactual scenario of competition clearly suggests the anticompetitive nature of the agreement in question. For the reasons explained in paragraph (1208), payments to avoid uncertainties of competition are not legitimate. Even if the reverse payment were necessary to allow the settlement to occur,[1725] this would only mean that the payment turned the settlement into the preferred option for both parties as compared to continued litigation. It must be noted that the settlement cannot be regarded as the ultimate objective of any dispute between competitors, in particular where parties cannot reach a solution based on the perceived merits of the case.

(1210) A report entitled "*Economic assessment of Lupin's agreement with Servier in relation to* the *supply of perindopril*" has been submitted as an annex to Lupin's reply to the Statement of Objections.[1726] The report develops a number of fact specific arguments, which are addressed in the individual assessment of the Lupin Settlement Agreement. Concerning the general argument that the Commission's assessment underestimates the value of patents transferred in the context of the settlement, the Commission notes that, even if the patents were acquired at arms' length, what matters is whether this deal was capable of inducing the generic competitor to accept restrictive settlement terms by distorting its incentives to engage in competition.[1727] In other words, the question is whether Lupin would accept the exact settlement terms without Servier's agreement to acquire Lupin technology for a sum in the order of EUR 40 million.

5.1.6 Conclusion

(1211) The analysis of individual patent settlement agreements in this Decision will therefore establish whether the content, objectives, and legal and economic context of the patent settlement agreement concluded between Servier and the generic company constitutes a restriction by object with emphasis on the elements mentioned above (see paragraph (1154)). The analysis will be complemented by an additional analysis of likely restrictive effects and will also look into the effects of the agreement on trade between Member States.

5.1.7 Assessment of patent settlement agreements with reverse payments as restrictions by effect pursuant to Article 101(1) of the Treaty

5.1.7.1 Applicable rules

(1212) According to settled case law, there is no need to take account of the concrete effects of an agreement when it is established that it has as its object the restriction of competition, the alternative nature of the conditions being indicated by the conjunction "or" in Article 101(1) of the Treaty.[1728]

1725 Annex to Matrix's reply to the Statement of Objections, ID8831, p. 32.

1726 Report prepared by Oxera Consulting for Lupin and annexe to its reply to the Statement of Objections, ID9316.

1727 See paragraphs (1190) and (1974).

1728 See, among others, Joined Judgment in *Consten and Grundig v Commission* 56/64 and 58/64, EU:C:1966:41, p. 342; Judgment in *Ferriere Nord v Commission*, C-219/95 P, EU:C:1997:375, paragraph 14; Joined Judgment in *Aalborg Portland and others v Commission*, C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P, EU:C:2004:6, paragraph 261; Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 55; Judgment in *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, paragraph 28; Joined Judgment of 20 April 1999, *LVM v Commission*, T-305/94, T-306/94, T-307/94, T-313/94 to T-316/94, T-318/94, T-325/94, T-328/94, T-329/94 and T-

(1213) In sections 5.2.1, 5.3.1, 5.4.1, 5.5.3 and 5.6.1, the analysis carried out by the Commission shows that the agreements between Servier and each of the generic companies (Niche/Unichem, Matrix, Teva, Krka and Lupin) had as their object the restriction of competition. Therefore, in application of the case law mentioned above, it is unnecessary to analyse whether the effects of the said agreements were also restrictive of competition, as both conditions are alternative. Nonetheless, for the sake of completeness, the Commission will also analyse below the likely restrictive effects of the agreements on competition.

(1214) In assessing the restrictive effects of an agreement, account should be taken of the actual conditions in which it produces its effects, namely the economic and legal context, the nature of the product concerned, the real operating conditions and the structure of the market concerned.[1729]

(1215) The examination of conditions of competition on a given market must be based not only on existing competition between the undertakings already present on the relevant market but also on potential competition. As the General Court has stated, *"the mere fact of [the existence of an undertaking outside that market] may give rise to competitive pressure on the undertakings currently operating in the market, a pressure represented by the likelihood that a new competitor will enter the market"*.[1730]

(1216) The Horizontal Guidelines contain the following definition of agreements restricting competition by their effect:[1731] "*For an agreement to have restrictive effects on competition within the meaning of Article 101(1) it must have, or be likely to have, an appreciable adverse impact on at least one of the parameters of competition on the market, such as price, output, product quality, product variety or innovation. Agreements can have such effects by appreciably reducing competition between the parties to the agreement or between any one of them and third parties. This means that the agreement must reduce the parties' decision-making independence, either due to obligations contained in the agreement which regulate the market conduct of at least one of the parties or by influencing the market conduct of at least one of the parties by causing a change in its incentives*" (emphasis added).

(1217) In *Tiercé Ladbroke*, the General Court recalled that "*the prohibition set out in Article 85(1) of the Treaty covers all agreements, decisions by associations of undertakings or concerted practices whose object or effect is to restrict not only actual or possible competition between the parties concerned but also any possible competition between them or one of them and third parties*".[1732] In this case, the

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335/94, ECR, EU:T:1999:80, paragraph 741; Joined Judgment of 24 May 2012, *MasterCard, Inc. v European Commission*, T-111/08, ECR, EU:T:2012:260, paragraph 139.

1729 Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 67.

1730 Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 169.

1731 *Communication from the Commission - Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, OJ C 11, 14/01/2011, point 27.

1732 Judgment of 12 June 1997, *Tiercé Ladbroke SA v Commission*, T-504/93, ECR, EU:T:1997:84, paragraphs 154-162. See also Joined Judgments of 15 September 1998, *European Night Services and Others v Commission*, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198 paragraph 137: "*the examination of conditions of competition is based not only on existing competition between undertakings already present on the relevant market but also on potential competition in order to*

Commission rejected a complaint on the ground that the alleged agreement not to grant a licence to third parties did not restrict competition as it was a "*normal consequence of the fact that neither [of the third parties] were currently present on the betting market"*. However, the General Court disagreed with this view and concluded such an agreement would "*be liable to impede the entry of each of [third parties] on to the Belgian market […] in general and thereby restrict such potential competition as might exist on that market, to the detriment of the interests of bookmakers and ultimate consumers. Moreover, the effect of such an agreement might be to `limit or control ... markets' and/or to `share markets.*'" The Court thus clarified that the Commission should look at the effects of the agreement on potential competition. Such analysis is directly relevant for the investigated settlement agreements, where value transfers constituted a significant inducement affecting the generic competitor's incentives to prepare for generic entry in one or more EU markets. As the specific assessment of each of the settlements will show, competition between the originator company and the respective generic company was significantly reduced as the latter accepted limitations on its ability to compete and was not able to launch its product, nor claim invalidity or non-infringement of the relevant patents, for the entire duration of the agreement.

(1218) Restrictive effects on competition must be established with a sufficient degree of probability and this will depend on several factors[1733] "*such as the nature and content of the agreement, the extent to which the parties individually or jointly have or obtain some degree of market power, and the extent to which the agreement contributes to the creation, maintenance or strengthening of that market power or allows the parties to exploit such market power*". According to the case law, the Commission must carry out an objective analysis of the impact of the agreement on the competitive situation.[1734]

(1219) The parties argue that the Commission's analysis has not shown concrete restrictive effects of the agreement and has ignored established case law of the Court of Justice. In their view, to establish the existence of restrictive effects, it is not sufficient to determine likely effects of the agreement, as only actual effects are relevant.[1735] This is incorrect. According to the Guidelines on the application of Article 81(3), account must be taken of both actual and potential effects. In other words, the agreement must have likely anti-competitive effects (paragraph 24). In the *Visa* case, the General Court held that the Commission was correct in assessing the effects based on "*potential competition represented by Morgan Stanley [the excluded party] and on the structure of the market*".[1736] The Commission will first establish the concrete effects of the settlement agreements on potential competition: the removal of the generic company as a potential competitor (which is also analysed under the rules for

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ascertain whether […] there are concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to penetrate the relevant market and compete with the undertakings already established". This was confirmed in Judgment of 14 April 2011, Visa Europe Ltd and Visa International Service v European Commission, T-461/07, ECR, EU:T:2011:181, paragraph 68.

1733 *Communication from the Commission - Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, OJ C 11, 14/01/2011, point 28. See also point 24, Guidelines on Article 81(3).

1734 Judgment of 2 May 2006, *O2 Germany v Commission*, T-328/03, ECR, EU:T:2006:116, paragraph 77.

1735 Servier's reply to the Statement of Objections, paragraphs 139-140, ID10114, p. 104-105, Lupin's reply to the Statement of Objections, paragraphs 371, 403-405, ID8752, p. 91, 97).

1736 Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 127.

restrictions by object). In the second step, the Commission will then examine whether the elimination of a single potential competitor was likely to have effects on the competitive structure,[1737] and ultimately, for the consumers.

(1220) The assessment of restrictive effects should be carried out based on the facts at the time of the settlement, while also taking into account how the agreement was actually implemented. Some of the parties disagree and claim that the assessment should take into account all posterior factual developments, and not be based primarily on the situation at the time the agreements were concluded.[1738] This is incorrect for a number of reasons. First, the principle of legal certainty mandates that the parties should be able to determine whether the conduct may raise antitrust liability at the time of the conduct itself. The qualification of an infringement can as a rule not depend on posterior developments. This is in keeping with the *AstraZeneca* judgment,[1739] where the Court of Justice found that the "*the anti-competitive nature of [the investigated party's] acts must be evaluated at the time when those acts were committed"*.[1740] Second, when elimination of potential competition is at issue, looking at what actually happened may have little to do with what would likely have happened absent the agreement, a core question for the competitive assessment. This is all the more so where the agreement significantly changes the incentives of one party, or both, to continue to compete.

(1221) The restrictive effects of an agreement must be assessed *"in comparison to the actual legal and economic context in which competition would occur in the absence of the agreement"*.[1741] Each assessment of the respective settlement agreement will therefore examine the degree of "*competition between the parties and competition from third parties, in particular actual or potential competition that would have existed in the absence of the agreement*".[1742]

(1222) In establishing that, in the light of the structure of the market and the economic and legal context within which it functions there were real concrete possibilities for the generic companies to enter the relevant markets and compete with Servier,[1743] the Commission examined whether the generic companies were potential competitors of Servier. In this respect, reference is made to the section on potential competitors

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1737 See also Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 63; Judgment in *T-Mobile Netherland and Others*, C-8/08, EU:C:2009:343, paragraph 38.

1738 For example, Servier's reply to Statement of Objections, paragraph 140, ID10114, p. 104. This view is not shared by all the parties, as Krka claims "*that the mere finding of the invalidity of a patent does not render the patent irrelevant to the appropriate competition law analysis (i.e. it is always necessary to conduct ex ante analysis and not resort to the inappropriate ex post analysis)"*. Krka's reply to the Statement of Objections, paragraph 13, ID8742, p. 12.

1739 Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 110.

1740 See, for example, Lupin's reply to the Statement of Objections, paragraph 407-408, ID8752, p. 98.

1741 Communication from the Commission - *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, Official Journal C 11, 14/01/2011, point 29. See also 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 69.

1742 Communication from the Commission - *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, Official Journal C 11, 14/01/2011, point 29.

1743 Joined Judgments of 15 September 1998, *European Night Services and Others v Commission*, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198, paragraph 137; Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 68.

developed in the context of each agreement as a restriction by object (see also section 5.1.3.). Potential competition is very relevant as there has been no actual generic entry with perindopril in the Member States affected by the settlements.

(1223) An analysis of restrictive effects should, according to the European Court of Justice, take into account that "*Article [101* of the Treaty*], like the other competition rules of the Treaty, is designed to protect not only the interests of competitors or consumers but also to protect the structure of the market and thus competition as such*".[1744] The Commission's assessment of effects on the structure will consider each of the following specific elements.

(1224) The notion of market power is central. According to the Guidelines on the application of Article 81(3), negative effects on competition within the relevant market are likely to occur when the parties individually or jointly have or obtain some degree of market power and the agreement contributes to the creation, maintenance or strengthening of that market power.[1745] As the next section (5.1.7.2) will show, Servier enjoyed market power, and the agreements, removing the generic competitors, the primary source of price competition for Servier, contributed to buttressing Servier's market position.

(1225) The Commission's assessment will also look at the content of the agreement (with its limitations) and the significant inducement that led the generic company to accept these limitations and turn away from its plan to enter the market. This will make reference to the relevant sections of each settlement agreement as a restriction of competition by object.

(1226) In analysing the conditions of competition that would have prevailed in the absence of the agreements, another element which will be considered by the Commission is the competitive behaviour that the generic undertakings would have been likely to engage in, in the absence of the agreement.

(1227) Finally, the Commission will examine whether competition would be restricted in view of the existence of other relevant sources of competition to Servier. The Commission has consistently held that even when there is effective competition on the market, the fact that the market is deprived of a new entrant can have appreciable restrictive effects.[1746] It is recalled that the existence of a certain degree of competition does not preclude a finding of an appreciable restriction of competition as a result of the foreclosure of potential competition. This is all the more so where the incumbent faces no actual generic competitors on the market, as was predominantly the case with Servier's perindopril. The subsequent sections will (a) identify Servier's position on the relevant market, (b) examine the structure of the market for perindopril at the time the settlement agreements were concluded and identify the remaining scope for competition.

1744 Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 126.

1745 Guidelines on Article 81(3), point 25.

1746 See, for example, points 199 and 200 of Commission Decision COMP/D1/37860 *Morgan Stanley / Visa International and Visa Europe*, of 3 October 2007, as confirmed by the General Court in Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181.

5.1.7.2 Servier's position on the relevant market

(1228) For the purposes of analysing the restrictive effects of an agreement it is normally necessary to define the relevant market. In some cases, however, it may be possible to show anti-competitive effects directly by analysing the conduct of the parties to the agreement on the market.[1747]

(1229) In section 6 below, the present Decision finds that the actual or potential restrictive effects of the patent settlements should be assessed within a market for the sale of perindopril in the retail (pharmacy) channel in France, the Netherlands, Poland and the UK. In the present Decision, the lack of significant constraints over the sales of perindopril is established with respect to France, the Netherlands, Poland and the UK, in the period 2000 to 2009.[1748] The main reasons for this finding are summarised below.

(1230) Starting from the product that is the subject of the practices under review, a relevant product market comprises all those products which are regarded as sufficiently substitutable by the consumer by reason of the products' characteristics, their prices and their intended use. Perindopril aims at lowering blood pressure. There were many other medicines with the same therapeutic use. Some used the same general mode of action. Others were more remote. None of them had clear evidence of superiority. Therefore at first sight, it may not seem completely intuitive that a medicine such as perindopril may constitute a market in its own right, where many other similar medicines were available. However, certain functional similarities are not sufficient to establish that those other medicines represented sufficiently close substitutes to constrain Servier's behaviour given the circumstances of the case.

(1231) Antihypertensive medicines' effectiveness and side effects differ from one patient to another.[1749] Many patients are likely to develop side effects for certain medicines. In other words, for any new patient, only an initially unknown subset of available medicines will be compatible. As soon as it is discovered that a given medicine alone, or in combination, adequately treats the patient's condition without side effects, the doctor is unlikely to risk provoking side-effects by deciding to switch this patient to another treatment. A doctor would be unlikely to risk her patient's well-being for a few euros of savings in the monthly treatment cost. This does not exclude that the health authorities or the patients who are asked to participate in their medical expenses may attempt to influence the doctor's choice of treatment on the basis of cost considerations.

(1232) The health risks related to switching of successfully treated patients will generally lead to a relatively low propensity to switch for so-called continued-use patients. For first time patients, the choice of medicine is guided by the nature of condition, the doctor's preference and the most likely side effects. The doctors' personal experience accumulated over prescription of drugs and reading literature leads to a narrowed-down array of medicines that each of them is ready to test on new patients. The doctors are surely aware of the broad choice of therapies, but they naturally tend to prescribe new patients with the medicines which have shown to be good for their

1747 *Commission Guidelines on the application of Article 81(3) of the Treaty*, point 27, OJ C 101, 27/4/2004.

1748 For full analysis of the product/technology markets and dominance, see sections 6 and 7.

1749 *2003 Guidelines for Management of Hypertension*, Journal of Hypertension (2003), Vol. 21 No 6.

previous patients. This well-known phenomenon is often referred to as "the doctors' inertia"[1750].

(1233) The degree of substitutability of a given molecule with other molecules will therefore depend, among other things, on the degree of doctors' inertia and on the relative proportion of continued-use patients out of all patients treated with a given medicine. These may differ over time and depend on the type of pathology. These are empirical questions which require due consideration on a case-by-case basis.

(1234) With respect to perindopril, it is established that perindopril could benefit from both effects. Already prior to the investigated period the medicine had accumulated a large base of continued-use patients. Those patients were expected to continue the treatment for a significant period, while the existing group of loyal prescribers continuously provided for an inflow of new patients.

(1235) The combination of the aforementioned factors, the *ex ante* uncertain effects of treatments and the doctors' personal experience, effectively restricted the substitutability between available therapies.

(1236) Substitutability is an economic concept when examined for the sake of defining a relevant market. Economic substitutability only exists if changes in their relative prices (or other important economic variables) shift a significant proportion of the sales from one product to another.

(1237) In the case of perindopril, decreases in the prices of other medicines that may have well been intended for the same use did not negatively affect the sales of perindopril. The reasons for this are the doctors' general disregard towards prices and the price rigidities induced by regulatory frameworks. Prices still mattered, sometimes because of incentives being gradually built in for doctors to prescribe cheaper medicines and sometimes because of payments by patients, however, not to a sufficient extent. Perindopril was virtually immune to changes in relative prices. There were also no other means to adequately replace competition in prices. Once the continued-use patients were known to dominate the patient base, and the doctors' inertia was established, other forms of competition, such as promotional efforts, could have, at best, a limited impact on the existing sales of perindopril.

(1238) The limited effectiveness of constraints imposed by other medicines stands in stark contrast to the strength of the constraint expected from (and eventually introduced by) perindopril's own generics. In principle, generic perindopril could challenge all the existing sales of original perindopril. The exposure of Servier's perindopril to the generic threat was neither limited by the existence of the continued-use patient base nor by the doctor's inertia (even if some doctors may prescribe the originator's brand only). Moreover, the regulatory frameworks promoted price competition between original and generic perindopril.

(1239) As a result of generic perindopril entry, the average prices of perindopril decreased substantially (in the range of 17% to 90%) and the volumes were, to a larger or lesser extent, shifted from Servier's original product to its generic substitutes.

(1240) The generic constraint must be regarded as critical for the assessment of the relevant product market in the case in which the objected practices were aimed at neutralizing

[1750] E.g. the General Court referred to *"the specific features of the markets for pharmaceutical products, which are characterised by 'inertia' on the part of prescribing doctors"* in the Judgment of 1 July 2010 *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 278.

the very same constraint. The fact that the generic constraint outweighs by an order of magnitude all other potential constraints facing original perindopril naturally leads to the finding of a narrow market comprising only the medicine in question. If compared to the generic constraint, other sources of constraints for perindopril were insufficient to exercise the effective competitive pressure. Elimination of the generic constraint had significant effects in terms of the overall customer spending on perindopril.

(1241) Regarding Servier's position on the relevant market, Servier had high market shares, deriving from its exclusivity over the product for most of the period in question. Servier's market position was strengthened by important barriers, notably Servier's patents relating to perindopril, aimed at dissuading potential competitors from entering the relevant product market for most of the investigated period. Servier was in a position to operate on the relevant market without facing any significant constraints, including countervailing buying power, which would introduce a downward pressure on its substantial economic rents enjoyed during the investigated period.

(1242) Servier's substantial economic rents can be derived from Servier's ability to charge on average the prices that were substantially higher than the competitive price level approximated by post-generic entry prices. Servier's ability to maintain supra-competitive prices shows its market power at the time the investigated settlements were concluded. In the absence of generic entry on the market for perindopril, Servier was not faced with effective competition capable of offsetting the effects of the agreements.[1751]

(1243) Insofar as Servier's ability to maintain supra-competitive prices was related to the investigated agreements, it is also possible to show direct anti-competitive effects. The delay of generic entry resulted in a distinctively higher customer spending on perindopril than in the counterfactual scenario of earlier generic presence. Each of the national markets for perindopril analysed in the present Decision was a multi-million market in terms of annual turnover in euro. As already explained above, the generic entries led to price decreases in the range of 17% to 90%. Therefore, it can be assumed that each day of generic delay represented a substantial cost for the affected customers.

5.1.7.3 Prevailing market structure at the time of the settlement agreements

(1244) In the period February 2005 - January 2007, during which the investigated settlements were concluded, the '947 patent was in force in all Member States in which it was granted, and national applications were still pending elsewhere. There were a number of other patents protecting manufacturing processes. Patent and regulatory barriers[1752] were thus high. Accordingly, the sources of competition to Servier, as identified in the Commission's market investigation, were thus limited to those operators which were, besides working on regulatory compliance, actively taking patent-related measures to launch lawfully a perindopril product.

1751 Undertakings have market power when *"competitive constraints are insufficient to maintain prices and output at competitive levels"*. Communication from the Commission - *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, Official Journal C 11, 14/01/2011, point 40.

1752 See section 4.1.2.2.

(1245) At the time of the Niche/Unichem Settlement Agreement, in early 2005, there was no generic perindopril on the EU market. A few companies had tried or were trying to develop a viable API (see section 7.3.3.1). After acquisitions of [company name]*'s and, to a lesser extent, Azad's perindopril API technologies by Servier, Niche/Unichem together with Matrix were the most advanced in developing generic perindopril and, even if encountering development difficulties, still enjoyed "limited lead over other generic competition", including Krka, concerning the expected launch of generic perindopril.[1753] Moreover, at the time of the settlement, Niche/Unichem was the only generic company engaged in litigation with Servier before a national, UK,[1754] court, as well as in the EPO opposition procedure. Other companies which later also concluded patent settlements with Servier had only filed opposition procedures before the EPO during autumn 2004 and were not yet in litigation with Servier at the time.

(1246) Following the acquisitions of [company name]* and Azad technologies, and the settlements with Niche/Unichem and Matrix, generic companies were aware of the risk that similar agreements could be concluded by Servier to remove further imminent generic threats. In June 2005, discussions between Krka and Ivax (acquired by Teva in 2006) refer to the fact that "*Krka feel there is a strong likelihood that Servier will attempt to buyout all API manufacturers (I have not advised them of our source except to say it is not Matrix, who were bought out with Niche)*".[1755] Such concerns of "buy outs" gradually materialised for the big majority of Servier's close competitors.

(1247) By mid-2006, a limited number of other generic companies were expected to possibly come on stream. The main outstanding sources of competition were identified in Servier's anti-strategy document prepared in June 2006:[1756] Teva, Krka, Glenmark, Apotex and [name of Lupin business partner]* (which was in fact sourcing its API from Lupin) were prominently listed.

(1248) Of these, Krka was the only one to have actually launched generic perindopril. This occurred in the period from late 2005 to mid-2006 in 5 several Central and Eastern European Member States where Servier had no relevant patents in force (yet). Krka was also preparing to launch in the Western European Member States, including the UK. Krka had informed Servier of its intentions to enter with its perindopril as of 14 June 2006 onwards[1757] as it had received its MA in the UK in May 2006 but had decided not to launch the product until the decision on the '947 patent by the EPO

1753 See paragraph (459).

1754 Launch strategies of most generic companies show that the UK was considered as a key entry market in the EU. This is exemplified by the high concentration of patent litigation before the UK courts, as compared to the rest of the EU. Thus, it is not surprising that the first litigaton to successfully overcome the patent barrier and led to independent entry took place in the UK. Thus, the competitive situation in the UK may be particularly representative of the overall state of competition for perindopril in the EU. Having said this, generic launch plans were by no means limited to UK alone, and it needs to be borne in mind that UK litigation had no legal effects in other markets.

1755 See paragraph (414).

1756 Another generic company, also mentioned in the report, did not have an own perindopril product and concluded a distribution agreement with Servier. See section 4.1.2.5.1.

1757 See section 4.3.3.3.1.. Following the initiation by Servier of infringement proceedings, Krka launched a counter-action in the UK for annulment of the '947 patent on 1 September 2006, and on 8 September2006 also for annulment of the '340 patent. See section 4.3.3.5.

Opposition Division.[1758] Following that decision, upholding the '947 patent, Servier filed an action for infringement of the '947 and the '340 patents and filed for interim injunctions. Krka filed a counterclaim for the invalidity of these patents, asking for a summary judgment. In October 2006, the Court granted the interim injunction and ordered a full trial on the issue of patent validity. On 27 October 2006, Krka settled with Servier.

(1249) Roughly in parallel to Krka, Teva was preparing for a launch in the UK and elsewhere. In September 2005, it brought an action for annulment of the '947 patent in the UK, which was, in agreement with Servier, subsequently stayed pending final decision by the EPO, during which time Teva would be essentially free to sell perindopril covered by the '947 patent provided other Servier patents were not infringed.[1759] Servier's assessment of the competitive landscape (see paragraph (1247)) largely coincides with the one made by Teva in an internal email from April 2006: "*[…] Krka is our first competitor. We do not know how far Apotex are in their development other than they have had a dossier in for some time and that it is based on Glenmark API*".[1760] While Teva expected to receive the UK marketing authorisation in the first half of 2006, this was actually delayed to December 2006. Teva was considering to source perindopril from Krka but abandoned this and settled with Servier in June 2006 for the UK. Teva remained a potential challenger in other Member States which were not covered by the Teva Settlement Agreement.

(1250) Apotex developed API in house for own production of formulations for sale by Apotex or licensed third parties. At the time of the Teva Settlement Agreement, Apotex's MA application was advanced ("*they have had a dossier in for some time*").[1761] Apotex concluded agreements to license and supply perindopril formulations.[1762] Servier's internal assessment from its June 2006 strategy document "*Coversyl:* defense against generics" was that Apotex API would not only infringe the '947, but also the process patents and a substance patent in Canada, where the API was produced at the time of the agreement.[1763]

(1251) Servier had already expected the first generic entry, in all likelihood by Niche/Unichem and Matrix, to occur by 2005,[1764] presumably in the UK. However, the first unsuccessful attempt after Niche/Unichem and Matrix settled was Apotex' launch at risk in the summer of 2006. Upon obtaining the UK marketing authorisation, Apotex immediately launched generic perindopril on 28 July 2006 only to see its entry promptly discontinued on 8 August 2006 by an interim injunction granted to Servier. The latter sued Apotex for the infringement of the '947 patent, and Apotex filed a counterclaim for annulment of the same.

1758 The aforementioned strategy document of Servier shows that Servier was aware that Krka would only launch depending on the outcome of the EPO Opposition Division heaing on 27 July 2006. Unlike for Apotex and Glenmark, and possibly Teva and Lupin/[name of Lupin business partner]*, Servier did not observe that Krka's perindopril would infringe any of the process patents. ID0105, p. 177-180.

1759 See paragraphs (681)-(685).

1760 ID0346, p. 24.

1761 See paragraph (1645). In fact, Apotex obtained its first EU marketing authorisation in the UK in July 2006.

1762 See paragraphs (2717) - (2721).

1763 Apotex was a party to a UK court action for infringement / invalidity of the '947 patent initiated in August 2006, after Servier received an interim injunction discontinuing Apotex's launch at risk.

1764 ID0105, p. 184-186.

(1252) On 27 July 2006 the EPO Opposition Division upheld the '947 patent with an Intermediate Decision, and the final EPO decision on the patent validity was postponed for a number of years. The legal uncertainty surrounding the '947 patent was persevering. Therefore, potential competition continued to stem from mainly two groups of operators which were trying either to: (i) contest the validity of the '947 patent, or (ii) develop novel perindopril forms not covered by Servier's polymorph patents.

(1253) In the second half of 2006, only Krka, Apotex, Teva[1765] and Lupin belonged to the first group, comprised of generic companies (i) with an advanced perindopril development, and (ii) which had initiated or were about to initiate invalidity actions against the '947 patent in the UK or were involved in infringement actions with Servier.

(1254) As mentioned above, Krka concluded a settlement with Servier in October 2006.

(1255) Lupin, somewhat less advanced than Krka, Teva or Apotex, had also reached an advanced stage of its internal development of perindopril products, and had applied for a marketing authorisation in January 2006. Lupin was seeking potential commercial partners and was supplying samples of generic perindopril to some of them.[1766] Lupin initiated a UK court action in October 2006 claiming invalidity of the '947 patent and non-infringement by Lupin's product.[1767]

(1256) By December 2006, after Niche, Matrix, Teva and Krka concluded respective settlement agreements with Servier, internal Servier correspondence reveals that Servier considered only "*two hostile player* [sic] *(i.e. Apotex and Lupin)*", were likely to remain.[1768]

(1257) Again, this assessment of the competitive landscape roughly coincides with the one by Lupin in its strategy document "Perindopril UK competitive scenario" dated 14 November 2006.[1769] Based on the marketing authorisation status, Lupin expected that Lupin (including [name of Lupin business partner]* with a Lupin product), Apotex (including Sandoz with an Apotex product) and Krka would be ready to enter with an independent generic product by April 2007 (under the assumption that the '947 patent would be annulled). This shows that the common market perception by both the originator and the generics was that the number of outstanding potential competitors was very limited.

(1258) On 30 January 2007, Lupin settled with Servier as the one of only two remaining "hostile players" following Servier's earlier patent settlements with Niche/Unichem, Matrix, Teva and Krka. Consequently, Apotex, which had a marketing authorisation and was contesting the '947 patent in full trial, remained the single most important competitive threat to Servier[1770] in the UK, coupled by Teva elsewhere in the EU.

1765 Teva settled for the UK market in June 2006.

1766 See section 4.3.4.2.

1767 See section 4.3.4.5.2.

1768 See paragraph (1024).

1769 See paragraphs (1020) - (1023).

1770 Glenmark was sometimes mentioned amongst the generic forerunners. However, Glenmark's development was less advanced at the time. Servier and other generics considered that Glenmark infringed both the process patents and the '947 patent, and was fraught by possible infringement of Servier's process patents (paragraphs (2724)-(2726)). Although it received marketing authorisation in November 2007, it only launched perindopril in the UK in August 2008, shortly before the lapse of

(1259) The second group consisted of a few generic operators developing non-infringing forms of perindopril. At the time of the Lupin Settlement Agreement as the last of the investigated settlements, only Sandoz and Cipla had advanced projects for perindopril possibly avoiding any of Servier's patents, including the '947 patent.[1771]

(1260) Sandoz developed a non-infringing form of perindopril API and the corresponding formulation products in-house for use in its own perindopril formulations.[1772] Sandoz first applied for marketing authorisations in September 2006, and these were granted as of May 2008. Servier itself appears to have recognised in 2008 that Sandoz's perindopril was non-infringing.[1773]

(1261) Cipla developed a potentially non-infringing form of perindopril API in-house for use in its own formulations and for supply to generic companies.[1774] Cipla applied for marketing authorisations in August 2006 in the UK, and these were granted in September 2007. Unlike Sandoz technology, Cipla's technology was viewed by Servier as potentially infringing Servier's beta polymorph patent,[1775] and was moreover perceived as a non-viable ("*If [Cipla] is the source, they will get slaughtered by Servier*") or non-economical source by some of the generic companies.[1776] Cipla took no legal action to clarify the patent position. Cipla launched perindopril in February 2008, after effective generic entry had actually occurred in the UK, but its perindopril was not commercially successful and Cipla planned not to market it as of of 2010.

(1262) As of February 2007, following the settlement with Lupin, Servier was thus effectively only faced with the imminent threat following from Apotex' invalidation action. At the time, Sandoz' advanced development of a new form of perindopril was another serious threat to its market position, although not as imminent (Sandoz' own product in a novel perindopril form was not mentioned either by Lupin in November 2006 or Servier in December 2006[1777]). On the contrary, Cipla's project, while advanced, was considered to possibly infringe Servier's patents and/or otherwise prove non-viable. Infringement of both the '947 and process patents was also a major concern for the Glenmark product. As neither Cipla nor Glenmark initiated any legal action to clear the way for lawful entry, these companies could not be regarded as a direct threat to Servier, comparable to the threat posed by Niche,

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Servier's original process patents by end of September 2008, In view of both the delays, and its passivity, Glenmark was thus a less direct threat to Servier. This was implicitly recognised by the latter which did not consider it as one of the "*two hostile players*" in December 2006.

1771 See section 7.3.3.1.

1772 See section 4.2.2.8.4.

1773 In parallel, Sandoz had also been developing perindopril in alpha crystalline form in cooperation with another company until February 2007, when this project was abandoned in view of the decision by the EPO Opposition Division in July 2006 (ID1480, p. 18).

1774 See paragraphs (2694) and subsequent.

1775 Servier claims that a report from the University of Rouen described in paragraph (2705) demonstrates that the Cipla product did not infringe.Servier's patents (reply to the Statement of Objections, paragraph 1826 and subs., ID9070, p. 530). The report however does not concern the question of infringement, as it was not done on the basis of testing Cipla's product. The report also observes that the patent lacks key information on the anhydrates from or to which Cipla's monohydrates could convert (including the alpha and beta form). This document is therefore not inconsistent with the remainder of the evidence. Servier explicitly confirmed that, once it had received the Cipla material in early 2005 and analysed it, it considered their product to be infringing, which was moreover corroborated by Servier's internal materials (see paragraph (2706)).

1776 See paragraphs (2706) - (2715).

1777 See paragraphs(1256) - (1257).

Matrix, Teva, Krka, Lupin, Apotex, and Sandoz. This concurs with the assessment in Servier's documents from December 2006 that the only remaining hostile players were Apotex and Lupin (Sandoz was not listed, but this could be explained by the fact that Sandoz applied for marketing authorisation only three months earlier and was probably perceived as less advanced than the rest).

(1263) To conclude, apart from the parties which settled, there were only two other direct generic threats to Servier with advanced perindopril development, either actively contesting the validity of the '947 patent (Apotex), or with non-infringing forms of perindopril (Sandoz). Hence, where there has been no actual generic entry,[1778] and there is only a very limited number of potential competitors with prospects of a viable launch in view of the persisting barriers to entry (in particular patent and regulatory compliance), the removal of a single competitor significantly reduces the likelihood of a timely and effective generic entry (and therefore increases the probability that generic entry will be delayed to the detriment of consumers).

(1264) When analysing potential future effects of restrictive agreements, as is necessarily the case where the elimination of a potential competitor is at issue, one cannot overlook that Servier's linear pattern of an acquisition and settlements sent a clear signal to the market that similar conduct in the future is not excluded, or is even likely.

(1265) As early as 2005, Teva and Krka discerned Servier's consistent attempts to buy out sources of perindopril API and formulations[1779]. Also Lupin was aware of the existence of settlement agreements.[1780] Given Servier's overall defensive strategy against generics, the market generally suspected that Servier would try to buy out all possible sources of competition. This is best illustrated by Teva's internal communication from February 2007, which intended to monitor whether the Apotex litigation would be withdrawn, as it considered a potential settlement between Servier and Apotex as a good result for Teva.[1781] Thus, third parties perceived that there was a strong possibility that Servier would attempt to reach similar agreements in the future.

(1266) If finally no settlement with Apotex was reached and subsequently Servier lost the '947 patent in the UK, Servier at least considered the settlement option with Apotex.[1782] In addition, Servier was trying to prevent Apotex' entry in other ways. Thus, it filed an action for infringement of the perindopril compound patent in Canada, where Apotex was producing perindopril products for the EU markets in 2006. Although Servier prevailed in the Canadian litigation, this was only in July 2008, after Apotex had succeeded in obtaining the annulment of the '947 patent in the UK and had entered the UK market and after Apotex had relocated its perindopril production from Canada to India.[1783]

(1267) Compared to Apotex, Servier's endeavours to buy out Sandoz, which was threatening to enter, amongst others, France, Servier's home market, were much more explicit

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1778 Or only a single new entry in the seven Member States where Krka was marketing generic perindopril based on a licence from Servier.

1779 See paragraphs (413) - (414).

1780 See paragraph (1023).

1781 ID0350, p. 1068.

1782 See paragraphs (179) and (191).

1783 While filed for in 1981, Servier's perindopril compound patent would, due to specificities of the Canadian patent system, run until 2018. See paragraphs (2717) - (2721).

and advanced. In the period mid-2007 to mid-2008, Servier was in intense discussions to acquire its entire perindopril technology for a total of USD 50 million and to turn Sandoz into a distributor of Servier. However, Sandoz eventually abandoned the negotiations with Servier and launched its perindopril, including in France. However, its first entry only took place in May 2008, at a time when Servier lost the '947 patent in certain markets and a number of generics, including Apotex and Teva, had already entered.[1784]

(1268) Thus, competition was already very limited, with only two sources of potential competition remaining after Servier's series of settlements, which were comparable to the removed generics. And yet, there was still a strong possibility that Servier would try to reach an agreement with them or otherwise remove them from competition. This does not exclude that other sources of perindopril could eventually emerge, but not without significant delays, compared to, for example, Teva, Apotex, or Krka.

(1269) In addition to Servier's market position, competitive relationship of the parties, and the content of the respective settlement agreements, the specific assessment of effect resulting from each of the investigated settlement agreements (sections 5.2.2.4, 5.3.2.4, 5.4.2.4, 5.5.3.5, 5.6.2.4) will combine the examination of the position of the settling generic company in view of the other existing competitive constraints on Servier as presented in this subsection, and the examination of competition that could have existed absent the respective settlement agreement.

5.2 Assessment of the Niche/Unichem Settlement Agreement

(1270) This section sets out the assessment of the Settlement Agreement concluded between Servier and Niche/Unichem[1785] on 8 February 2005 (the "Niche/Unichem Settlement Agreement") pursuant to Article 101 of the Treaty.

(1271) In the context of the settlement, Niche/Unichem[1786] agreed to restrict its ability to compete and agreed not to challenge any of Servier's main perindopril patents. In addition, Niche/Unichem accepted restrictions on its behaviour concerning regulatory procedures and Niche's customer relationships. In return for these commitments, Servier paid Niche the sum of GBP 11.8 million in two instalments in 2005. A further inducement stemmed from the Biogaran Agreement following which Servier transferred GBP 2.5 million to Niche.

(1272) In a first step, this section will assess the Niche/Unichem Settlement Agreement as a restriction by object under Article 101(1) of the Treaty. In a second step, and even though it is not necessary to examine the effects of an agreement when it is established that its object is to restrict competition, an analysis of the Niche/Unichem Settlement Agreement as a restriction by effect is undertaken.[1787]

1784 See section 4.2.2.8.4.

1785 Although Unichem had at first denied to have entered into any agreement with Servier, see paragraph (421).

1786 When referring to Niche/Unichem, the Commission refers to obligations of both companies under the settlement agreement. As a general point, the Commission will treat Niche/Unichem as one party for the purpose of this assessment.

1787 Judgment in *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, paragraphs 28-30; and Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 55.

5.2.1 The Niche/Unichem Settlement Agreement is a reverse payment settlement which restricts competition by object under Article 101(1) of the Treaty

(1273) This assessment is divided into five sub-sections. First, a brief introduction will recall the specific context of the Niche/Unichem Settlement Agreement. Second, the Commission will establish that Niche/Unichem and Servier were potential competitors at the time of their settlement agreement. Third, the restrictive terms of the settlement agreement will be assessed. Fourth, the parties' intentions will be described. Fifth, a concluding sub-section will summarise the assessment of the Niche/Unichem Settlement Agreement as a restriction by object.

5.2.1.1 Introduction

(1274) The general economic and legal context for the assessment of reverse payment patent settlements has been set out in section 5.1. In addition, the general factual background to the Niche/Unichem Settlement Agreement has been set out in section 4.3.1.

(1275) The specific legal and economic context of the Niche/Unichem Settlement Agreement can be summarised as follows.

(1276) At the time the agreement was concluded, there was no generic perindopril on the market and perindopril was Servier's most important product. Servier held the monopoly of sales of perindopril since 1989, owing to the compound patent protecting the product. Servier's sales of perindopril in the year before the settlement agreement (i.e. 2004) on the top 13 EU markets had generated an EBIT profit of EUR 158 million.[1788] Moreover, Niche's lawyer referred to the fact that Servier *"would lose 42 months of profitable trading if Niche launch"*[1789] in April 2005.

(1277) Since 2001, Niche and Matrix had been cooperating to bring a generic form of perindopril to the market and they were well advanced in that process. In fact, Niche's development of generic perindopril in the alpha crystalline form seems in retrospect to have been the most advanced challenger to Servier's perindopril at the time of the settlement agreement.[1790] This is confirmed by Niche's statement from September 2004: *"we* [Niche, Unichem and Matrix] *have limited lead over other generic competition which should not be squandered"*.[1791] Niche had applied for a marketing authorisation in 2003 and was in intensive preparations to receive regulatory approval which it expected in 2005 in the UK.[1792] It had numerous customers who had also applied for MA's throughout the EU. Niche seemed to face some financial tests, yet its parent company Unichem (which owned 60% of Niche) was in good financial health.

(1278) In terms of legal disputes between the parties, Niche was one of the ten opponents of Servier's '947 patent before the EPO.[1793] Moreover, Niche was the first company against which Servier had brought infringement proceedings. These proceedings were pending in the High Court. With this action, Servier opposed its process patents to Niche's perindopril, but did not invoke the '947 patent, which had been granted in

1788 ID1158.
1789 See paragraph (544).
1790 See paragraph (1245).
1791 See paragraph (459).
1792 See paragraphs (454) and (456).
1793 See section 4.3.1.2.4.

2004. It is important to note that in the same proceedings, Niche unsuccessfully attempted to provoke an invalidity action in relation to the '947 patent.[1794]

(1279) Therefore, Niche/Unichem was amongst the main generic threats (which were limited) to Servier's most important product at the time. Servier originally looked at purchasing Niche in late 2004. Despite its awareness of Niche's financial position following the first phase of the due diligence, Servier carried out a second phase of the due diligence in late January 2005. In return for the exclusive disclosure of information and the exclusivity of the negotiations until 28 February 2005, Servier paid a non-refundable deposit of EUR [0–5]* million to Niche (see section 4.3.1.3).[1795] Ultimately, Servier chose not to purchase Niche and decided instead to enter into the Niche/Unichem Settlement Agreement. Settlement discussions began in January 2005 and concluded rapidly on 8 February 2005, the date of the process patents trial before the High Court.[1796]

(1280) As will be shown below, Servier agreed with Niche/Unichem that the latter would restrict its ability to enter the EU markets and compete with Servier's perindopril. Crucially, this was done in return for the transfer of a very significant sum of money from Servier to Niche. This kind of arrangement is a restriction of competition by its very nature.

5.2.1.2 Niche/Unichem and Servier as actual or potential competitors

(1281) In order to examine whether Article 101 of the Treaty can apply to the Niche/Unichem Settlement Agreement, it needs to be assessed whether Niche/Unichem and Servier were actual or potential competitors.

(1282) At the time of the conclusion of the settlement agreement, Niche had not yet received a marketing authorisation and had not launched a generic version of perindopril. However, the Commission considers that Niche/Unichem was a potential competitor to Servier for the following reasons.

(1283) First, Niche/Unichem had for some years invested resources – together with Matrix – in order to develop a product which could be launched as a generic alternative to Servier's perindopril. This venture was well-progressed by the time of the conclusion of the settlement agreement although there were certain issues that still needed to be resolved. The advanced development is notably shown by both the work towards obtaining a marketing authorisation (Niche was the first generic company to apply for a marketing authorisation in the UK – October 2003) and the commercial batches of API which were "under way" in preparation for the planned commercial launch.[1797] On the one hand, Niche expected a marketing authorisation in the course of 2005. This can be seen from an update sent to Niche's customers on 30 November 2004, in which Niche stated that *"there have been some delays in obtaining regulatory approval in the UK and this is now not expected until early in the New Year"* (emphasis added).[1798] Based on this forecast, Niche had a significant

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1794 See paragraph (499).

1795 One of the draft settlement agreements exchanged between the parties indicates that there had already been an "advance" payment of GBP [0–5]* million which appears to correspond to the sum of EUR [0–5]* million (ID3778, p. 6 and ID0028, p.281), a sum that could have been deducted from the final price in case an alternative transaction (to the acquisition) was signed (see paragraph (534)).

1796 See section 4.3.1.4.1.1.

1797 See paragraph (517).

1798 See paragraph (456).

time advantage over other generic competitors. Indeed, a customer of Niche, DAA, received a marketing authorisation on the basis of the Niche/Matrix dossier in May 2005.[1799] On the other hand, Matrix's witness statements in the English proceedings between Servier and Niche confirm that Matrix had produced API which it considered sufficient.[1800] In particular, Matrix's statement of 25 November 2004 indicates that *"a number of batches are under way in preparation for [Niche's] commercial launch"* and that *"this level of production is sufficient to satisfy the anticipated orders for API from Niche"*.[1801]

(1284) Second, Niche had also concluded fourteen agreements with commercial partners that were keen on selling perindopril based on Matrix's/Niche's dossier in Europe. Niche and its cooperation partners had applied for a marketing authorisation in a number of Member States.[1802] Most customer licences' approvals were expected by the first quarter of 2005 with variations in the second quarter of 2005 (see paragraph (457).[1803] Deficiency letters were received by Niche and its customers but the latter were being answered (see paragraph (455)) in the period surrounding the conclusion of the settlement agreement. In October 2004 Niche requested one of its customers, i.e. Ratiopharm, to indicate its launch orders for the year 2005 as Niche needed it for its production planning of 2005.[1804] Niche was also negotiating a future supply agreement with Teva, one of the largest generic companies, just a few days before the Niche/Unichem Settlement was concluded.[1805] Notwithstanding the fact that some customers (Ratiopharm and Sandoz) had concerns about infringement, Niche had 14 other customers who had concluded contracts for the supply of the Niche/Matrix product and who had to terminate or suspend such contracts only as a

1799 See paragraph (461).

1800 See paragraph (517).

1801 See paragraph (517). Niche confirmed in its reply to the Statement of Objections (see ID8524, p. 18) that it never intended to scale up production in the manner as alleged by Servier in the litigation but only to produce sufficiently small batches that would meet demand.

1802 See paragraph (454).

1803 In this respect, Niche notes in its reply to the Letter of Facts that these licences were for a product not subject of the litigation and which infringed the process patents (ID10220, p. 12). This first argument appears incorrect given that customers would have been supplied with Niche/Matrix's product which was subject to the litigation and no judgment was ever rendered with respect to the issue of (non)infringement. Niche also notes that the MA variations would not have taken place in the timeframe suggested and even if they could be granted, Niche faced further patent barriers and more generally was not ready to launch perindopril given issues with the updated DMF and was therefore not at an advanced stage (ID10220, p. 11-14). Servier makes a similar argument, arguing that these licences were based on an outdated process and therefore regulatory processes were not advanced. The need for a new DMF was critical, the variations were complex processes which would have taken long (if at all) to be completed. According to Servier, the fact that some efforts were made for possible entry is insufficient to prove potential competition between Niche and Servier, in particular given that Niche's document citing approval with variations by second quarter 2005 is unreliable given Niche's habitual posturing (see reply to the Letter of Facts, ID10289, p. 82-91). First, the Commission notes that the absence of a marketing authorisation is not a bar to potential competition (see section 5.1). Second, while the Commission does not contest that most customer licences were based on the old DMF, this does not question the fact that these marketing authorisation applications were advanced – deficiency letters were being answered and variations would need to be submitted in order to take into account the amended DMF. This is disconnected from Servier's statement that there were *"certain efforts"* made by Niche and its customers in the regulatory process. The latter were actively engaged before several regulatory authorities and although such processes were not yet complete, it is evident that bringing them to completion was the intended result.

1804 See paragraph (470).

1805 See paragraphs (450) - (452).

result of the settlement agreement.[1806] This shows Niche's belief that it would be able to commercialise generic perindopril within a short period of time.

(1285) Third, a contemporaneous document suggests that entry by Niche/Unichem (and Matrix) would have been economically viable. Niche was expecting to yield a gross annual profit of GBP [50,000–200,000]* during the financial year 2003/2004.[1807]

(1286) Fourth, Servier itself considered that Niche/Unichem was a generic threat. An email from Niche's lawyer of 5 February 2005 explicitly states that *"Servier believe that Niche will launch in April 2005 plus or minus 1 month"*[1808] which suggests that based on the information communicated throughout the litigation, Servier believed that Niche would be launching shortly thereafter. It is worth noting in this regard that Servier's assessment of the competitive threat posed by Niche/Unichem was well grounded in factual analysis. In particular, Servier had engaged in significant market intelligence regarding Niche/Unichem and carried out a due diligence to acquire Niche (i.e. had a precise knowledge of Niche and Matrix's project).[1809] After the first phase of the due diligence was completed in January 2005, Servier decided to proceed with the second phase of the due diligence despite its awareness of Niche's financial situation.[1810] Hence, knowing Niche's financial situation, Servier still decided to proceed, on 10 January 2005, with the second phase which would give Servier information on perindopril – according to Niche, Servier had expressed around the same time preference to *"pay a patent settlement rather than acquire shares"* and was *"struggling to devise a method that is acceptable"*.[1811] As a subsidiary point, it might be added that it is hard to see why Servier would pay the total sum of GBP 23.6 million to Niche/Unichem and Matrix, under the settlement agreements with those companies, if Servier did not see them as potential competitors.

(1287) Fifth, Niche was engaged in litigation before the High Court (with respect to the (non)infringement of the process patents) and before the EPO (with respect to the (in)validity of the '947 patent) with Servier.

(1288) As to the question of the (non)infringement of Servier's process patents, Niche's lawyers refer shortly before the start of the English litigation to the fact that they believed that there was *"no infringement"*[1812] and that *"Servier have not come back with anything substantial beyond a mere assertion of infringement"*.[1813] A similar situation can be observed following the start of the litigation. Niche believed that it had a realistic chance to win the case on the process patents against Servier and admits in the reply to the Statement of Objections that it was reasonably confident of

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1806 See Niche's reply to the Statement of Objections, ID8524, p.20. Niche's claim of loss of customer support is therefore dismissed given that it was Niche itself who had sent letters to customers indicating the impossibility to supply them with the product as of mid-February 2005 (see paragraph (634)).

1807 ID0025, p.15-16.

1808 See paragraph (544).

1809 See section 4.3.1.3.

1810 See paragraph (529). Servier argues that it was not purely concerned about Niche's financial performance but about the strength of its generic product pipeline by which it was not convinced during phase 2 of the due diligence (see reply to the letter of facts, ID10289, p.112). It appears however that it was "**product P*" that Servier was concerned with (see paragraphs (530) and (531)).

1811 See paragraph (533).

1812 See paragraph (490).

1813 See paragraph (496) . See also paragraph (467).

winning it.[1814] The confidence in a successful outcome of the litigation[1815] is demonstrated by the following statements, although Servier had opposing views in this respect.

(1289) A note by Niche's lawyers indicates that *"[Servier's] case on infringement on the process patents is hopeless"*.[1816] In further notes, Niche's lawyers explain that Servier's new allegation concerning scale up is *"a tactic to delay the trial which is unlikely to succeed"*[1817] and point to the awareness of the judge *"of the weaknesses in Servier's case"*.[1818] Equally illustrative, an internal email of November 2004 expresses Niche's legal team's satisfaction relating to the strength of Niche's case: *"our legal team were buoyant following the hearing as they believe that many of the arguments put forward by Servier and the judges comments in response to them have strengthened our case"*.[1819] A notable example can be found in an internal draft communication from Niche right after the settlement agreement: *"we felt confident that we would have won the case against the three patents in suit (...)"*.[1820] As to Servier, it believed that Niche would infringe its process patents given that *"Niche are following exactly the same strategy as Servier, but are using 'slightly' cosmetic modifications"*.[1821] More generally, Niche had written to Matrix in August 2004 that *"we can confirm that we do not believe that it [the process] can validly infringe any patent rights owned by Servier. The latest version of the process description is consistent with the strategy we have recommended"*.[1822]

1814 See Niche's reply to the Statement of Objections, ID8524, p.21.

1815 Servier contends in its reply to the Statement of Objections (paragraph 323, ID10114, p.156) that the Commission has taken at face value Niche's declarations of its confidence in the outcome of the English litigation whereas the independent evaluations by Sandoz and Ratiopharm offer a better view of the real risks of infringement. In the reply to the Letter of Facts, Servier reiterates these arguments and questions the appropriate handling by the Commission of the evidence about the infringements risks (ID10289, p.91-96), noting that Niche's statements should be given little weight and that more independent and experienced third parties had a different opinion. While it is true that Sandoz and Ratiopharm had concerns (see paragraphs (465) and (466)), these concerns did not necessarily relate to the UK as the bigger risks and concerns related to countries like France where the doctrine of equivalence applies (and where no litigation existed between Niche and Servier). In any event, Niche's customers did not have the updated information on the amended process, in particular Sandoz who ceased its commercial relations before the refinement of the process by Matrix (see paragraph (465)). In addition, Servier claims in paragraph 318 of its reply to the Statement of Objections that contrary to the Commission's interpretation, Niche's internal documents paint a different picture of the infringement risks (ID10114, p.155): it refers to a document from January 2004 where Niche mentioned that a declaration of non-infringement will be *"difficult to achieve"* (ID0027, p.191). Servier omits however to cite the reasons behind the difficulties that are mentioned in the same document, i.e. the high number of patents that would need to be considered and the cost that will result from this. The same document points to the fact that advice was sought and that the Matrix process would not be infringing in either Germany or the UK (ID0027, p.189). Finally, the newsletters sent by Niche give an overview of infringement risks and are also consistent with Niche's statements in its reply to the Statement of Objections (see in particular ID8524, p.21) that it was reasonably confident not to infringe the process patents.

1816 See paragraph (503).

1817 See paragraph (506).

1818 See paragraph (507).

1819 See paragraph (507).

1820 See paragraph (593).

1821 See Servier's reply to the Letter of Facts, ID10289, p.96.

1822 See paragraph (467).

(1290) As to the '947 patent, numerous examples show Servier's reluctance *"to risk suit on the '947 patent",*[1823] a patent which Servier *"seemed too scared to enforce"*.[1824] According to Servier, there was no such apprehension from its side and the absence of any action was a result of a lack of a sample to test.[1825] Niche's attempt to file a counterclaim for invalidity before the High Court was put aside although the grounds for invalidity were ready – it instead opted for an opposition against the '947 before the EPO. In addition, Niche's lawyers stated that *"there are too many problems with this patent for Servier to risk asserting it against Niche"*.[1826] Nevertheless, when it came to the settlement agreement, Niche/Unichem accepted that the '947 patent could be included and specifically that they would not challenge that patent, that Niche would withdraw its opposition to the '947 patent before the EPO and would not compete using a process violating that patent.

(1291) Niche contends that the '947 barrier would not be resolved by the litigation on the process patents and that Niche had the option of going through a legal battle with Servier or launching at risk.[1827] It is acknowledged that the '947 issue would not be resolved by the litigation before the High Court which concerned the process patents only. The '947 would need to be overcome in one way or another and Niche had already attempted to serve an invalidity action during 2004. In any event, there was no litigation between Servier and Niche on this patent before any national court in early 2005 and no certainty that any litigation would take place at all.

(1292) Based on the above, the Commission considers that Niche/Unichem was a potential competitor which had the intention and ability to enter the market within a short period of time had it not been for the settlement agreement.

(1293) In its replies to requests for information, Niche argues that it did not consider itself as a competitor of Servier. In particular, Niche alleged that it did not have a viable product at the time of conclusion of the settlement as it had encountered difficulties during the API development and tablet manufacturing which were becoming "insurmountable".[1828] Niche reiterates this claim in its reply to the Statement of Objections and explains it was unable to obtain a sufficiently pure and non-infringing API with the obvious consequence of not being able to obtain regulatory approval.[1829] These problems causing delays in the development and marketing of the product have been listed in section 4.3.1.1.5.2 and in particular paragraphs (471) and following. The so-called recurring problems were being addressed in the period prior to the settlement agreement and Niche cannot claim that these problems were the cause for the MA not having been granted. The grant of a MA was pursued actively before the settlement agreement[1830] and before the suspension of the

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1823 See paragraph (501).

1824 See paragraph (504).

1825 Servier's reply to the Statement of Objections, paragraph 336, ID10114, p.161.

1826 See paragraph (504).

1827 Reply to Statement of Objections, ID8524, p.24 and 26. See also reply to the letter of facts with respect to the '947 patent, i.e. that Niche could not launch without conclusively proving its invalidity (ID10220, p.15-16).

1828 See paragraph (463).

1829 See reply to Statement of Objections, ID8524, p.56.

1830 See for example document cited by Servier in its reply to the Statement of Objections, paragraph 347, ID10114, p.166-167. Contrary to what is claimed by Servier that numerous obstacles still needed to be overcome, the document cited in its reply (ID0466, p.37) shows that Niche continued putting pressure on Matrix to find solutions to the issues that they encountered in order to counter delays and possible rejections of MA applications.

development agreement with Matrix in June 2005. A similar argument to that of Niche has been made by Servier, i.e. that there was a credible risk that no MA would be granted to Niche, basing itself partly on documents post settlement agreement (e.g. *"this product is doomed in respect of the comparative dissolution data: it's never ending"* which dates from March 2005).[1831] However, the factual situation is such that the MA was not pursued by the parties following the settlement agreement (see section 4.3.1.5.1) and there has been no rejection of the MA as such, even though Niche and its customers received deficiency letters.

(1294) Niche also explained that due to its weak financial position (including potential litigation) it had no alternative but to accept the terms of the Settlement Agreement.[1832] Niche reiterated in its reply to the Statement of Objections that had it not entered into the settlement agreement, it would not have entered the perindopril market and would have most likely been dissolved and would not compete in any generics market. It could not afford any expensive litigation in the future, be it on the '947 or in other jurisdictions with respect to Servier's patents.[1833] However, as Niche submitted *ex post*, Niche had entered into an […]* arrangement with [company name]* in December 2004 which provided it with […]*.[1834] In addition, Niche had received from Servier in January 2005 a non-refundable deposit of EUR [0–5]* million in the context of the due diligence exercise which allowed it, as Niche admitted, to continue to trade.[1835] It should be stressed that Niche could have also improved its financial situation by either asking for a parent guarantee[1836] or asking Matrix to contribute to future litigation costs, especially in view of the importance of sales that perindopril was projected to yield. Moreover, there was no litigation on the '947 at the time of the settlement agreement. Whatever the financial state of Niche in the beginning of 2005, this did not justify the significant payment received for withdrawing from competition.

(1295) Servier disputes the fact that Niche was a prominent potential competitor and claims that Niche's product was not well advanced at the time of the settlement agreement due to numerous problems which, taken together, appear to be insurmountable.[1837] In this regard, Servier claims that the Commission has confused Niche's intention with

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1831 Servier's reply to the Statement of Objections, paragraphs 347- 353, ID10114, p.167-169.

1832 See paragraph (606).

1833 ID8524, p. 43 and 56. Niche claims in particular that different Member States have different approaches and there were therefore different prospects of success in litigation for Niche and possible costs and delay and Niche would not have been able to survive (ID8524, p.16 and p.43). Servier also argues in its reply to the Statement of Objections that the potential consequences for Niche stemming from the litigation were particularly serious in view of its financial situation (see paragraphs 371-372, ID10114, p.177). While different outcomes of litigation may occur, an English court ruling would have persuasive authority in other Member States (and this, only had any litigation taken place in other Member States in the future). In addition, there was no other pending litigation or even potential litigation in any Member State other than the UK at the time. Moreover, litigations in other Member States could take place on a staggered basis and entry could take place gradually. Furthermore, Niche may have asked its partners to share the costs of any future litigation and it had also received EUR 2 million from Servier for the exclusivity of negotiations during the due diligence.

1834 See paragraph (606).

1835 See paragraph (535).

1836 According to Niche, this was unlikely and in any event, the loans came at very high interest rates (reply to Statement of Objections, ID8524, p.201).

1837 Servier's reply to the Statement of Objections, ID10114, p.169 and following (see in particular paragraph 358).

its ability to enter the market.[1838] The Commission does not dispute the fact that delays and difficulties occurred during the development of Niche's and Matrix's product and this is noted in section 4.3.1.1.5.2 Niche was however the first ever applicant for a perindopril MA in the UK and had a large number of customers with which it had concluded supply contracts and which had applied for a MA in other Member States, Matrix had updated the DMF in the second half of 2004 and at the time of the settlement, the resulting difficulties due to the change in the process were being dealt with. In addition, the project was not doomed as claimed by Servier since the discussions between Niche/Unichem and Matrix on perindopril continued even following the agreement and were only suspended in accordance with the provisions of the settlement agreement. Servier also claims that with respect to the '947 patent, it was clear that Niche was not a potential competitor (given the alpha ratio in Niche's product).[1839] With respect to this claim, reference is made to section 5.1.3 which has covered similar arguments, i.e. no blocking position because of the mere existence of patents.

(1296) However, a potential competitor does not have to have a readily marketable product, as long as the company is able to enter within a "*short period of time*"[1840]. A potential competitor must have "real and concrete possibilities to enter the market"[1841] and the fact that Niche and Matrix were working towards finding solutions and making adjustments in view of the future commercialisation of the product are common in the pharmaceutical sector. The evidence presented above contradicts Niche's claim that it was not a potential competitor and that it was facing *"insurmountable difficulties"*. In addition, Niche's claims can be further rebutted by reference to the following contemporaneous evidence which show that it was working with its commercial partners towards an anticipated market entry.

(1297) Notably, Matrix – Niche's cooperation partner in the development of generic perindopril – has submitted that it *"did not consider abandoning its perindopril research and development efforts for perindopril erbumine prior to the settlement with Servier"*.[1842] This suggests that Matrix was confident it could overcome any outstanding obstacles.[1843] Likewise, the cooperation between Niche and Matrix was not terminated prior to the conclusion of the settlement agreement, which was possible in case of insurmountable difficulties (see clause 4 of the cooperation agreement with Matrix, paragraph (430)), nor was the project suspended immediately

1838 Servier's reply to the Statement of Objections, paragraph 355, ID10114, p.169.

1839 Servier's reply to the Statement of Objections, paragraph 379, ID10114, p.178.

1840 Period of up to three years according to point 10 of the *Communication from the Commission - Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements.*

1841 See paragraph (1157).

1842 See paragraph (618).

1843 Servier cites in its reply to the Statement of Objections (paragraph 362, ID10114, p.174) an *ex post* statement by Niche in a RFI reply whereby Niche noted that *"Matrix was confident of being able to produce a non-infringing API, whether or not Niche shared this confidence"* (ID1577, p.10). According to the Commission, this statement does not suggest that Niche thought that Matrix's confidence was unrealistic as Servier claims. It was in any event Matrix which was responsible for the API manufacture and best placed to assess the situation. In addition Servier mentions capacity problems which Matrix would have had – however, the document mentioned at paragraph 365 of its reply to the Statement of Objections (ID10114, p. 174-175 citing ID0027, p.248) does not say that Matrix did not have enough capacity but only that it may not be able manufacture sufficient quantities for the expected launch shortly. Hence, the Commission understands the document as a matter of timing to produce the tablets for launch and not as a matter of capacity.

following the Settlement Agreement. Niche continued to resolve outstanding difficulties throughout the discussions and even after the settlement, when it asked Matrix for its assistance in the completion of the UK registration.[1844]

(1298) Based on the different elements listed above, the Commission concludes that Niche/Unichem[1845] was a prominent potential competitor to Servier in the production and supply of perindopril on the EU markets at the time the settlement with Servier was concluded. The elements presented in the above paragraphs indicate that Niche/Unichem had the ability and the intention to enter the market within a short period of time and was actively looking for solutions (together with Matrix) to have a final product ready for commercialisation. Hence, Niche/Unichem[1846] was near to having a viable product, with which it and/or its distribution partners could have entered various EU markets after receiving the necessary regulatory approvals.

5.2.1.3 Terms of the Niche/Unichem Settlement Agreement

5.2.1.3.1 An agreement between undertakings

(1299) It is therefore necessary to assess whether the settlement agreement concluded between Niche/Unichem and Servier constitutes "*an agreement between undertakings*" under Article 101(1) of the Treaty.

(1300) The concept of agreement has been interpreted broadly by the case-law.[1847] It is certainly clear that a legally enforceable contract qualifies as an agreement. The Niche/Unichem Settlement Agreement is therefore an agreement under Article 101(1) of the Treaty. In addition, the Court of Justice has clarified that an agreement is not excluded from the application of Article 101 of the Treaty merely because its purpose is to settle patent litigation, as Article 101 of the Treaty makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind.[1848]

(1301) Turning to the concept of undertaking, the Court of Justice has held that it *"encompasses every entity engaged in an economic activity regardless of the legal status of the entity and the way in which it is financed"*.[1849] In the present case, Niche, Unichem and Servier are undertakings as these companies are engaged in activities *"consisting in offering goods or services on a given market"*.[1850]

1844 See paragraph (625).

1845 Unichem claims that it had no role in the overall technical and commercial development of perindopril and cannot be considered as a potential competitor of Servier. It would have been required to obtain its own MA had it been a potential competitor (reply to the Statement of Objections, ID8520, p.11). It also claims that Unichem's role as a signatory is a mere formality and no allegation of infringement of Servier's patents was ever made against Unichem. At the same time, Unichem indicates that Niche and itself agreed not to infringe Servier's patents (reply to the Statement of Objections, ID8520, p.11-12). In reality, Unichem was subject to the same obligations as Niche under the settlement agreement and was prevented to compete with the product that it was going to manufacture according to its contract with Matrix.

1846 Unichem was part of the production process. In fact, Unichem was explicitly mentioned in the settlement agreement as the manufacturer of the tablets which would have been marketed in the EU markets.

1847 See, for an example of the broad interpretation of this concept Judgment in *Chemiefarma v Commission*, 41/69, EU:C:1970:71 (a "gentleman's agreement").

1848 See, to that effect, Judgment in *Bayer v Süllhöfer*, C -65/86, EU:C:1988:448, paragraph 15.

1849 Judgment in *Höfner e Elser v Macrotron*, C-41/90, EU:C:1991:161, paragraph 21.

1850 Judgment in *Pavlov and Others*, C-180/98, EU:C:2000:428, paragraph 75.

(1302) Hence, the Niche/Unichem Settlement Agreement is an agreement between undertakings within the terms of Article 101(1) of the Treaty.

5.2.1.3.2 Restrictions on competition disabling or hampering Niche's/Unichem's ability to enter the market in a timely and viable manner

(1303) Before the settlement agreement was concluded, Niche/Unichem was free to continue its commercial activities to enter the market in a timely and viable manner, including by pursuing the legal actions involving Servier. The settlement agreement contains two key restrictions of this ability to compete, namely (i) a non-challenge obligation, and (ii) a non-compete obligation. These restrictions were obtained in exchange for an inducement in the form of a very significant reverse payment from Servier to Niche.

(1304) The subsequent analysis aims to establish whether the Settlement Agreement, viewed as a whole, can be seen as a restriction of competition by eliminating Niche/Unichem as a potential competitor, at least for the periods foreseen in the agreement itself.

5.2.1.3.2.1 The non-challenge obligation

(1305) The non-challenge obligation for Niche/Unichem is contained in two different clauses.[1851] Pursuant to clause 7, Niche committed to withdraw its oppositions at the EPO to the '947 and '948 patents. Niche/Unichem also agreed, pursuant to clause 8, to abstain from any invalidity and non-infringement actions against any of the *"Servier Patent Rights"*, namely patents '339, '340, '341, '947, '689 and '948.[1852] Clause 8 encompasses all countries in which these patents or corresponding patent rights exist and relates to Niche/Unichem's challenges whether of direct or indirect nature (i.e. through third parties). The non-challenge obligation is a wide one as Niche/Unichem is prohibited from seeking any declaration or ruling of non-infringement (see clause 8 (iii)). However, Niche/Unichem was allowed to defend itself were Servier to assert infringement against it.

(1306) The non-challenge obligation had two main consequences with respect to Servier's Patent Rights. First, it prevented Niche/Unichem from establishing the technology of Matrix as *de iure* non-infringing technology for the production of perindopril for the relevant geographic market, available both for own distribution of final perindopril products and supplying customers for distribution in various markets. Second, the non-challenge obligation also prevented the possibility of an objective legal review of patent validity, disabling the possible benefit for Niche/Unichem, other generic producers and consumers in case the patents were finally invalidated.

(1307) Moreover, the non-challenge clause concerning the crystalline form patents, including the '947 would continue to be in force after the expiry of the process patents in September 2008 and the consequent discontinuation of the non-compete obligation (see section 5.2.1.3.2.2). This was liable to affect Niche's incentives to compete after the expiry of the process patents, as it could not challenge in particular the '947 patent.

(1308) In sum, the non-challenge obligation granted Servier a 100% certainty that Niche/Unichem would not represent a competitive threat by challenging Servier's patent position.

1851 See paragraphs (557) and (558).

1852 As well as any equivalent patents anywhere in the world.

5.2.1.3.2.2 The non-compete obligation

(1309) Clause 3 of the Settlement Agreement provides that: *"Niche and Unichem shall not, and shall procure that its Affiliates shall not, carry out in relation to Perindopril made using the Process any Restricted Act in any country of the world where Patent Rights and/or Alpha Patent Rights exist"*.[1853]

(1310) This non-compete obligation prevented Niche/Unichem from launching a generic version of perindopril in the EU (and elsewhere) in the following manner. Niche/Unichem committed not to launch perindopril manufactured on the basis of the process developed in cooperation with Matrix (including similar processes) or any other process that would fall within the scope of '339, '340 and '341 in any country of the world where these (or equivalent patents) and/or the '947 (or equivalent patent) exist.

(1311) Niche contends that the settlement was a *bona fides*, necessary contract which did not preclude it from developing or marketing generic perindopril that would not infringe Servier's patents.[1854] On this point, the Commission considers that Niche was prevented from launching the perindopril it had developed with Matrix and any other product based on a substantially similar process to the latter but also any infringing process. Hence, Niche was not prevented in theory from developing another product but the process of this product should not have been even "substantially similar" to the Matrix process, and such development could have taken up to three years unless another API was readily available (which was not the case, see section 7). Such restricted acts could not have been obtained if Niche and Servier went before the court. Moreover, contemporaneous documents illustrate Niche's expectation to only proceed with launching in 2008 when the process patents expire (see paragraphs (594) and (647)).[1855] The Commission notes that Niche had no intention to launch any perindopril before 2008, but only wished to complete the registration of its marketing authorisation in the months following the settlement's conclusion. In this regard, Niche's response to the letter of facts that it had no intention to stop the process of manufacturing "non-infringing perindopril" appears incorrect and is contradicted by Niche's own statements in the reply to the same document.[1856] As said earlier, the only aim of completing the project with Matrix was to obtain regulatory approval for which more tablets needed to be produced. The nature of these tablets (infringing or not) had no bearing on whether Niche would obtain a

1853 See paragraph (550).

1854 Reply to Statement of Objections, ID8524, p. 32-33. Servier also notes in its reply to the Letter of Facts that restricted acts were limited in scope (ID10289, p.106).

1855 In its reply to the letter of facts, Servier claims that the email sent by Niche to the Bank of Baroda in 2008 (see paragraph (603)) was not an accurate summary of the settlement and was drafted three years later (ID10289, p.113). This summary nevertheless shows the essential features of the agreement as understood by one of Niche's employees who also worked for Niche in 2005. As to the document cited in paragraph (594), Niche claims that the Commission inference with respect to the fact that launch of perindopril was forbidden until 2008 only relates to infringing perindopril (reply to letter of facts, ID10220, p. 21-22). The Commission notes that the expression "infringing perindopril" cannot be used in this context given that an alleged infringement could only be determined by a competent court, and this had not been done. Niche may have taken steps to develop another product but it would have taken long to be able to reach a final decision on the infringing nature or not of such product. Moreover, contrary to Niche's statement that it had invited Matrix to continue its work in developing perindopril (reply to the letter of facts, ID10220, p.22), Niche in fact only wished to complete the registration of its UK licences and not to engage in a new development allowing it to launch a non-infringing perindopril.

1856 Niche's reply to the letter of facts, ID10220, p. 22-23.

marketing authorisation since non-infringement is not a condition for approval. Also, the development of Niche's product at the time of the agreement which represented an almost immediate threat to Servier's patent position and which was the subject of the infringement litigation with Servier had to be suspended although Niche had denied infringement in the Preamble to the Settlement Agreement.[1857]

(1312) Clause 6 of the settlement agreement states that: *"Servier recognises that Niche shall be free to deal in Perindopril made in accordance with the Process*[1858] *without infringing the Patent Rights* [i.e. the process patents] *in such a country after the Local Expiry Date* [expiry date of the process patents] *in that country"*.[1859] Whilst a superficial reading could suggest that Niche is granted an entry as of 2008 (i.e. the date of expiry of the process patents), Servier considered that Niche would only be able to manufacture perindopril on the basis of the Matrix process if it did not infringe the '947 patent.[1860] Hence, no early entry would ensue since the '947 patent would expire in 2021 (unless revoked earlier by other companies given that Niche had committed to refrain from challenging Servier's patents or if Niche had entered at risk and Servier had launched proceedings against it). Therefore, Niche was restricted from entering before 2008 with "perindopril made using the process" and was also restricted from entering thereafter with an alpha product.

(1313) Niche claims that it was free to use the processes covered by the patents once the patents expire:[1861] however, such an outcome would have been possible upon patent expiry independently from the conclusion of the settlement agreement and does not reduce the importance of the restriction. The argument of a limited duration of the restriction cannot hold since any generic company willing to market a product covered by Servier's process patents has the possibility to do so after their expiry.

(1314) The non-compete obligation was reinforced by Niche's commitment to *"cancel, terminate or suspend until the relevant Local Expiry Date at the option of Niche, each and every one of the Niche Contracts"* (clause 11).[1862] This was also a strong deterrent for Niche to continue with a new perindopril development project (e.g. different API not covered by the definition of *"perindopril made using the Process"*), as its existing customer base was severed.[1863]

(1315) Niche claims that it did not have to cancel its customer contracts related to non-infringing perindopril.[1864] First, the Commission considers that the fact that clause 11 only concerns contracts relating to "perindopril made using the process" does not reduce the importance of the restrictions. Second, such contracts relating to

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1857 ID0119, p.136.

1858 This is defined as perindopril made using *"the Process in Suit [=the Matrix process], any process that is substantially similar to the Process in Suit, and any process that if carried out in a country of the wolrd where a Patent Right exists would fall within the scope of such Patent Right"*.

1859 See paragraph (552).

1860 See paragraph (554).

1861 Reply to Statement of Objections, ID8524, p.51.

1862 See paragraph (556).

1863 In this respect, Servier claims that the Commission exaggerates by stating that the obligation to suspend or terminate customer contracts would have deterred Niche from continuing with a new perindopril project (reply to the Statement of Objections, paragraph 398, ID10114, p.184). However, given that Niche's customer base had to be severed pursuant to clause 11 - Niche had 14 customer contracts which all had to be suspended or terminated – Niche would have had no incentive to pursue a new perindopril development. In addition, the significance of the payment (see section 5.2.1.3.3.3) was also a deterrent given that it compensated Niche for its non-entry on the perindopril market.

1864 Reply to Statement of Objections, ID8524, p.33.

perindopril other than the one made using the process were non-existent given that Niche had developed one product together with Matrix. Hence, all contracts which Niche had concluded with customers in relation to perindopril had to be suspended or cancelled. The settlement itself lists a precise number of contracts which Niche had in relation to perindopril made using the process (14 contracts). All of these were cancelled or suspended following the settlement agreement.[1865] In any event, such a clause could not have been obtained if the parties went before a judge.

(1316) The non-compete obligation was further reinforced by clause 10,[1866] which effectively prevented Niche/Unichem from filing a new application for regulatory approval before patent expiry, if Servier could argue that the product would infringe its process patent rights or if it concerned the Matrix process. Concretely this meant that, in such a case, the time for the regulatory approval was effectively added to the protection period of Servier.[1867] However, Niche had no obligation to withdraw applications for regulatory approval made under its own name.

(1317) To summarise, the non-compete obligation meant that Niche/Unichem and/or its distribution partners in the EU were contractually prevented from commercialising perindopril based on the process developed between Niche/Unichem and Matrix (and similar/infringing processes) in the EU until September 2008. The prohibition related to all Member States, irrespective of whether litigation or marketing authorisation applications were pending.[1868] After the expiry of the process patents, Niche/Unichem was not allowed to enter with an alpha containing product. The restriction applies both to situations where Niche would supply generic perindopril directly and to situations where it would supply the market through a local partner, as was planned for most EU markets.

5.2.1.3.3 Financial or other considerations for the restriction

(1318) The assessment of the Niche/Unichem Settlement Agreement as a restriction of competition by object requires an identification of the value transfers to Servier and/or Niche/Unichem. The aim of this assessment is to establish whether there was a net value transfer from Servier to Niche/Unichem and to quantify that value transfer with a view to establishing its importance in the agreement.

(1319) This section is divided into four sub-sections. First, the Commission will assess the precise purpose of the net value transfer and what was gained by Servier from this compensation. Second, this section will verify whether the value transferred by Servier was justifiable as remuneration for the costs incurred by Niche. Third, the significance of the quantum transferred by Servier to Niche will be assessed. Fourth, the Biogaran Agreement will be described as a further inducement to Niche to conclude the settlement agreement.

1865 See paragraph (638).

1866 See paragraph (555).

1867 Since *"perindopril made using the process"* covered more than just the Matrix process but also similar processes and any process falling within the scope of the process patents, this meant that Niche could only file a new application for regulatory approval before the date of their expiry in limited circumstances.

1868 The Mutual Recognition Procedure allows a generic company whose drug has been authorised in one Member State to seek further marketing authorisations in other Member States. The latter agree to recognise the validity of the original, national marketing authorisation.

5.2.1.3.3.1 Assessment of precise purpose of the net value transfer and the value gained by Servier from this compensation

(1320) In the framework of the settlement agreement, Servier agreed to pay to Niche GBP 11.8 million for Niche/Unichem's commitment to respect the "*undertakings*" contained in the agreement and as compensation for the "*costs*" and "*liabilities*" that may result from the cessation of the perindopril programme.[1869] According to the general methodology for the assessment of value transfers as laid out in section 5.1.4.2, the value transfer in the settlement agreement falls into the category of a one-way transfer, where only a payment from Servier to Niche took place.[1870] Unichem indirectly benefited from the payments to its subsidiary, making it a more valuable asset.

(1321) The "*undertakings*" at issue can only refer to the non-challenge obligation foreseen in clauses 7 and 8, the non-compete obligation foreseen in clause 3 (as complemented by clauses 4 and 6), the commitment not to request new marketing authorisations (clause 10) and the termination or suspension of the existing customer relationships foreseen in clause 11 (see section 5.2.1.3.2). Save for these provisions, the settlement agreement does not mention any specific goods, rights or services that Niche/Unichem had to provide to Servier.

(1322) Thus, the language used in the agreement (payment *"in consideration for the undertakings"*) indicates the clear link which exists between the value transfer and the limitations on entry.[1871] This is exactly how the mutual obligations of the parties were interpreted by Niche in response to a RFI of 16 January 2009, i.e. a payment in

1869 Clause 13 of the Niche/Unichem Settlement states that the payment of GBP 11.8 million was made *"in consideration for the undertakings set out above, and the substantial costs and potential liabilities that may be incurred by Niche and Unichem as a consequence of ceasing their programme to develop Perindopril made using the Process […]"*, see paragraph (548).

1870 According to Niche, the payment represented a skilfully negotiated outcome and not an inducement. It claims that it was not the payment which led to Niche's inability to enter the market (ID8524, p. 52 and 141). However, it was the inclusion of a payment which induced Niche to conclude the settlement agreement on such terms, in particular to agree to a prohibition on entry with the current development until expiry of the process patents. See also paragraph (603) pointing to the same conclusion, i.e. that a payment was received by Niche against non-entry until the expiry of the process patents. As to Servier's argument that this was not a one way-transfer (reply to Statement of Objections, paragraph 425, ID10114, p.192), the Commission reiterates that no marketable value was transferred to Servier by Niche – in particular, the legal certainty gained was not only an advantage gained by Servier but also by Niche.

1871 Servier claims that the Commission attaches too much importance to a boilerplate formula used in clause 13, i.e. *"in consideration for"* which was necessary to ensure that the contractual obligations were efficient in accordance with English law (reply to the Statement of Objections, paragraph 410, ID10114, p.186). The suggestion that this "boilerplate formula" was added for enforceability reasons under contract law does not hold. The Commission notes that reciprocity is necessary under English contract law to demonstrate the mutual obligations of the parties – Niche had agreed to restrictions in the agreement, whereas Servier agreed to transfer a significant sum for the restrictions and their consequences. However, the settlement agreement between Servier and Niche/Unichem is a valid contract whether or not the word "in consideration" is used in the agreement: "*The doctrine of consideration is based on the idea of reciprocity: that "something of value in the eye of the law" must be given for a promise in order to make it enforceable as a contract*" (Chitty on contracts, 30th edition, Volume 1, general principles, 3-002). Servier has not demonstrated that the payment was not given in return for the "undertakings" as was plainly expressed in clause 13 of the agreement, a clear and precise phrase.

exchange for Niche's non-challenge and non-compete obligations.[1872] By its terms, the purpose of Servier's payment consisted in the inducement of Niche/Unichem to refrain from competing on the perindopril market for a number of years.

(1323) Apart from being consideration for the "*undertakings*" provided by Niche/Unichem, the settlement agreement also stated that the payment was for the "*substantial costs and potential liabilities that may be incurred by Niche and Unichem as a consequence of ceasing their programme to develop perindopril…*" (clause 13).

(1324) As an initial point, it should be noted that the above wording was only added to the settlement agreement on 4 February 2005 and therefore at a late stage in the negotiation process. Previously, the agreement just referred to the payment as being consideration for the "*undertakings*".

(1325) It is necessary to assess what is meant by *"substantial costs and potential liabilities that may be incurred by Niche and Unichem as a consequence of ceasing their programme to develop perindopril…"*. Judging by the plain words used in clause 13, this quite simply covers costs and liabilities arising as a consequence of the cessation of their perindopril programme. This clearly covers any indemnification which might need to be paid to customers of Niche for a possible breach of contract. However, by its own terms, clause 13 does not refer to covering the costs already incurred in developing generic perindopril.[1873]

(1326) According to Niche, the notion of "substantial costs" essentially covered the "costs of development and legal costs"[1874] and the notion of "potential liabilities", covered *"compensation payments to be made to customers for breach of contract"*.[1875]

(1327) Next, it needs to be considered whether Servier gained any marketable value or commercial benefit from compensating Niche/Unichem for those costs. The plain answer appears to be that the "*substantial costs and potential liabilities*" incurred by Niche/Unichem as a result of the settlement agreement were worthless to Servier.

(1328) First, Niche/Unichem's costs associated with ceasing the perindopril programme, be they incurred or avoided, do not represent a separate benefit to Servier.

(1329) Second, the termination/suspension of the customer relationships and the commitment not to request additional marketing authorisations has no commercial value to Servier, except as a reinforcement of Niche/Unichem's non-compete obligation for the present and the future.

1872 ID0382, p.250. Niche also confirmed in its reply to the Statement of Objections that *"the payment of GBP 11.8 million was made inter alia "in consideration for the undertakings"*, which undertakings it admitted referred to clauses imposing obligations on Niche/Unichem (clauses 3, 4, 6, 7, 8, 10 and 11). See ID8524, p. 190-191.

1873 Servier claims that the Commission should have also taken into account the risks Niche avoided, i.e. risks in case it lost the UK litigation, risks relating to a litigation on the '947 and the means to find a way out of a doomed project (reply to Statement of Objections, paragraph 411, ID10114, p.187). Most of these risks are however inherent to the litigation and cannot justify such a significant payment. In addition, if we follow Servier's line of reasoning, Servier provides thereby good reasons why it is Niche who should have transferred a payment to Servier, and not the opposite. As to avoided costs, these cannot be taken into account since Servier also avoided certain costs by concluding the settlement agreement, for example costs relating to further litigation (if any). More generally, the claim that the payment transferred by the originator to the generic company results from the asymmetry of risks cannot hold (see paragraph (1149)) and suggests that Niche was a threat to Servier's perindopril.

1874 See paragraph (548).

1875 See paragraph (548).

(1330) The only commercial benefits to Servier foreseen in the settlement agreement and relating to a performance by Niche/Unichem are thus contained in the non-challenge and non-compete obligations (as supplemented by the other undertakings). This was also explicitly confirmed by Niche. In a response to a RFI, it indicated that it was not aware of any value transfer from Niche to Servier taking place in the context of the settlement agreement.[1876] As to Servier, it did not even try to provide an explanation in its reply to the Statement of Objections about the reason why Servier had to bear the costs of termination of the customer contracts of Niche and the costs associated with the termination of Niche/Unichem's perindopril project.

(1331) Thus the costs and liabilities described above were not of any commercial value to Servier and therefore cannot be considered as a legitimate justification for the payment.

(1332) In light of the above, it is concluded that the payment from Servier to Niche totalling GBP 11.8 million can be understood as a net value transfer.[1877]

5.2.1.3.3.2 Settlement payment as possible remuneration for settlement specific costs

(1333) For the sake of completeness, the below analysis will show that the net value transfer by far exceeded any "costs" for Niche/Unichem stemming from the settlement.

(1334) As noted, according to Niche, the notion of "*substantial costs*" essentially covered the *"costs of development and legal costs"*.[1878] Niche reported that these costs - relating to the period 30 June 2000 until 18 March 2005 - amounted to around GBP [0–3]* million.[1879] Niche has not explained why it considers that development costs would be compensated nor has it provided any substantiation for this claim and in any event, these costs are not avoidable costs of entering into the agreement.

(1335) As to the notion of "*potential liabilities*", it covered, according to Niche, "*compensation payments to be made to customers for breach of contract*".[1880] According to the provisions of the settlement (clause 11 and 12), Niche had to terminate or suspend its customer contracts for which it refunded in total around GBP [0–2]* million to [0–20]* customers between 2005 and 2008.[1881] Servier claims in its reply to the Statement of Objections that the Commission adopts an *ex post* view of the situation as the liabilities could not have been known at the time of the agreement.[1882] However, after the settlement agreement, Niche made an overall provision of GBP [0–3]* million (see paragraph (635)) hence these were the overall costs that Niche envisaged to pay back. Therefore, claims made by certain clients were clearly disproportionate since the estimated provision corresponds globally to what was finally reimbursed.

1876 ID4718, p. 2.

1877 The Biogaran Agreement provides a further inducement and will be described in section 5.2.1.3.3.5.

1878 Although the Settlement *Agreement* explicitly stated that *"there shall be no order for costs"* (ID0119, p. 138 and 142).

1879 See paragraph (601).

1880 See paragraph (548).

1881 See paragraph (639).

1882 Servier's reply to the Statement of Objections, paragraph 414, ID10114, p.188. See also Servier's reply to the letter of facts (ID10289, p.113-114) and Niche's reply to the letter of facts (ID10220, p.32). The Commission acknowledges that the document where a provision of GBP [0–3]* million was made is an *ex post* document. However, there is no evidence from the time of the agreement that Niche had any major concerns with respect to the amounts to be refunded to customers.

(1336) If – to the benefit to Niche – one were to add up these cost factors at face value (i.e. GBP [0–5]* million for development and legal costs as well as GBP [0–5]* million for termination of customer relationships), the total costs reported by Niche amount to GBP [0–5]* million. Compared to the overall consideration received from Servier (GBP 11.8 million), this cost represents only approximately [5–30]* % of the settlement payment.

(1337) Thus, even if costs of withdrawing from competition were accepted as a legitimate consideration for the value transfer to Niche (*quod non*), the actual payment by far exceeds Niche's incurred costs. It is important to add in this regard that the parties have not given any explanation for how they calculated the sum of at least GBP 11.8 million. Given the evidence on file, the appropriate conclusion is that this sum was negotiated by the parties as an amount to compensate Niche/Unichem for the profits that it would have earned during a substantial period of time if it had entered the market. Therefore, no deduction from the net value transfer described in the previous subsection is made by the Commission given that Servier did not receive any marketable value in return.

5.2.1.3.3.3 Assessment of quantum

(1338) It is central to the assessment of the Niche/Unichem Settlement Agreement that the amount of the net value transfer was very significant and induced Niche/Unichem to conclude the agreement. The quantum of the net value transfer, and its significance to the parties, is assessed below.

(1339) First of all, an internal Niche document stresses the significance of the amount of the reverse payment in relation to planned future sales of perindopril: "*Perindopril sales sacrificed in settlement. Settlement was equivalent to over [0–20]* year planned sales and [10–50]* years planned gross profit*".[1883] This quote is explicit on the reason which led Niche to "sacrifice" its sales and refrain from competing on the market, namely the large sum that was given in exchange for the settlement terms. The importance of the quantum of money to Niche can be seen in the correlation between the net value transfer and the [10–50]* years of gross profit. Instead of earning those gross profits by taking the risk of competing on the market, Niche simply received it from the originator. This is all the more evident given Niche's lawyer statement during the negotiations of the settlement agreement according to whom *"[…]*"* is *"[…]*"*.[1884] In turn, this payment was a way for Servier to prevent Niche from competing with it and negatively affecting its profit margins for perindopril. The Commission notes that undertakings should not be entitled to avoid the uncertainty and risks related to competition on the market by transferring money to prevent market entry.[1885]

(1340) Another document shows that the settlement represented a windfall for Niche: *"it was indeed the agreement to postpone the development/launch [of perindopril] which gave rise to the windfall mentioned above"*.[1886]

(1341) In addition to the previous statements, the Commission finds it instructive to compare the sums of money transferred by Servier to Niche with the levels of profits

1883 See paragraph (600).

1884 See paragraph (544).

1885 Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraphs 33 - 34.

1886 See paragraph (602).

which were contemporaneously expected by each of the parties in the alternative scenario of generic market entry.

(1342) Regarding Niche, it received from Servier a one-off payment of at least GBP 11.8 million in exchange for settling the dispute and refraining from entry into the market for perindopril. If Niche's entry had taken place, it would have had an EU-wide character with Niche selling directly on the UK and Irish markets[1887] and being present on other EU markets through its licensed partners.

(1343) According to Niche's gross profit analysis from March 2004, perindopril sales were expected to yield a gross annual profit of GBP [100,000–200,000]* from perindopril sales and GBP [700,000–1,200,000]* from out-licensing income during the financial year 2003/2004[1888]. Taking into account the 50:50 profit sharing arrangement agreed by Niche and Matrix, Niche was correct in stating that *"the settlement was equivalent to […] 20 years planned gross profit"*.[1889]

(1344) However, it must be noted that the said statement appears to be based on a simple multiplication of the profits expected in the initial year of perindopril sales. Since it is known that in the generic business the first years of product commercialisation are usually the most profitable,[1890] the payment received by Niche was in all likelihood worth more than 20 consecutive and real years of gross profits from commercialising the product. In addition, any future profits should also be discounted for the time value of money which further increases the comparative financial attractiveness of the settlement agreement with Servier.

(1345) From Servier's perspective, it paid Niche a lump-sum of GBP 11.8 million and as a result it secured its continued monopoly over the sales of perindopril. According to Servier's own data provided in the course of the present investigation, the sales of perindopril on the top 13 EU markets[1891] generated an EBIT profit of EUR 158 million in 2004 which rose to EUR 244 million in 2005.[1892]

(1346) In case of generic entry, Servier would have lost a considerable part of its profits from the sales of perindopril. According to an internal calculation prepared by Niche in August 2004, its market presence was expected to cause Servier an annual loss of GBP 57 million in terms of foregone profits. This calculation should be regarded as conservative as it assumed that Servier would suffer from lower sales on only

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1887 ID0025, p. 29.

1888 ID0025, p. 16.

1889 See paragraph (600). Contrary to Servier's suggestions (see Servier's response to the Statement of Objections, paragraphs 420-421, ID10114, p. 190-191), the Commission's interpretation given to Niche's budgeted figures is confirmed in Niche's submissions made during the Commission's investigation. Niche explains that for the financial year ending on 31 March 2005 it budgeted the gross profit of GBP [400,000–800,000]* over the sales of perindopril. This amount was based on the assumption that *"Niche would launch the first generic perindopril in UK and therefore a market share of [20–60]* % was assumed selling at [15–55]* % below the originator price. However, as you are no doubt aware prices in the UK market are subject to rapid reduction due to increased numbers of competitors and therefore these numbers were by no means certain of being achieved"*. (see ID1577, p. 1-2). It is evident that Servier's alternative figure of GBP 15.48 million is expressed in terms of turnover, and not gross profit, and does not take into account the rapid erosion of price following generic entry and other uncertainties related to the pre-launch profit forecasts.

1890 For the evidence of gradual price erosion prompted by generic entry, see among others the Report on the pharmaceutical sector inquiry published by DG Competition on 8 July 2009.

1891 Belgium, the Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Poland, Portugal, Romania and the United Kingdom.

1892 ID1158.

eight EU markets[1893] and that there would be no official price reductions triggered by generic entry.[1894] The latter assumption was conservative in view of the cost containment measures aimed at lowering prices of medicines available generically that were adopted in most of the Member States.[1895] The most striking example is provided by the price developments in the UK (see Table 23), where the availability of generic perindopril caused the average price per DDD to fall from GBP [0.20-0.50] in the first half of 2007 to GBP [0.02-0.10] in the second half of 2009. Because of the assumptions made by Niche, the Commission considers that the figure estimated by Niche constitutes at best a lower bound of profits that were at stake for Servier.

(1347) Moreover, the agreement was an attempt by Servier to secure its market position for a multi-year period, possibly even until the '947 patent's expiry in 2021. Therefore, the sum of money transferred to Niche must be regarded as a small fraction of the total profits that Servier hoped to protect by entering into the settlement in question. Given the magnitude of profits made by Servier on the market, the existence of the parallel settlement with Matrix, even if it virtually doubles the total amount paid to the generic counterparts by Servier, does not alter the overall finding that the settlement arrangement was highly beneficial to Servier as compared to the situation of generic entry.

5.2.1.3.3.4 Conclusion on the financial consideration

(1348) In the light of the above, it is concluded that the settlement agreement involved a net value transfer for the amount of GBP 11.8 million without any value transferred in return to Servier. As indicated, the purpose of this transfer was clearly linked to Niche/Unichem's limitations on entry, and represented a rent sharing arrangement between Servier and Niche/Unichem in return for the obligations limiting Niche/Unichem's ability and incentives to compete.[1896]

5.2.1.3.3.5 Additional inducement in the form of a separate agreement

(1349) In addition to the net value transfer, Servier provided an additional inducement to Niche through the Biogaran Agreement.

(1350) As explained in section 4.3.1, on 8 February 2005, the same day Niche/Unichem concluded the settlement agreement with Servier, Niche also concluded a licence and supply agreement with Servier's generic subsidiary Biogaran. Biogaran paid Niche GBP 2.5 million in the framework of this agreement for the transfer of the product dossiers and one marketing authorisation for pharmaceutical products unrelated to perindopril.

(1351) Formally speaking, the settlement agreement and the Biogaran Agreement are separate legal acts. However, the following elements suggest the existence of a link between these agreements:

1893 The loss was calculated for the following markets: the UK, France, Belgium, Germany, Portugal, Denmark, Hungary and Slovenia.

1894 ID0025, p. 176.

1895 See section 6.4.1.1.

1896 See also the following section concerning the additional inducement stemming from the Biogaran Agreement.

- Both agreements were negotiated during the same time period[1897] and ultimately concluded between the same undertakings[1898] on the same date and at the same location (London).
- In both agreements the payments were scheduled to be paid in two instalments. The instalments in both agreements refer to the same dates for the payment (i.e. 14 February 2005 and 5 October 2005).

Moreover, there are indications that the Biogaran Agreement was not an arm's length deal:

- While Servier denies the Biogaran Agreement had any link with the Settlement Agreement,[1899] Niche explicitly acknowledges that the Biogaran Agreement *"was proposed by Les Laboratoires Servier to provide Niche with the total overall consideration agreed for entering into the Global Settlement Agreement"*.[1900] Niche also confirmed that the price was fixed *"as part of the total overall consideration Niche required"*.[1901] Niche admitted that the magnitude of the payment formed part, in its opinion, of the Settlement Agreement.[1902]
- An email dated 4 February 2005 sent by Biogaran's counsel to Niche suggests that the amount to be transferred to Niche was agreed before any exhaustive agreement on the scope of the products had been made: *"in consideration of the amount at stake we find it necessary to have further rights on additional products and certain freedom on the supply side of the Products"*.[1903] According to Biogaran, this email correspondence shows that Biogaran accepted to pay the sum Niche required only against *"further rights on additional products"* thereby making sure to avoid any restriction of its freedom to compete.[1904] This explanation cannot hold – there is no commercial explanation for a prior agreement on a given sum requested by one of the parties, i.e. 2.5 million, without an agreement on the subject-matter of the agreement (i.e. the products) at the same time.
- According to Niche, Biogaran did not obtain marketing authorisations on the basis of the product dossiers transferred to it by Niche (except the French MA for [product name]* transferred to Biogaran).[1905] In addition, clause 14.4 of the Biogaran Agreement foresees an automatic termination of the agreement in case marketing authorisations are not obtained

1897 Contacts between Biogaran and Niche on [product name]* already took place in 2004. At the time, only [product name]* was discussed and a confidentiality agreement signed (see footnote 809 under paragraph (561)) whereas the Biogaran agreement concluded in February 2005 concerned three different molecules in total. Hence, the negotiations of the Biogaran agreement which covered [product name]* but also other molecules must have taken place shortly before the settlement agreement. No documents from January-February 2005 when the negotiations must have taken place were submitted in this respect by the parties.

1898 Biogaran is a 100 % subsidiary of Servier. See paragraph (14).

1899 See paragraph (569).

1900 See paragraph (560).

1901 See paragraph (562).

1902 See paragraph (562).

1903 See paragraph (566).

1904 Reply to the Statement of Objections, paragraphs 78-80, ID9243, p.12.

1905 See paragraph (567).

"within 18 months from the date of coming into force of the Agreement".[1906] This clause together with clause 14.5 providing that *"neither party shall be entitled to any compensation in the event of termination […] by the other party pursuant to clauses 14.2 or 14.4"*[1907] indicates that Servier could not have claimed the repayment of the sum it transferred to Niche.

- Moreover, comparing the Biogaran agreement with other deals on product dossiers concluded by Biogaran, the latter featured a clause whereby any payments made by the latter to its commercial partners will be refunded in case MA's are not obtained within 18 or 12 months respectively (see footnote 815).[1908] Hence, the Biogaran agreement appears to have been concluded with the intention to induce Niche. In Niche's own words, this was *"not normal commercial practice"* (see paragraph (562)), although such agreements may happen on occasions.
- The total turnover achieved by Servier/Biogaran following a deal for which it transferred GBP 2.5 million amounted to only EUR [100,000-200,000].[1909]

(1352) Niche claims in its reply to the Statement of Objections that the Biogaran agreement was an arm's length deal which could realistically only be concluded once the dispute between Servier and Niche had ended. Niche also contests that the Biogaran agreement was an inducement for it to enter into the settlement agreement.[1910] This contradicts previous statements made by Niche in reply to the Commission's RFIs (see paragraphs (560) and (562)). In addition, this agreement seems to have been part of the settlement discussions as the sum of GBP 2.5 million is mentioned with hand-written "[product name]*", one of the three molecules covered by the Biogaran agreement, on one of the drafts of the settlement agreement.[1911]

(1353) According to Biogaran's reply to the Statement of Objections, the fact that these were separate legal acts is an essential element of the analysis, since one agreement was

1906 See paragraph (564).

1907 See paragraph (564).

1908 According to Niche, the difference between the Biogaran agreement and other agreements concluded by Biogaran is the result of Niche not being the sole supplier of the product whereas it had given up the profits from [product name]* sales in France, the United Kingdom and the United States. The payment of GBP 2.5 million was Niche's only security. It also notes that if the payment had been refundable, Biogaran would have less incentive to pursue and maintain a supply relationship with Niche (see Niche's reply to the letter of facts, ID10220, p. 19-20). However, contrary to Niche's statement that Biogaran retained the right to purchase the product from other suppliers (see ID10220, p. 20), Biogaran actually undertook to buy all of its requirements for the product from Niche once the marketing authorisations were obtained. Turning to Biogaran, it argues that the difference between the different agreements as to the non-refundable nature of the consideration is irrelevant given that contrary to these agreements, the Biogaran agreement was an exclusive one. Also, Biogaran explains that its negotiation power was limited given the importance of obtaining the [product name]* tablets and [product name]*. Finally, Biogaran mentions other agreements signed by Niche which did not feature a reimbursement clause (reply to the letter of facts, ID10317 p.2-3). However, the agreements mentioned by Biogaran featured payments in instalments and such payments for the first instalment (prior to the licence approval) were insignificant, hence there would have been limited reimbursement, contrary to the one-off payment of GBP 2.5 million in the present case.

1909 See paragraph (569).

1910 ID8524, p. 35 and 54. See also Niche's reply to the letter of facts, ID10220, p. 28.

1911 ID3778, p.6. Niche appears to admit in the reply to the letter of facts that [product name]* was mentioned during the settlement agreement's discussions (see ID10220, p. 29).

not conditional upon the other agreement, the signatories, governing law and jurisdictions were different, the consideration was paid by Biogaran and not by Servier. In addition, the conclusion of the agreements on the same day is not illicit: the litigation between Niche and Servier had the effect of paralysing the negotiations between Biogaran and Niche.[1912] This reasoning is however flawed: the email of 4 February 2005 (see paragraph (566)) shows that negotiations between Biogaran and Niche were advanced on this date whereas the litigation between Servier and Niche was still on-going and only settled on 8 February 2005. In addition, a document submitted by Biogaran in its reply to the Statement of Objections[1913] shows commercial negotiations on [product name]* in August 2004, i.e. more than a month after the litigation had started in the UK hence the negotiations did not seem to have been paralysed because of the litigation which had started in June 2004.

(1354) Therefore, and despite claims contesting any link to the settlement agreement, there is evidence that the Biogaran Agreement served as an additional inducement for Niche to enter into the settlement agreement with Servier.

5.2.1.4 The parties' intentions

(1355) The intention of the parties can be an additional indication of the object of a given agreement. A description of respectively Niche/Unichem's and Servier's intentions will be made in the following paragraphs.

5.2.1.4.1 Niche/Unichem's intentions

(1356) By the time of the agreement, Niche had reached an advanced stage of perindopril development and seemed to have a commercial lead over other generic companies. Niche anticipated that it would shortly obtain a marketing authorisation, enter the market and directly compete with Servier's branded perindopril. It was also confident that it did not infringe Servier's process patents.

(1357) Yet, already before the start of the infringement litigation, Niche took steps to find an advantageous commercial arrangement with Servier and avoid competing on the merits. As indicated below (see paragraph (1367)), it was Servier who decided to switch in January 2005 from an acquisition to a patent settlement.

(1358) Hence, in May 2004 (i.e. before the start of the litigation), Niche's lawyers had contacted Servier's lawyers in order to discuss *"ways of achieving a negotiated settlement"*.[1914] Servier's lawyer reported to Servier's patent department on the conversation it had with Niche's lawyer:

"In the view of Niche, it was in the interests of neither party to engage in litigation on the validity and infringement of Servier's patents in open court. If Niche were successful in revoking Servier's patents, this would obviously be damaging for Servier. However, it would also not be particularly advantageous for Niche, given that it would open the way for other generic entrants into the market. Niche did not want to "win the battle but lose the war".[1915]

1912 Paragraphs 68-76, ID9243, p. 10-12.

1913 Annex 3 to Biogaran's reply to the Statement of Objections, ID9244, p. 16; see also footnote 809.

1914 See paragraph (492).

1915 See paragraph (493).

(1359) This shows that Niche considered that generic entry would be harmful for itself and for Servier, and that it was willing to reach an arrangement with Servier to prevent this. Niche was willing to align itself with Servier in this respect.

(1360) Similarly, another contemporaneous document shows that Niche's intention was to agree with Servier on a *"commercial arrangement that will suit Niche and to an extent Servier by keeping other generic versions of perindopril off the market for as long as possible"*.[1916]

(1361) Separately, the evidence on the file summarised in section 5.2.1.2 shows that Niche was confident in the strength of its position in the English patent litigation against Servier. Despite this confidence, it opted to abandon this litigation in return for the significant payment from Servier. This shows an intention to avoid competition on the market. An example in this regard dating from a few days before the conclusion of the settlement is an email of 5 February 2005 from Niche's lawyer to Niche indicating that *"[…]*"*. Niche's lawyer stated that *"[…]*"* (emphasis added) is a safe course of action.[1917]

(1362) In light of the above, it can be concluded that Niche opted for a patent settlement in exchange for a substantial sum of money instead of continuing the English litigation which it was confident to win.

5.2.1.4.2 Servier's intentions

(1363) Turning to Servier's intentions, the following facts describing the contextual situation before the conclusion of the settlement agreement are illustrative of Servier's limited belief in the strength of its remaining patent protection as well as the set of options that it had in mind shortly before the conclusion of the settlement. Servier has not submitted any contemporaneous internal evaluations of its chances to succeed in the litigation with Niche. In any event, there was a genuine dispute between the parties and the litigation documents indicate that Servier believed that Niche infringed its process patents.[1918]

(1364) The reason why Servier had initially filed for the "**cluster of blocking patents*" was that it expected that the remaining process patents expiring in September 2008 would be insufficient to block all alternative ways of producing perindopril.[1919] Servier thus knew that the three process invoked against Niche had thus only a limited possibility to exclude.

(1365) Moreover, Servier was according to Niche apprehensive of a possible invalidity action relating to the '947 patent.[1920] Servier did not enlarge the scope of the English

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1916 See paragraph (489). This is contrary to the notion inherent in the Treaty provisions on competition, according to which each economic operator must determine independently the policy which he intends to adopt on the internal market (see Joined Judgment in *Suiker Unie and Others v Commission*, 40/73 to 48/73, 50/73, 54/73 to 56/73, 111/73, 113/73 and 114/73, EU:C:1975:174, paragraph 173; Judgment in *Züchner v Bayerische Vereinsbank*, 172/80, EU:C:1981:178, paragraph 13; and Judgment in *Deere v Commission*, C-7/95 P , EU:C:1998:256, paragraph 86).

1917 See paragraph (544).

1918 See Servier's reply to the Statement of Objections, paragraphs 325-326, ID10114, p. 157.

1919 See paragraph (115)-(116).

1920 In its reply to the Statement of Objections, Servier claims that it was in fact Niche that was reluctant to risk a suit on the '947 (section 6.1.1.2, ID10114, p. 159-164). While Niche decided finally not to pursue a revocation action at the same time as the infringement proceedings, Niche had prepared grounds for invalidity whereas Servier had never considered suing Niche for infringement– it all depended on whether Niche decides *"to start a claim to revoke the '947"* (Annex 06-07 to Servier's reply to the

patent litigation to also cover the infringement of the '947 patent (allegedly due to an absence of a sample to test),[1921] a patent which, according to Niche's lawyers, Servier seemed "*too scared to enforce*".[1922] Neither did Niche launch an invalidity action before a national court, but only an EPO opposition. Consequently, Niche considered that Servier's failure to rely on the '947 patent can only be explained by a perceived weakness of this patent: "*The position on the alpha polymorph patent, 947 is that Servier are still asserting insufficient information. They seemed remarkably reluctant to risk suit on the 947 patent"*.[1923]

(1366) In addition, Servier attempted to acquire Niche before concluding the patent settlement. As noted by Niche *ex post*, Servier's offer to acquire Niche *"was driven by their desire to prevent generic perindopril being launched"*.[1924]

(1367) Moreover, a contemporaneous document indicates that, in January 2005, Servier had two options in mind: acquiring Niche's shares or paying a patent settlement. It decided in favour of the latter as can be read in said document: *"[Servier] expressed preference to pay a 'patent settlement' rather than acquire shares. […] I think they are struggling to devise a method that is acceptable"*.[1925] Servier was therefore trying to find options to eliminate Niche from entering the market – it tried to acquire and finally settled with Niche on the day of the trial in the process patents litigation.

(1368) Finally, Servier's internal document "*Coversyl: defense against generics*" (by [employee name of Servier]*, who also negotiated and signed the agreement for Servier) confirms beyond doubt that Servier considered patent settlements to form a part of that (successful) strategy. The section entitled "*Did it work?*" explicitly refers to the Niche and Matrix settlements.[1926] Therefore, Servier's claim that a presentation post-dating the settlements by more than a year cannot demonstrate Servier's intentions at the time of their conclusion[1927] cannot be upheld – while the analysis by the Commission is made from an ex ante perspective, this document drafted after the conclusion of the settlement agreement concurs with the Commission's ex ante perspective of Servier's intentions.

5.2.1.5 Conclusion - the Niche/Unichem Settlement Agreement restricts competition by object

(1369) In summary, the Niche/Unichem Settlement Agreement is an agreement between undertakings whereby Niche/Unichem limited their ability to compete through the non-challenge and non-compete obligations. In exchange for these commitments, Niche received a payment of GBP 11.8 million, a substantial sum of money which

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Statement of Objections, paragraph 43, ID9060, p. 48). Servier argues that such action was never undertaken because of Niche's inability to determine the percentage ratio of polymorphs in its intended commercial product (Annex 06-07 to Servier's reply to the Statement of Objections, paragraph 27, ID9060, p. 43) and that it would have therefore been irresponsible to initiate such action in the absence of a sample to test (Servier's reply to the Statement of Objections, paragraph 336, ID10114, p.161 and reply to the letter of facts, ID10289, p. 101-105). It appears that Niche decided to launch an opposition before the EPO instead of launching an invalidation action on the '947 patent in the UK and this patent was left outside the scope of the English litigation by both parties.

1921 Servier's reply to the Letter of Facts, ID10289, p.104.

1922 See paragraph (504).

1923 See paragraph (501).

1924 See paragraph (537).

1925 See paragraph (533).

1926 See paragraph (111).

1927 Servier's reply to the Statement of Objections, paragraph 449, ID10114, p. 198.

served as an inducement to refrain from competing on the perindopril market.[1928] The Biogaran Agreement was a further inducement to enter into the settlement agreement.

(1370) The terms of the settlement agreement itself show that the reverse payment was made "in consideration for" Niche/Unichem's commitment to discontinue their activities necessary for a possible effective and legitimate market entry until at least the expiry of the process patents in September 2008 (i.e. a period of three and a half years) and possibly until the expiry of the '947 patent in 2021. To use the words of Niche's counsel, it was "*bought out*" of the market.[1929]

(1371) As explained in the general assessment section 5.1, patent settlement agreements can properly be based on an assessment of e.g. (i) the validity of the patent(s) at issue, and/or (ii) the strength of the infringement case, without objections being made from a competition law perspective. However, it is a blatant violation of Article 101(1) of the Treaty for one competitor to pay another competitor to stay out of a market since every operator should determine independently the policy which it intends to adopt on the market.[1930]

(1372) In the present case, the Commission's view based on the evidence at hand is that the payment to a potential competitor of a significant amount of money is the central and essential consideration for the conclusion of the agreement.[1931] If such a reverse payment were not deemed necessary to reach the same negotiating outcome, it is reasonable to assume that Servier would behave as any profit maximising economic operator and not pay out such a significant amount of cash. By the same token, Niche would have thus either insisted on more favourable settlement terms allowing for earlier market entry or would have continued litigation and could have become an actual competitor with its generic perindopril.

(1373) Both parties to the settlement, Servier and Niche/Unichem, were better off in agreeing the settlement than in the alternative scenario of generic entry and resulting competition. It is also evident that the mutually beneficial arrangement was only possible at the expense of the perindopril consumers who as a consequence were required to continue paying higher prices than in the scenario of competitive entry. In economic terms, the Niche/Unichem Settlement Agreement must be considered as a classic rent sharing agreement by which the interests of the counterparties are aligned.

(1374) Finally, at the time of conclusion of the settlement agreement, both parties' intentions were clear as evidenced by a number of facts assessed above (see section 5.2.1.4).

1928 Servier notes in its reply to the Statement of Objections that Niche did not need any inducement to conclude the agreement given the problems it was facing with its product (paragraph 409, ID10114, p.186). The Commission reiterates that absent the agreed inducement, Niche as a reasonable economic operator would not accept the commercial limitations and would instead resort to a more pro-competitive solution – Niche had proposed to Servier options different from a reverse payment settlement (see also general assessment section, paragraph (1138)). There is in fact no other plausible explanation provided by the parties for the payment transferred by Servier other than it being an inducement to accept restrictions on entry.

1929 The fact that Servier was first envisaging an acquisition and then opted for a patent settlement as an alternative to the acquisition shows that the agreement was made with the aim of buying out Niche and excluding it as a potential competitor to Servier.

1930 Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 34.

1931 While the parties clearly retained their views of their litigation cases, the respective strengths of their cases no longer dominated the outcome. Rather, the payment became the decisive factor.

First, the generic company decided to forego the competitive commercial incentives in exchange for "a lot of money". Second, Servier had considered two options as a way of eliminating its competitor (acquisition of shares or conclusion of a patent settlement) and chose the second option. The latter option allowed the elimination of the possibility of generic entry against the certainty of non-entry.

(1375) Given the above assessment of the agreement concluded between Servier and Niche/Unichem, the Niche/Unichem Settlement Agreement should be considered as a restriction of competition by object.[1932] The Commission refers to sections 5.1 (and in particular to paragraph (1112)) and 5.2.1 for its considerations on the appreciable degree to which the agreement in question restricted competition and to section 5.2.2.6 for its analysis of effect on trade between Member States. The analysis in those sections shows that for a restriction by object that may affect trade between Member States, the Commission does not have to prove an appreciable restriction of competition, but that in any case the Niche/Unichem Settlement Agreement did restrict competition to an appreciable degree.

5.2.2 Niche/Unichem Settlement Agreement is a reverse payment settlement which restricts competition by effect under Article 101(1) of the Treaty

(1376) The previous section concluded that the Niche/Unichem Settlement Agreement was a restriction of competition by its very nature. Although in these circumstances, and according to the case law, it is unnecessary to analyse the effects of the agreement, the Commission will nonetheless, for the sake of completeness, show in the present section that the agreement was also likely to cause restrictive effects on competition between Servier and Niche/Unichem, as well as on competition between Servier and other generic companies to which perindopril formulations would have been supplied by Niche based on a MA licence. For the general framework for assessment of restrictive effects, reference is made to section 5.1.7 above.

(1377) To determine if the Niche/Unichem Settlement Agreement was likely to entail restrictive effects on competition, the following elements need to be considered: (i) Servier's market position, (ii) whether Niche/Unichem was a potential competitor of the originator company, (iii) the content of the agreement (significant reverse payment changes the incentives of the generic party to accept the exclusive clauses of the agreement), and (iv) competition that would have existed in the absence of the agreement. The latter point will focus on the competitive behaviour that Niche/Unichem would have been likely to engage in, absent the agreement, and on the other relevant sources of competition to Servier, thereby demonstrating the importance of Niche/Unichem as a competitive threat to Servier.

(1378) The findings of this "effects analysis" are limited to the perindopril formulations markets where Servier has been, in the preceding analysis, found to hold significant market power (i.e. France, the Netherlands, Poland and the UK). For points (i) to (iii), the analysis in this section will rely on the preceding conclusions of the present Decision. Thus, the present section will focus in more detail on point (iv).

[1932] Niche's argument going against the settlement being a restriction by object given that it is not an obvious restriction and not based on experience (see Niche's reply to the Statement of Objections, ID8524, p.46) is addressed at paragraph (1116).

5.2.2.1 Servier's competitive position

(1379) In the framework of the dominance assessment under the standards of Article 102 of the Treaty, it was established that Servier held significant market power on the final perindopril product market and the upstream perindopril API technology market (see sections 6.5 and 7.3). According to the Horizontal Guidelines, these findings are directly transposable to the assessment of market power under Article 101(1) of the Treaty.[1933]

(1380) In the context of the Niche/Unichem Settlement Agreement, Servier had an interest in protecting its significant market power, as there had been no launch of generic perindopril and therefore its supra-competitive rents were intact. This also afforded Servier the means to protect its significant market power: continued inflow of rents in the absence of price competition from generics provided the "deep pocket" to Servier from which it was able to finance rent sharing with generic companies in return for their withdrawal from competition. To illustrate the significant financial incentive from the originator company, one can compare the transfer of at least GBP 11.8 million pursuant to the Niche/Unichem Settlement Agreement to the [0–20]* years of planned sales and [10–50]* years of gross profit that Niche/Unichem was expecting with the launch of perindopril.[1934] This internal assessment is self-explanatory on the significance of the payment transferred to the generic company.

5.2.2.2 Niche/Unichem was a prominent potential competitor of Servier

(1381) Based on the facts in section 4.3.1 and according to the assessment in section 5.2.1.2, the Commission has concluded that Niche/Unichem was a prominent potential competitor to Servier in the production and supply of perindopril on the EU markets at the time the settlement with Servier was concluded.

(1382) In fact, the efforts and investments made by Niche/Unichem since the beginning of the perindopril project (together with Matrix) show the intentions of the company to enter the EU perindopril markets. More importantly, Niche/Unichem would have been able to enter the market within a short period of time if it was not for the settlement agreement.

5.2.2.3 Content of the Niche/Unichem Settlement Agreement

(1383) The terms of the settlement agreement have already been described in detail in section 5.2.1.3. Therefore, reference is made to the said section where it was concluded that, against a significant reverse payment, Niche/Unichem accepted contractual limitations to its commercial freedom which disabled or hampered Niche/Unichem's ability and incentives to enter the EU markets in a timely and viable manner and restricted competition by object.

5.2.2.4 Competition that would have existed in the absence of the restrictive agreement and the importance of Niche/Unichem in view of the remaining competition

(1384) This section will examine the competition that would have existed in the absence of the restrictive provisions of the Niche/Unichem Settlement Agreement. The section will focus on the competitive behaviour that Niche/Unichem would have been likely to engage in, absent the agreement, and on the other relevant sources of competition

1933 *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, OJ C 11, 14/01/2011, point 42.

1934 See section 5.2.1.3.3.3.

to Servier thereby demonstrating the importance of Niche/Unichem as a competitive threat to Servier.

(1385) In the absence of the restrictive provisions of the Niche/Unichem Settlement Agreement, Niche/Unichem which considered itself to have a *"limited lead over other generic competition"* in September 2004 and which was the first undertaking involved in infringement proceedings with Servier would have remained a competitive threat as a potential generic entrant with perindopril in the UK and in other EU markets. Niche/Unichem would have retained significantly more ability and incentive to compete and challenge Servier's significant market power if it had not settled or if it had settled on less restrictive terms in the absence of the reverse payment, notably allowing for earlier generic entry.

(1386) First, in the absence of the non-challenge obligation, Niche/Unichem would have remained the only undertaking involved in litigation with Servier before a national court. As explained above (see section 4.3.1.2.2.), this litigation concerned Servier's perindopril process patents (it appears that Niche decided not to attack the validity of the '947 patent although it had prepared a counterclaim, and Servier did not assert its rights with respect to that patent either). With respect to the process patents, Niche considered that it had a realistic chance to win the case on non-infringement. Given that litigation, Niche constituted a significant competitive threat for Servier and this may explain why Servier settled the litigation on the day of the hearing before the High Court.[1935] In the absence of the settlement agreement, this threat would have been maintained and Niche may have been able to establish Matrix's API technology as an enabling technology for the production of perindopril.

(1387) In addition, with respect to the '947 patent, Niche was also one of the opponents to that patent before the EPO. It agreed to withdraw this opposition in the settlement agreement. The '947 patent would likely have come into play in litigation between Niche and Servier in England. Niche could have launched separate invalidity proceedings before the English courts concerning the '947 patent although this did not seem to be its immediate intention.[1936] Also, had Niche won the litigation on the process patents (as it reasonably expected), it could have entered the market at risk which would have been an important competitive development. In reaction, Servier could have introduced an infringement action based on the '947 patent and sought an interim injunction. It would be highly probable that Niche would then have sought to defend its position by making a counterclaim alleging that the '947 patent was invalid (indeed, it had already tried to make the validity of the '947 patent an issue in the English litigation but did not pursue this claim further). These various developments would have put considerable competitive pressure on Servier, and its carefully protected '947 patent, which was avoided because of the settlement agreement.

(1388) Niche contends that the counterfactual of a launch at risk of an infringing product would prompt an injunction and litigation on the '947 would involve lengthy and

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1935 In its reply to the Statement of Objections, Servier claims that the Commission's theory is vitiated since it presupposes that Niche would have won the English litigation whereas if a victory by Servier is taken as a hypothesis, then there would be no effects whatsoever according to Servier (paragraph 509, ID10114, p.215). This claim is baseless since the Commission has not assumed that Niche would have prevailed in the English proceedings although it has listed Niche's perceptions in a successful outcome of the litigation. There was a genuine dispute between the parties and Niche exerted competitive pressure on Servier through the English litigation and EPO opposition and the threat of potential entry.

1936 ID3740, p. 8.

costly proceedings in addition to uncertainty.[1937] Servier argues that launch at risk was not a possibility given Niche's financial situation and the risk of Niche having to pay damages.[1938] While launch at risk could have prompted an injunction, there was no certainty of such an outcome given that Servier did not assert this patent in the previous (process patent) litigation. Litigation on the '947 may have well given rise to costly, uncertain and lengthy proceedings but this is the characteristic of any patent litigation.

(1389) Niche also argues that it is difficult to see the effects of the agreement if the '947 context is taken into account: Niche would have to litigate on the '947 and this patent was upheld in 2006. Any other company could have litigated and even if invalidated in 2006, it would be unattractive for Niche to enter as other generics would have also entered.[1939] It is useful to note in this respect that the '947 was not an issue in the English litigation and it is impossible to predict what would have happened following that litigation – hence the effects analysis was made ex ante. What is important is that Niche could have been the first to invalidate the patent since there was no national litigation on the said patent in the beginning of 2005. Moreover, it is uncertain whether other companies would have entered in 2006, as claimed by Niche.

(1390) Secondly, in the absence of the non-compete obligation, Niche/Unichem would have remained a threat due to its advanced development of perindopril, either as a direct supplier of perindopril formulations or through distribution partners (Niche had signed fourteen contracts which were cancelled or suspended).[1940] Absent the agreement, Niche/Unichem would have retained the competitive ability and incentives to pursue commercial strategies independently of Servier, taking into account the patent situation. The competitive threat from Niche/Unichem would have likely been maintained irrespective of whether the parties would settle on less restrictive terms, notably allowing earlier generic entry, or would not settle at all.

(1391) Therefore, absent the agreement and its restrictive provisions, Niche/Unichem would have remained a prominent potential competitor to Servier through its opposition before the EPO, its challenge before the High court and its advanced product development. In its reply to the Statement of Objections, Servier claims that the Commission refers to different actions that Niche could have undertaken but which would not have had the expected effects. In particular, Servier argues that (i) the outcome of the process patent litigation could not be anticipated, (i) it was unlikely that Niche enters at risk, (iii) Niche would not launch a revocation action on the '947, (iv) withdrawal from the EPO opposition had no appreciable effect on competition, and (v) Niche had no interest or financial resources to oppose the beta patent).[1941] However, the counterfactual described by the Commission refers to a number of possibilities which were likely since Niche was well advanced in its development project with Matrix – had it not been for the settlement with Servier, Niche would have remained a competitive threat (through litigation and potential entry).

(1392) Given the removal of a potential source of generic competition to Servier, the subsisting market structure at the time of the conclusion of the agreement will be

1937 Reply to the Statement of Objections, ID8524, p.28-29.
1938 Reply to the Statement of Objections, paragraph 471, ID10114, p. 206.
1939 Reply to the Statement of Objections, ID8524, p. 57.
1940 See paragraph (448).
1941 Servier's reply to the Statement of Objections, paragraphs 479-496, ID10114, p.208-211.

examined, in particular by identifying other relevant sources of competition and whether they could be perceived as capable of sufficiently constraining Servier to offset the likely effects of the agreement. The analysis will focus on generic competition which was by far the most important source of constraint on Servier's prices and volumes for perindopril.[1942]

(1393) As indicated in section 5.1.7.3, there was no generic perindopril in the EU at the time the agreement was concluded and no effective entry took place until May 2009, with only a few exceptions such as the UK and the Netherlands. After acquisitions of [company name]*'s and Azad's perindopril API technologies by Servier, there were no further generic companies except Niche/Unichem together with Matrix which could have entered the EU markets in the short term.

(1394) In addition, and as stated in paragraph (1245) in early 2005, there was only Niche, assisted by Matrix, which was engaged in litigation with Servier before a national court. Other companies which later also concluded patent settlements with Servier had only filed opposition procedures before the EPO during autumn 2004 and were not yet in litigation with Servier at the time.

(1395) The close generic competitors to the settling parties were limited to Teva, Apotex, Krka and Lupin. While Servier had already expected the first generic entry, in all likelihood by Niche/Unichem and Matrix, to occur by 2005,[1943] the first unsuccessful attempt by Apotex only followed in the second half of 2006, while Teva, Krka and Lupin respectively concluded settlement agreements with Servier.

(1396) Referring again to section 5.1.7.3, other relevant sources of competition at the time of conclusion of the settlement agreement between Niche/Unichem and Servier had not reached a sufficiently advanced stage of development of the perindopril product to counteract the likely effects of the Niche/Unichem settlement agreement. In addition, generic companies were possibly aware of the risk that similar agreements could be concluded by Servier to remove further imminent generic threats.[1944]

5.2.2.5 Conclusion – the Niche/Unichem Settlement Agreement was likely to entail restrictive effects for competition

(1397) The above analysis establishes that Servier held significant market power in the market for perindopril formulations and the upstream market for perindopril API technology, in which Niche/Unichem (together with Matrix) was active as a potential competitor. As the incumbent facing no price related constraints, and thus charging supra-competitive prices, Servier had the commercial interest and the financial means to offer significant inducements for close potential competitors to withdraw from competition. Thus, by inducing Niche/Unichem with a payment of at least GBP 11.8 million to accept the restrictive terms of the Settlement Agreement, Servier effectively removed Niche/Unichem from competition on perindopril. Niche/Unichem was no longer able to pursue the opposition procedures before the EPO or to pursue and/or introduce patent challenges against Servier as a key avenue for viable generic entry, and was also not able to enter at risk had it chosen this avenue.

1942 See section 5.5.1.2.6.
1943 ID0105, p. 184-186.
1944 See paragraphs (413) - (420).

(1398) The Niche/Unichem Settlement Agreement thus reduced competition between the parties to the agreement. Niche/Unichem could no longer compete with Servier the way it would have in the absence of the agreement with its existing development. As Niche/Unichem was also a potential supplier of perindopril formulations to other generic companies, the agreement also affected competition between Servier and these additional companies. In addition, the agreement also had effects on the technology of its development partner, Matrix, which could not establish its technology as a non-infringing technology for the production of finished perindopril products.

(1399) In the period of conclusion of the Niche/Unichem Settlement Agreement, the agreement's likely effects on competition were appreciable, as Niche/Unichem was an important, and one of the first, sources of competition to Servier's perindopril. It was likely ready to launch perindopril within a short period of time after concluding the settlement agreement and thus to also supply other generic operators.[1945] Moreover, Niche/Unichem and Matrix did maintain a time lead over all other generic challengers. In addition, there was considerable uncertainty as to whether the remaining sources would subsequently also reach an agreement with Servier, or be otherwise blocked by it. The removal of Niche/Unichem thus likely affected the overall competitive structure concerning perindopril.

(1400) On the basis of the foregoing considerations, the Commission finds that the Niche/Unichem Settlement Agreement was such as to appreciably restrict potential competition among Servier and generic companies and barred *"real concrete possibilities"* for Servier and Niche/Unichem to compete among themselves or *"for a new competitor to penetrate the relevant market and compete with the undertakings already established"*.[1946] By discontinuing Niche's patent challenge and removing the possibility of launch at risk with Niche's/Matrix's product, the Niche/Unichem Settlement Agreement appreciably increased the likelihood that Servier's significant market power would remain uncontested for a longer period of time and that consumers would forego a significant reduction of prices that would ensue from timely and effective generic entry.

5.2.2.6 Effects on trade within the meaning of Article 101(1) of the Treaty

(1401) Article 101(1) of the Treaty only applies to agreements and concerted practices "*which may affect trade between Member States*". This criterion has three basic elements.[1947]

(1402) First, *"trade between Member States"* must be affected. The concept of trade covers all forms of economic activity, including establishment. According to settled case law,[1948] an agreement that has an impact on the competitive structure in more than

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1945 In its reply to the Statement of Objections, Servier claims that Niche's ability to enter absent the agreement was hypothetical and that the developments post-2008 prove the unrealistic view of the Commission (paragraph 473, ID10114, p.207). As explained in section 5.2.1.2., Niche's ability to enter was not hypothetical but rested on concrete possibilities that entry occurs within a short period of time.

1946 Joined Judgments of 15 September 1998, *European Night Services and Others v Commission*, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198, paragraph. 137.

1947 *Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81–96, point 18.

1948 Joined Judgment of 8 October 1996, *Compagnie maritime belge transports and Others v Commission*, T-24/93, T-25/93, T-26/93 and T-28/93, ECR, EU:T:1996:139, paragraph 203; Joined Judgment in *Commercial Solvents v Commission*, 7/73 and 6/73, EU:C:1974:18, paragraph 23.

one Member State is by its very nature capable of affecting trade between Member States. Trade between Member States may be affected also in cases where the relevant market is national.[1949]

(1403) Second, it is sufficient that the practice "may" affect trade, meaning that it is sufficiently probable that the practices are capable, based on an objective assessment (as well as subjective elements, if any), of having an effect on the patterns of trade, or on the competitive structure.

(1404) Third, the effect on trade of the agreement must be "appreciable". This element requires that the effect on trade between Member States must not be insignificant and it is assessed primarily with reference to the position of the undertaking(s) on the market for the products concerned.

(1405) By discontinuing Niche's/Unichem's efforts to viably enter the market, including through its commercial partners in several Member States, the economic activities in which such undertakings were engaging were affected. Since Niche had concluded, at the time of settlement, 14 supply agreements for its generic perindopril in the EU (some of them covering all Member States), which had to be suspended pursuant to the obligation contained in the settlement agreement, the practice had both an effect on trade and on the competitive structure. The suspension of the development agreement between Matrix and Niche also affected trade as some of Niche's customers who had obtained marketing authorisations after the conclusion of the settlement agreement could not be supplied with the product. The example of the significant price decrease following the annulment of the '947 patent in the UK illustrates the actual and potential effect on the competitive structure in the Member States (see paragraph (2529)).

(1406) By removing Niche/Unichem as a potential competitor to Servier across the EU, the Niche/Unichem Settlement Agreement, actually or at least potentially, affected trade between Member States. In view of the magnitude of perindopril sales in the Member States concerned the actual or potential impact on trade can be said to be appreciable.[1950]

5.2.3 Conclusion – the Niche/Unichem Settlement Agreement restricts competition within the meaning of Article 101(1) of the Treaty

(1407) The above analysis has demonstrated that the Niche/Unichem Settlement Agreement consisted of a payment by Servier to Niche/Unichem for withdrawal as a close potential competitor from the market which had as its object to restrict competition. Niche/Unichem discontinued all activities needed for a viable and timely generic entry, which would challenge Servier's market position, and in return received a significant payment, which effectively amounts to rent sharing. The Niche/Unichem Settlement Agreement thus constitutes a restriction of competition by object in terms of Article 101(1) of the Treaty which was also likely to produce restrictive effects on competition.

(1408) The parties' claims under Article 101(3) of the Treaty are analysed in section 5.7.

1949 *Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81–96, points 19-22.

1950 See paragraph (2129).

5.3 Assessment of the Matrix Settlement Agreement

(1409) This section sets out the assessment pursuant to Article 101 of the Treaty of the Settlement Agreement concluded between Servier and Matrix on 8 February 2005 ("Matrix Settlement Agreement").

(1410) In the context of the Matrix Settlement Agreement, Matrix agreed to restrict its ability to compete and agreed not to challenge any of Servier's main perindopril patents. In addition, Matrix accepted restrictions concerning its contracts related to perindopril and regulatory procedures. Servier paid Matrix GBP 11.8 million in return for these commitments applicable to all countries in which the process patents and/or the alpha patent exist including, amongst others, the Member States.

(1411) It is important to note that Matrix and Servier did not have a direct dispute about any of Servier's patent rights before 7 February 2005. Servier sent Matrix a letter threatening infringement proceedings only one day before the settlement, at the time when Servier was already in advanced settlement discussions with Matrix's cooperation partner, Niche/Unichem. Thus, it could be inferred from the circumstances surrounding the rather quick conclusion of the Matrix settlement that the latter needed to be concluded together with the Niche/Unichem settlement agreement and this is what actually happened.[1951]

(1412) In a first step, this section will assess the Matrix Settlement Agreement as a restriction of competition by object under Article 101(1) of the Treaty. In a second step, and even though it is not necessary to examine the effects of an agreement when it is proved that its object is to restrict competition, an analysis of the Matrix Settlement Agreement as a restriction by effect is undertaken.[1952]

5.3.1 The Matrix Settlement Agreement is a reverse payment settlement which restricts competition by object under Article 101(1) of the Treaty

(1413) This assessment is divided into five sub-sections. First, a brief introduction will recall the specific context of the Matrix Settlement Agreement. Second, the Commission will establish that Matrix and Servier were potential competitors at the time of their agreement. Third, the restrictive terms of the settlement agreement will be assessed. Fourth, the parties' intentions will be described. Fifth, a concluding sub-section will summarise the assessment of the Matrix Settlement Agreement as a restriction by object.

5.3.1.1 Introduction

(1414) The general economic and legal context for the assessment of reverse payment patent settlements has been set out in section 5.1. In addition, the general factual background to the Matrix Settlement Agreement has been set out in section 4.3.1.

(1415) The specific legal and economic context of the Matrix Settlement Agreement can be summarised as follows.

1951 Servier itself states in reply to the Statement of Objections that Niche could have violated its contractual obligations towards Matrix if it had been the only one concluding a settlement agreement with Servier (paragraphs 534-535, ID10114, p.223).

1952 Judgment in *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343paragraphs 28-30 and Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 55.

(1416) At the time the agreement was concluded, there was no generic perindopril on the market and perindopril was Servier's most important product. Servier held the monopoly of sales of perindopril since 1989, owing to the compound patent protecting the product. Servier's sales of perindopril in the year before the settlement agreement (i.e. 2004) on the top 13 EU markets had generated an EBIT profit of EUR 158 million.[1953]

(1417) Since 2001, Niche and Matrix had been cooperating to bring a generic form of perindopril to the market and they were well advanced in that process. Matrix had a co-development agreement with Niche and was meant to supply the API, whereas Niche was responsible for obtaining the marketing authorisation and distributing the product. Yet, Matrix maintained a stake in the prospective supplies of perindopril formulations: the profits from the sale of the perindopril dossier and/or finished formulations of the product were to be shared between Matrix and Niche, irrespective of whether Niche or Matrix would market the dossier/the product.

(1418) In fact, the generic perindopril in the alpha crystalline form which Niche had produced with Matrix's API seems in retrospect to have been the most advanced challenger to Servier's perindopril at the time of the settlement agreement.[1954] This is confirmed by Niche's statement from September 2004 with respect to the status of the product development: *"we have limited lead over other generic competition which should not be squandered"*.[1955] Niche had applied for a marketing authorisation already in 2003 and was in intensive preparations to receive regulatory approval which was expected in 2005 in the UK.[1956] Moreover, Niche had numerous customers who had also applied for MA's throughout the EU.

(1419) As will be shown below, Servier agreed with Matrix that the latter would restrict its ability to enter the EU markets and to compete with Servier's perindopril. Crucially, this was done in return for the transfer of a very significant sum of money from Servier to Matrix. This kind of arrangement is a restriction of competition by its very nature.

5.3.1.2 Matrix and Servier as actual or potential competitors

(1420) In order to examine whether Article 101 of the Treaty can apply to the Matrix Settlement Agreement, it needs to be assessed whether Matrix and Servier were actual or potential competitors.

(1421) As explained in section 4.3.1, in 2001 Matrix had engaged – together with Niche – in the development of a generic version of perindopril. At the time of the settlement though, Niche had not yet received a marketing authorisation and had not yet launched a generic version of perindopril. However, the Commission considers that Matrix was a potential competitor to Servier for the following reasons.

(1422) First, Niche/Unichem and Matrix had for some years already invested resources in order to develop a product which could be launched as a generic alternative to Servier's perindopril. The venture was well progressed by the time of the conclusion of the settlement agreement. This is notably shown by both the work towards obtaining a marketing authorisation and the commercial batches of API which were

1953 ID1158.
1954 See paragraph (1245)
1955 See paragraph (459).
1956 See also paragraphs (454) and (456).

"*under way*".[1957] On the one hand, Niche expected the grant of the UK marketing authorisation in the course of 2005. This can be seen from an update sent to Niche's customers on 30 November 2004, in which Niche states that *"there have been some delays in obtaining regulatory approval in the UK and this is now not expected until early in the New Year"* (emphasis added).[1958] Based on this forecast, Niche and Matrix had a significant time advantage over other generic competitors. Indeed, a customer of Niche, DAA[1959], received a marketing authorisation on the basis of Niche's dossier in May 2005.[1960] On the other hand, Matrix's witness statements in the English proceedings between Servier and Niche confirm that Matrix had produced API which it considered sufficient.[1961] In particular, Matrix's statement of 25 November 2004 indicates that *"a number of batches are under way in preparation for [Niche's] commercial launch"* and that *"this level of production is sufficient to satisfy the anticipated orders for API from Niche"*.[1962]

(1423) Second, Niche had also concluded a number of agreements with commercial partners that were keen on selling perindopril based on Matrix's/Niche's dossier in Europe. Niche and/or its cooperation partners had applied for a marketing authorisation in a number of Member States.[1963] Most customer licences' approvals were expected by the first quarter of 2005 with variations in the second quarter of 2005 (see paragraph (457)).[1964] In addition, Niche requested from one of its customers, i.e. Ratiopharm, to indicate its launch orders for the year 2005 as Niche needed it for its production planning of 2005.[1965] Niche was also negotiating a future supply agreement with Teva, one of the largest generic companies, just a few days before the Niche/Unichem and the Matrix settlements were concluded (see paragraphs (450)-(452)). This shows Niche's belief that its cooperation with Matrix would result in commercialising generic perindopril within a short period of time.

(1424) Third, Servier itself considered that the cooperation between Matrix[1966] and Niche/Unichem was a generic threat. An email from Niche's lawyer of 5 February 2005 explicitly states that *"Servier believe that Niche will launch in April 2005 plus or minus 1 month"*[1967] which suggests that based on the information communicated throughout the litigation, Servier believed that Niche (and therefore Matrix) would be launching shortly thereafter. It is worth noting in this regard that Servier's assessment of the competitive threat posed by the cooperation of Niche/Unichem and Matrix was well grounded in factual analysis. In particular,

1957 See paragraph (517).

1958 See paragraph (456).

1959 This company was acquired by Matrix in June 2005.

1960 See paragraph (461). According to Servier, this element does not demonstrate that Matrix was a potential competitor since this cannot prejudge on the outcome of MA applications in other Member States and this MA was probably based on the earlier DMF version (paragraphs 564-565, ID10114, p. 233-234). While Servier's claim that this application was based on the earlier DMF appears to be correct, the fact that the MA was obtained by DAA allows to trace the progress in this grant process at the time of the settlement agreement and to show that the progress in this direction had reached an advanced stage. See also paragraph (457) for the expected dates of approval of most customer licences.

1961 See paragraph (517).

1962 See paragraph (517).

1963 See paragraph (454).

1964 See footnote 1803 for the arguments regarding the timelines for approval of the customers' licences.

1965 See paragraph (470).

1966 Matrix was considered by Servier much more than a "simple supplier of the API" and acknowledged Matrix's active role with respect to perindopril. See paragraph (510)

1967 See paragraph (544).

Servier had engaged in significant market intelligence regarding Niche/Unichem and carried out a due diligence to acquire Niche (i.e. had a precise knowledge of Niche/Matrix's project).[1968] As a subsidiary point, it might be added that it is hard to see why Servier would pay the total sum of GBP 23.6 million to Niche/Unichem and Matrix, under the settlement agreements with those companies, if Servier did not see them as potential competitors.

(1425) Fourth, Niche – assisted by Matrix – was engaged in litigation with Servier before the High Court (with respect to the (non)infringement of the process patents) - and before the EPO (with respect to the invalidity of the '947 patent). As Matrix was the API producer of Niche and the process used for its production was the subject of the litigation before the English courts, Matrix was informed about that litigation on a continuous basis and Matrix contributed, e.g. by providing witness statements.[1969] In addition, during 2004 Matrix had to tweak the process in order to avoid infringement and this had been done in a satisfactory way.[1970] Niche was reasonably confident that it would succeed in the English litigation and therefore that it would be able to gain market entry but given the existence of a dispute on the process patents, there was no certainty about the outcome of the litigation.[1971] The evidence in that regard is set out in section 5.2.1.2. A notable example can be found in an internal draft communication from Niche right after the settlement agreement: *"we felt confident that we would have won the case against the three patents in suit (...)"*.[1972] This quote is illustrative of Niche's belief that it stood a realistic chance of winning the English patent litigation. In addition, Niche also considered that the '947 patent was invalid and filed an opposition before the EPO.[1973]

(1426) Fifth, Matrix also shared the view that its venture with Niche could create a serious generic competitor when stating in reply to a RFI that *"had Niche been first to market with a generic product Niche and Matrix could have been expected to share significant revenues, at least prior to the entry of further generic competition"*.[1974] Matrix thus believed in the common project which would have been economically viable ("significant revenues") and considers it could have been together with Niche the first one on the market, save for the settlement.

(1427) Based on the above, the Commission considers that Matrix - together with Niche/Unichem - was a potential competitor which had the intention and ability to enter the market within a foreseeable time frame had it not been for the settlement

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1968 See section 4.3.1.3.

1969 See section 4.3.1.2.3.2 Matrix claims in its reply to the Statement of Objections (paragraph 1.16, ID8835, p. 8) that it was an independent entity and not necessarily aware of all developments surrounding the litigation. However, according to Matrix's own reply to an RFI (see paragraph (513)), there were regular contacts between Niche and Matrix during the litigation, Matrix was providing input and was involved in draft replies to Servier.

1970 See paragraph (467).

1971 In its reply to the Statement of Objections (paragraph 2.38 h) to j), ID8835, p. 26-27), Matrix claims that contrary to the Commission's allegations, it was not the case that Niche was confident of victory using Matrix's API. In support of this claim, Matrix cites a document mentioning the possibility of infringement of the '947 patent and possible damages in the future. However, when the Commission notes Niche's confidence in the successful outcome of the litigation, it focuses on the process patents and this should be distinguished from the '947 patent on which no national revocation or infringement action had been initiated.

1972 See paragraph (593).

1973 See section 4.3.1.2.4.

1974 ID2579, p. 4.

agreement. This assessment also holds true if one considers the counter arguments put forward by Niche.

(1428) In its replies to requests for information, Niche, Matrix's cooperation partner, argues that it did not consider itself as a competitor of Servier. In particular, Niche asserts that the cooperation with Matrix had not resulted in a viable product at the time of conclusion of the settlement as it had encountered difficulties during the API development and tablet manufacturing which were becoming "insurmountable".[1975] In other words, according to Niche's assertions, neither Niche/Unichem nor Matrix could have been a potential competitor due to the difficulties in the development and manufacturing process.

(1429) However, a potential competitor does not have to have a readily marketable product, as long as the company is able to enter within a "*short period of time*".[1976] The evidence presented above contradicts the assumptions that Niche/Unichem and Matrix were not potential competitors to Servier and that they were facing difficulties which were becoming insurmountable. In addition, these assumptions can be rebutted by reference to the following facts which show that Niche and Matrix were working towards an anticipated market entry.

(1430) Notably, Matrix has submitted that it "*did not consider abandoning its perindopril research and development efforts for perindopril erbumine prior to the settlement with Servier"*.[1977] This confirms that Matrix was optimistic about overcoming any outstanding obstacles with respect to the manufacturing of the product and that there were no insurmountable difficulties as claimed by Niche. Likewise, the cooperation between Niche and Matrix was not terminated prior to the conclusion of the settlement agreements with Servier, which was possible in case of insurmountable difficulties (see clause 4 of the development and license agreement),[1978] nor was the project suspended immediately following the conclusion of the agreements. Niche continued to resolve outstanding problems throughout the discussions and even after the settlement, when it asked Matrix for its assistance in the completion of the UK registration.[1979]

(1431) In its reply to the Statement of Objections, Matrix claims that it did not have the capability to produce a final perindopril product (it only had the capability to produce an API at the time) and had limited experience of EU markets.[1980] It had no presence in the EU so could not even apply for a MA and whereas it could have found another

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1975 See paragraph (463).

1976 Period of up to three years according to *Communication from the Commission - Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, OJ C 11, 14/01/2011, point 10.

1977 See paragraph (618). Matrix points out that this statement is not indicative of whether it could have succeeded in identifying a non-infringing process or demonstrating that its process was non-infringing (reply to the Statement of Objections, paragraph 2.21, ID8835, p. 17). The Commission notes that this statement was referred to in this paragraph to point out that the manufacturing difficulties (infringement issues taken aside) were not insurmountable, contrary to what Niche claimed in this respect. As to Matrix's claim that the Commission has failed to identify evidence setting out Matrix's views on its chances of success in the litigation, it is stressed that Matrix was not directly involved in litigation with Servier. However, Matrix's process being the subject-matter of these proceedings, Matrix was certainly briefed by Niche and aware of the stage of the dispute and the need to produce a non-infringing product (see paragraph (467)).

1978 See paragraph (430).

1979 See paragraph (625).

1980 Paragraph 1.14, ID8835, p. 7. See also Matrix's reply to the letter of facts, paragraph 2.6, ID10200, p.4.

marketing partner, this was not a viable commercial option.[1981] It argues that as a result of losing Niche, Matrix was out of the race and would not have been able to find another partner willing and able to overcome all barriers and produce in a timely manner a final perindopril product.[1982] Matrix also claims that the Commission confused the appropriate competitive environment in which to assess potential competition: it argues that both Servier and Niche would have settled irrespective of Matrix's position and that the Commission needs to establish that each of Niche and Servier would not settle without Matrix in order to substantiate its claim that Matrix was a potential competitor.[1983]

(1432) The assessment of potential competition between Servier and Matrix undertaken by the Commission is based on the product that was co-developed between Niche and Matrix which exercised a competitive threat on Servier at the time and resulted in the settlement agreement's conclusion. In addition, the Commission has referred to the options that Matrix would have in the absence of the agreement both with and without the involvement of Niche (see paragraph (1493)) and has therefore not confused the relevant competitive environment contrary to what is claimed by Matrix. There are elements which enable to doubt that Servier would have settled only with Niche or that it would not have imposed obligations on Matrix's behaviour through Niche. The negotiation of the Niche/Unichem settlement agreement is illustrative of Servier's wish to subject the payments to Niche to the performance of obligations not to manufacture perindopril by Matrix (see paragraph (543)).[1984] It is evident that the source of the active ingredient which could also market the product had to be eliminated to prevent any entry sooner or later (see paragraph (622)). The documents cited at paragraphs (543) and (622) show that it would be irrational for Servier to settle with Niche without making sure that Matrix will be prevented from importing a product onto the UK market. In any event, the Commission has demonstrated that the settlement agreement covered the product co-developed by Niche and Matrix and that it was with this product that these companies were potential competitors of Servier. As to the absence of EU presence, the Commission notes that Matrix had acquired two companies based in the EU a few months following the settlement (see paragraph (649)). Although these companies are alleged by Matrix to have been primarily distribution businesses,[1985] these acquisitions show that Matrix could have looked for (and enter into a relationship with) an EU company looking to develop and commercialise the perindopril product. Hence the possibility to find an alternative EU partner was not as impossible as claimed, in particular if the termination clause of the development agreement between Niche and Matrix is taken into account (see footnote 2032). This clause

1981 Matrix's reply to the Statement of Objections, paragraphs 1.14 and 1.15, ID8835, p.7. A similar argument has been made by Servier in its reply to the Statement of Objections, i.e. that Matrix was an Indian company with no EU presence or experience and would need a partner in the absence of Niche (see paragraph 566, ID10114, p.234). This is however not the way the Commission had assessed potential competition between the parties given that it was unclear whether Niche and Servier would have settled absent Matrix.

1982 See Matrix's reply to Letter of Facts, paragraph 5.13, ID10200, p. 10.

1983 ID8835, p. 7, 19-20 and p. 47, see also Matrix's reply to Letter of Facts, paragraphs 3.2 to 4.2, ID10200, p. 6-7.

1984 Servier notes in its reply to the letter of facts that it did not know whether Matrix had other avenues to the market at the time. It entered into the settlement in preference to placing obligations on Matrix under the settlement with Niche/Unichem which would have been difficult to enforce (ID10289, p.115).

1985 Matrix's reply to the letter of facts, paragraph 5.13, ID10200, p.10.

allowed Matrix to gather certain data from Niche and, however limited this information could be,[1986] this clause would have permitted Matrix not to start the whole project anew.

(1433) As to Servier, it claims that Matrix was not a potential competitor given the multiple problems encountered with the product co-developed with Niche in terms of manufacturing, infringement and regulatory delays rendering entry with this product unlikely.[1987] The same argument having been addressed in the section dealing with potential competition between Niche and Servier, reference is made to section 5.2.1.2.

(1434) Based on the above, the Commission concludes that Matrix (together with Niche/Unichem) was a prominent potential competitor to Servier in the production and supply of perindopril at the time the settlement with Servier was concluded. The elements presented in the above paragraphs indicate that Matrix (together with Niche/Unichem) had the ability and the intention to enter the market within a short period of time and was actively looking for solutions to have a final product ready for commercialisation. The development partners (Niche/Unichem and Matrix) were closely intertwined in their activities to launch a generic perindopril on the market. Hence, Matrix and Niche/Unichem were near to having a viable perindopril product which would have been marketed by Niche and Matrix and/or through distribution partners of Niche in various EU markets after regulatory approvals were received.

5.3.1.3 Terms of the Matrix Settlement Agreement

5.3.1.3.1 An agreement between undertakings

(1435) Matrix and Servier concluded a written, legally enforceable contract with obligations for both parties which, in view of the case law mentioned in section 5.2.1.3.1., clearly qualifies as an agreement. Given that these companies *"offer goods or services on a given market"*, they can be considered as undertakings within the meaning of Article 101 of the Treaty. Hence, the Matrix Settlement Agreement is an agreement between undertakings within the terms of Article 101 of the Treaty.

5.3.1.3.2 Restrictions on competition disabling or hampering Matrix's ability to enter the market in a timely and viable manner

(1436) Niche and Matrix were co-developing generic perindopril for which they appeared confident that it could overcome patent barriers, either by non-infringement or invalidity of the enforced patents.[1988] Before the settlement agreement was concluded, Matrix was free to continue its commercial activities to enter the market in a timely and viable manner, including by pursuing legal actions involving Servier.[1989] The Matrix Settlement Agreement contains two key restrictions of this

1986 See Matrix's reply to the letter of facts, paragraphs 5.5-5.8, ID10200, p. 8-9.

1987 Servier's reply to the Statement of Objections, paragraphs 541-542, 569-570, ID10114, p.225-227 and p. 236.

1988 It should be pointed out that Niche was confident about the litigation on the process patents and had agreed with Matrix under the development agreement that they would produce a non-infringing product (see paragraph (429)). In addition, it can be inferred from an email between Niche and Matrix from August 2004 that both aimed to have a non-infringing process (see paragraph (467)).

1989 Servier claims in its reply to the Statement of Objections (paragraph 556, ID10114, p.231) that the Commission's statement whereby Matrix was free to continue its commercial activities to enter the market is contradicted by the Commission's analysis of the '947 patent as a major obstacle and because of other obstacles to entry. Servier's claim is unfounded – reference is made to section 5.1. indicating that although patents protecting perindopril existed, these did not constitute an insurmountable barrier

ability to compete, namely (i) a non-challenge obligation, and (ii) a non-compete obligation. These restrictions were obtained in exchange for an inducement in the form of a very significant reverse payment from Servier to Matrix.

(1437) The subsequent analysis aims to establish whether the settlement agreement viewed as a whole, can be seen as a restriction of competition by eliminating Matrix as a potential competitor, at least for the periods foreseen in the agreement itself.

5.3.1.3.2.1 The non-challenge obligation

(1438) The non-challenge obligation for Matrix is contained in clause 5.[1990] Matrix agreed to abstain from any invalidity and non-infringement actions against any of the *"Servier Patent Rights"*, namely patents '339, '340, '341, '947, '689 and '948. Clause 5 encompasses all countries in which these patents or corresponding patent rights exist except the United States and relates to Matrix's challenges whether of direct or indirect nature (i.e. through third parties). The non-challenge obligation is a wide one as Matrix was prohibited from seeking any declaration or ruling of non-infringement (clause 5 (iii)) but was allowed to defend itself if Servier were to assert infringement against it.[1991]

(1439) The non-challenge obligation had two main consequences. First, it prevented Matrix from establishing its technology as *de iure* non-infringing technology for the production of perindopril API for the relevant geographic markets. Second, the non-challenge obligation also prevented the possibility of an objective legal review of the validity of Servier's patents, disabling the possible benefit for Matrix and other generic producers in case patents were finally invalidated.

(1440) In sum, the non-challenge obligation granted Servier a 100% certainty that Matrix would not represent a competitive threat through its challenge to Servier's patent position.

5.3.1.3.2.2 The non-compete obligation

(1441) Clause 1 of the Matrix Settlement Agreement stipulates that: *"Matrix shall not, and shall procure that its Affiliates shall not, (i) carry out in relation to Perindopril made using the Process any Restricted Act in any country of the Territory; and/or (ii) manufacture and/or supply Perindopril made using the Process, for use anywhere in the Territory"*.[1992]

(1442) The non-compete obligation prevented Matrix from launching a generic version of perindopril manufactured on the basis of the process developed in cooperation with Niche (including similar processes or any process that would fall within the scope of patents '339, '340 and '341) in the *"Territory"*, i.e. all countries, except the US, in which the three process patents and the '947, '689 and '948 patents (or equivalent patents and patent applications) exist.

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to entry/ a blocking position (see paragraph (1168) and following). Hence Matrix was free, prior to the settlement agreement, to pursue its commercial activities towards a potential entry, a possibility it did not have following the settlement agreement with the product developed with Niche since 2001.

1990 See paragraph (589).

1991 Servier claims that clause 5 (iii) is the natural consequence of the context since the litigation in the UK related to infringement and not to validity (reply to the Statement of Objections, paragraph 577, ID10114, p.238). However, this clause encompassed not only the process patents alleged to be infringed by Servier in the English litigation but also the crystalline form patents. Hence, it was not narrowly tailored but encompassed the non-challenge of all six Servier patents until their expiry.

1992 See paragraph (582).

(1443) Clause 4 of the Settlement Agreement states that, *"Servier recognises that Matrix shall be free to deal in Perindopril made in accordance with the Process*[1993] *without infringing the Patent Rights [the process patents] in a country of the Territory after the Local Expiry Date [date of expiry of the process patents] in that country"*.[1994] Matrix considers that the non-compete obligation extended only until September 2008. However, Servier affirmed that Matrix could not have marketed a product infringing the '947 patent.[1995] Whilst a superficial reading of clause 4 could suggest that Matrix would be able to enter the market as of 2008 (i.e. the date of expiry of the process patents), it appears that Matrix would only be able to manufacture perindopril on the basis of the Matrix process post-2008 if it did not infringe the '947 patent. Hence, no early entry would ensue since the '947 patent would expire in 2021 (unless revoked earlier by other companies as Matrix had committed to refrain from challenging Servier's patents or unless Matrix entered at risk and Servier launched proceedings against which Matrix could defend itself). Therefore, Matrix was restricted from entering before 2008 with *"perindopril made using the process"* and was also restricted from entering thereafter with an alpha product.

(1444) The non-compete obligation was reinforced by Matrix's commitment to *"cancel, terminate or suspend until the relevant Local Expiry Date at the option of Matrix, each and every one of the Matrix Contracts"* by 30 June 2005, and provide a written report to Servier (clause 8).[1996]

(1445) Matrix explained ex post that it did not have any contracts with customers that would market perindopril on the European markets. However, Matrix itself indicated that clause 8 affected its agreement with Niche which *"was likely covered by clauses 7 and 8"*.[1997] Matrix suspended the Product Development Agreement with Niche until expiry of the three process patents and sent a "compliance status" letter to Servier to inform it that it had respected its obligations pursuant to the Settlement Agreement.[1998] Matrix also confirmed to Servier that: *"From 9th of February 2005, Matrix and its Affiliates have not entered into any agreement, arrangements or other undertakings with any third party that are inconsistent with the provisions of this Agreement"*.[1999] Although this clause related to perindopril made using the process (but also a similar one, or one falling within the scope of the patents), Matrix had in fact concluded only two agreements on perindopril (with Niche and Unichem) and the former was suspended pursuant to the terms of the Settlement Agreement. Servier's claim that said agreement between Niche and Matrix could only be suspended, and not necessarily terminated,[2000] does not diminish the importance of such a restriction which led to the suspension of relations between Matrix and Niche four months after the settlement agreement.

1993 This is defined as perindopril made using *"the Process in Suit [=the Matrix process], any process that is substantially similar to the Process in Suit, and any process that if carried out in a country of the wolrd where a Patent Right exists would fall within the scope of such Patent Right"*.

1994 See paragraph (585).

1995 See paragraph (585).

1996 See paragraph (588).

1997 See paragraphs (588) and (641).

1998 See paragraph (631).

1999 See paragraph (631).

2000 Servier's reply to the Statement of Objections, paragraphs 586 and 588, ID10114, p. 240.

(1446) The non-compete obligation was further reinforced by clause 6 of the Matrix Settlement Agreement, in which Matrix agreed *"not [to], and [to] procure that its Affiliates shall not, make any application for Regulatory Approval in any country of the Territory, nor assist any third party to obtain any such Regulatory approval. This undertaking shall apply in respect of a country until the Local Expiry Date in that country of the Territory"*.[2001]

(1447) Clause 6 effectively forbade Matrix from filing an application for regulatory approval before expiry of the process patents. Concretely this means that in such a case the time for the regulatory approval is effectively added to the protection period of Servier, and could cause a delay in entry given the impossibility to file a new application for regulatory approval based on the "Process" before expiry of the process patents.

(1448) To summarise, the non-compete obligation meant that Matrix (together with Niche/Unichem) was unable to commercialise perindopril formulations and/or API based on the process developed with Niche (or a similar one) in the EU until September 2008 (after this date, Matrix was not allowed to enter with an alpha containing product) and was obliged to suspend its cooperation agreement with Niche until the expiry of the process patents.

5.3.1.3.3 Financial consideration for the restriction

(1449) The assessment of the Matrix Settlement Agreement as a restriction of competition by object requires an identification of the value transfers to Servier and/or Matrix. The aim of this assessment is to establish whether there was a net value transfer from Servier to Matrix and to quantify that value transfer with a view to establishing its importance in the agreement.

(1450) This section is divided into three sub-sections. First, the Commission will assess the precise purpose of the net value transfer and what was gained by Servier from this compensation. Second, this section will verify whether the value transferred by Servier was justifiable as remuneration for the costs incurred by Matrix. Third, the significance of the quantum transferred by Servier to Matrix will be assessed.

5.3.1.3.3.1 Assessment of precise purpose of the net value transfer and the value gained by Servier from this compensation

(1451) In the framework of the settlement agreement, Servier agreed to pay to Matrix GBP 11.8 million. The payment was made *"in consideration for the undertakings set out above, and the substantial costs and potential liabilities that may be incurred by Matrix as a consequence of ceasing its programme to develop and manufacture Perindopril made using the Process (...)"* (emphasis added).[2002] In other words, Matrix received GBP 11.8 million for the commitment to respect the "undertakings" contained in the agreement and as compensation for the "costs" and "liabilities" resulting from the conclusion of the agreement. According to the general methodology for the assessment of value transfers as laid out in section 5.1.4.2, the value transfer in the settlement agreement falls into the category of a one-way transfer, where only a payment from Servier to Matrix took place.[2003]

2001 See paragraph (586).

2002 See paragraph (580).

2003 With respect to Servier's argument that this was not a one way-transfer and that Servier has obtained an important legal certainty through the conclusion of the agreement (reply to Statement of Objections,

(1452) The *"undertakings"* in question can only refer to the non-challenge obligation foreseen in clause 5, the non-compete obligation foreseen in clause 1, the commitment by Matrix not to apply for regulatory approval (clause 6) and the termination or suspension of Matrix's contracts in relation to perindopril made using the process (clauses 7 and 8) as confirmed by Matrix.[2004] Save for these provisions, the Matrix Settlement Agreement does not mention any specific goods, rights or services that Matrix would be obliged to provide to Servier.

(1453) As is explicit from the terms of the settlement agreement, Matrix received the payment "*in consideration for the undertakings set out"* in the settlement, as listed above.[2005] Thus, the language in the agreement indicates a clear link which exists between the value transfer and the limitations on entry. To sum up, the purpose of Servier's payment consisted in the inducement[2006] of Matrix to accept the settlement terms and refrain from competing on the perindopril market for a number of years.

(1454) Apart from being consideration for the "undertakings" provided by Matrix, the settlement agreement also stated that the payment was for the *"substantial costs and potential liabilities that may be incurred by Matrix as a consequence of ceasing its programme to develop and manufacture Perindopril…"* (clause 9). Judging by the plain words used in this clause, this quite simply covers costs and liabilities arising as a consequence of the cessation of the perindopril programme, notably cancellation or suspension of customer contracts. However, by its own terms, this clause does not refer to covering the costs already incurred in developing generic perindopril.

(1455) According to Matrix, the notion of *"substantial costs"* likely refers to development costs of the perindopril API over a certain period, costs associated with providing expertise to Niche and its advisors in defence of the patent proceedings brought by Servier and additional costs and management resources associated with further litigation.[2007] As to the notion of *"potential liabilities"*, Matrix explained that it would refer to any liabilities that Matrix may incur towards third parties as a result of cancelling any contracts or arrangements it had entered into relating to perindopril (i.e. Niche, Unichem or third party distributors).[2008]

(1456) Next, it needs to be considered whether Servier gained any marketable value or commercial benefit from compensating Matrix for those costs. The plain answer appears to be that the *"substantial costs and potential liabilities"* incurred by Matrix as a result of the conclusion of the settlement agreement were worthless.

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paragraph 606, ID10114, p. 245), the Commission considers that no marketable value was transferred to Servier by Matrix– in particular, the legal certainty gained was not only an advantage gained by Servier but also by Matrix. In addition, the avoided risks of Servier were also avoided risks of Matrix, and one element that should not be forgotten is that the payment only went in the direction of Matrix.

2004 ID5044, p. 5.

2005 With respect to Servier's argument concerning the nature of the phrase "in consideration of" (see Servier's reply to the Statement of Objections, paragraph 596, ID10114, p. 242), see the Commission's reasoning rebutting this argument in footnote 1871 .

2006 In its reply to the Statement of Objections (paragraph 595, ID10114, p. 242), Servier claims that the Commission defines the value transfer as an "inducement" which suggests that Matrix would have acted differently absent the payment whereas Matrix itself claimed not to have had another option. While it is correct that Matrix claimed it had no other option but to settle, Matrix also admits that it wanted to *"recoup its investment"* (see paragraph (617)). Therefore, absent the payment, Matrix would not have concluded the agreement or would have concluded an agreement on different terms, i.e. it had other options available different from this reverse payment settlement.

2007 ID5044, p. 5.

2008 ID5044, p. 6.

(1457) First, Matrix's costs associated with ceasing the perindopril programme do not represent a separate benefit to Servier.

(1458) Second, the termination or suspension of Matrix's contracts and the commitment not to request any marketing authorisations has no commercial value to Servier, except a reinforcement of Matrix's non-compete obligation for the present and the future.

(1459) The only commercial benefits to Servier foreseen in the Matrix Settlement Agreement and relating to a performance by Matrix are contained in the non-challenge and non-compete obligations (as supplemented by the other undertakings).

(1460) Thus, the costs and liabilities described above were not of any commercial value to Servier and therefore cannot be considered as a legitimate justification for the payment. In light of this, it is concluded that the settlement agreement contained a net value transfer to Matrix for the amount of GBP 11.8 million.

5.3.1.3.3.2 Settlement payment as possible remuneration for settlement specific costs

(1461) For the sake of completeness, the analysis below will show that the net value transfer by far exceeded any "costs" for Matrix stemming from the settlement agreement.

(1462) As noted, according to Matrix, the notion of "substantial costs" essentially covered development costs, costs resulting from providing expertise to Niche during the patent infringement proceedings and additional costs and management resources. Concerning the development costs, Matrix did not submit a precise figure.[2009] However, if comparison is made to other projects to develop perindopril API, the development costs may have reached up to EUR [1 - 4] million,[2010] which is still only a fraction of the payment. As to legal costs, Matrix explained it had not appointed *"its own legal advisors in the EEA for perindopril as Niche took the lead on all issues in the EEA"*.[2011]

(1463) As to the notion of *"potential liabilities"*, it covered, according to Matrix, any liabilities that may be incurred by Matrix towards third parties as a result of cancelling any contracts or arrangements in relation to the purchase of perindopril intermediates or supply of perindopril API or services contracted to third parties. It can be inferred from submissions, however, that there were no such liabilities. Matrix had not contracted with any customers in the EU and *"was not in a position to licence the dossier to customers"*.[2012] Even in case Matrix were to share the liabilities stemming from contracts concluded between Niche and its customers, as Servier claims,[2013] then that amount shall be deduced from the amount assessed in section 5.2.1.3.3.2. for Niche's potential liabilities. In any event, contrary to the Niche/Unichem settlement agreement where it was indicated that Niche had concluded 14 contracts for the EU,[2014] there was no such clause in the Matrix

2009 ID1452, p. 17.

2010 Development costs of Krka which comprised not only the development of the API, but also of the perindopril formulations. See paragraph (920). Hence Servier's claim in its reply to the Statement of Objections (paragraph 598, ID10114, p.243) that Krka's development took less time and that therefore Matrix may have incurred more costs than Krka does not hold, since Matrix was sharing the costs of the project with Niche.

2011 ID1452, p. 18.

2012 See paragraph (641).

2013 Servier's reply to the Statement of Objections, paragraph 599, ID10114, p. 243.

2014 See ID0119, p.140. Niche's and Servier's arguments in their respective replies to the letter of facts (see ID10220, p.36 and ID10289, p.116) are insufficient to disprove the fact that Servier was only aware of

settlement agreement and it can be assumed that the payment made to Matrix did not include liabilities for such termination/suspension of contracts (and of which Servier was not aware). The only potential liability could have therefore resulted from the suspension by Matrix of its agreement with Niche relating to the development of generic perindopril and its agreement with Unichem for the manufacture of perindopril tablets (the latter agreement does not seem to have been formally terminated).[2015] Yet, Niche and Unichem also concluded a settlement simultaneously with Matrix, and this liability was immaterial.

(1464) The parties have not given any explanation for how they calculated the sum of GBP 11.8 million. Given that the Matrix Settlement Agreement was negotiated alongside the Niche/Unichem Settlement Agreement and that Matrix and Niche/Unichem were cooperation partners hoping to share profits, the appropriate conclusion is that this sum was negotiated by the parties as an amount to compensate Matrix for the profits that it would have earned if it had entered the market. Therefore, no deduction from the net value transfer described in the previous subsection is made by the Commission given that Servier did not receive any marketable value in return.

5.3.1.3.3.3 Assessment of quantum

(1465) It is central to the assessment of the Matrix Settlement Agreement that the amount of the net value transfer was very significant and induced Matrix to conclude the agreement. The Commission finds it instructive to compare the sums of money transferred by Servier to Matrix with the levels of profits which were contemporaneously expected by each of the parties in the alternative scenario of generic market entry.

(1466) Matrix received from Servier a one-off payment of GBP 11.8 million in exchange for settling the (potential) dispute and refraining from entry into the market for perindopril. Before the settlement, Matrix had planned to enter the EU market in co-operation with its UK partner, Niche. Taking into account the 50:50 profit sharing arrangement agreed between Niche/Unichem and Matrix, the earlier assessment (see section 5.2.1.3.3.3.) regarding the quantum of the monies paid by Servier under the settlement with Niche/Unichem applies *mutatis mutandis* to the parallel settlement between Servier and Matrix. Based on the same line of argumentation as used in the analysis of the settlement between Servier and Niche/Unichem, the Commission holds that both Servier and Matrix were better off in agreeing the settlement than in the alternative scenario of generic entry and resulting competition.

5.3.1.3.3.4 Conclusion on the financial consideration

(1467) In the light of the above, it is concluded that the settlement agreement contained a net value transfer in the amount of GBP 11.8 million without any value transferred in return to Servier. As indicated, the purpose of the transfer was clearly linked to Matrix's limitations on entry, and represented a rent sharing arrangement between Servier and Matrix in return for the obligations limiting Matrix's ability and incentives to compete.

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perindopril contracts concluded by Niche. It still paid Niche and Matrix exactly the same amount in the settlement agreement.

[2015] ID5044, p. 6. See also paragraph (641).

5.3.1.4 The parties' intentions

(1468) The intention of the parties can be an additional indication of the object of a given agreement. A description of respectively Matrix's and Servier's intentions will be given in the following paragraphs.

5.3.1.4.1 Matrix's intentions

(1469) There was no litigation between Servier and Matrix in February 2005. As noted, Matrix had a co-development agreement with Niche aiming at bringing perindopril on the market. Matrix was meant to supply the API, whereas Niche was responsible for completing the marketing authorisation dossier. According to Matrix's submissions, it was contacted on the eve of the settlement with Niche and urgently travelled from India for discussions. It did not have time to consult a lawyer and signed the settlement agreement after reviewing it for "*less than one hour*".[2016] The attractive premium received by Matrix was certainly a stimulus for the quick settlement of a potential patent dispute between the parties (the warning letter was sent by Servier on 7 February and the settlement was concluded on 8 February).

(1470) In addition, the report on the due diligence prepared for Mylan's acquisition of shares indicates that Matrix has received "*compensation*" and that it is "*not allowed to manufacture and sell the specific product over the remaining term of the contract*".[2017] This statement describes the main elements of the deal as those allowing for compensation in return for staying out of the market. Matrix claims that significant weight is placed on the due diligence report and that it is unclear why this document is considered relevant since Mylan was not a party to the settlement agreement and was not privy to the facts prevailing at the time. Matrix states that, in any event, the summary provides nothing more than what is set out in the actual agreement other than the word "compensation".[2018] However, this document was drafted *in tempore non suspecto* and even a third party's reading (Mylan's auditors) of the agreement reached a similar conclusion to that of the Commission: Matrix was not allowed to enter the market and received compensation stemming from a *"favourable settlement"*.

(1471) Moreover, Matrix has submitted that *"the only commercially rational option [at the time of the settlement] was to mitigate the exposure [Matrix] faced by recouping its investment in the project by means of the settlement"*.[2019] Thus Matrix wanted to recoup its investment and receive a substantial payment instead of striving to compete and finding a commercial partner other than Niche/Unichem for the commercialisation of perindopril in the EU if the latter concluded an agreement with Servier. According to Matrix, the Commission has no evidentiary basis for this conclusion – the fact that Matrix considered this to be its only option does not evidence any anticompetitive intention in itself.[2020] However, this submission shows that absent the recoupment of the investment, Matrix would not have concluded the settlement or would have concluded it on different terms Also, Matrix agreed to share proceeds from the patent settlements with Servier on an equal footing with

2016 See paragraph (576).

2017 ID5383.

2018 Reply to Statement of Objections, paragraph 4.45, ID8835, p. 58. Servier also wonders how the Commission can establish intentions on the basis of a third party document post-dating the settlement agreement (Servier's reply to the Statement of Objections, paragraph 615, ID10114, p. 247).

2019 See paragraph (617).

2020 Reply to Statement of Objections, paragraph 4.46, ID8835, p. 58-59.

Niche.[2021] This suggests that Matrix has given up on competing with Servier in return for a substantial cash payment.

5.3.1.4.2 Servier's intentions

(1472) As Matrix and Niche had a co-development arrangement, Servier's intentions to enter into a settlement agreement with either party was driven by similar motives. Therefore, Servier's intentions to enter into an agreement with Niche/Unichem also apply in Matrix's case (see section 5.2.1.4.2), with the caveat that only potential litigation was settled between Matrix and Servier.

(1473) Moreover, although Servier was litigating with Niche, Servier knew that Matrix was the ultimate producer of the API as a possible source of effective generic entry. Servier explained *ex post* that its interest in negotiating with Matrix stemmed from the fact that it could prevent Matrix's DMF being licensed to third parties as this could have led to new violation of Servier's patent rights.[2022] In fact, as Matrix and Niche were co-developing perindopril the generic threat posed could only entirely be put to an end once Servier also settled with Matrix. Otherwise, Matrix may have looked for another company to pursue the co-development of generic perindopril. In its reply to the Statement of Objections, Servier reiterated that its intention was to avoid any further violations of its patents and any litigation which could have led to an unfavourable decision against its "*produit phare*", perindopril.[2023]

(1474) Finally, Servier's internal document "*Coversyl: defense against generics*" (by [employee name of Servier]*, who also negotiated and signed the agreement for Servier) confirms beyond doubt that Servier considered patent settlements to form a part of that (successful) strategy. The section entitled "*Did it work?*" refers explicitly to the Niche/Unichem and Matrix settlements.[2024]

5.3.1.5 Conclusion - the Matrix Settlement Agreement restricts competition by object

(1475) In summary, the Matrix Settlement Agreement is an agreement between undertakings whereby Matrix limited its ability to compete through non-challenge and non-compete obligations. In exchange for these commitments, Matrix received a payment of GBP 11.8 million, a substantial sum of money which served as an inducement to refrain from competing on the perindopril market.

(1476) Thus, Matrix, whose joint perindopril project with Niche/Unichem represented the most imminent challenge to Servier's patent position, was effectively eliminated as a source of competitive threat, both as a potential direct supplier of generic perindopril (formulations or API), or as a source of supplies for other generic companies. Matrix was equally removed as a co-operation partner for Niche/Unichem, who settled with Servier on the same day as Matrix. These restrictions extended at least over a period of 3 ½ years, i.e. until expiry of the process patents in September 2008 and possibly until the expiry of the '947 patent in 2021.

(1477) As explained in the general assessment section 5.1, patent settlement agreements can properly be based on an assessment of e.g. (i) the validity of the patent(s) at issue, and/or (ii) the strength of the infringement case, without objections being made from a competition law perspective. However, it is a blatant violation of Article 101(1) of

2021 See paragraph (577).
2022 See paragraph (622).
2023 Servier's reply to the Statement of Objections, paragraph 610, ID10114, p. 246.
2024 See paragraph (111).

the Treaty for one competitor to pay another competitor to stay out of a market since every operator should determine independently the policy which it intends to adopt on the market.[2025]

(1478) In the present case, the Commission's view based on the evidence described in this section is that the payment of a significant amount of money is the central and essential consideration for the conclusion of the agreement. If such a reverse payment were not deemed necessary to reach the same negotiating outcome, it is reasonable to assume that Servier would behave as any profit maximising economic operator and not pay out such a significant amount of cash. By the same token, Matrix would have thus either insisted on more favourable settlement terms allowing for earlier market entry or could have engaged in litigation and could have become an actual competitor with its generic perindopril.[2026]

(1479) Both parties to the settlement, Servier and Matrix, were better off in agreeing the settlement than in the alternative scenario of generic entry and resulting competition. It is also evident that the mutually beneficial arrangement was only possible at the expense of the perindopril consumers who as a consequence were required to continue paying higher prices than in the scenario of competitive entry. In economic terms, the Matrix settlement must be considered as a classic rent sharing agreement by which the interests of the counterparties are aligned.

(1480) Finally, at the time of conclusion of the settlement agreement, both parties' intentions were clear as evidenced by a number of facts assessed above (section 5.3.1.4). First, the generic company decided to forego the competitive commercial incentives in exchange for a significant inducement. Second, Servier had to settle with Matrix if it wanted to eliminate the generic threat posed by the cooperation of Niche/Unichem and Matrix.[2027]

(1481) Given the above assessment, the Matrix Settlement Agreement should be considered as a restriction of competition by object. The Commission refers to sections 5.1 (and in particular to paragraph (1112)) and 5.3.1 for its considerations on the appreciable degree to which the agreement in question restricted competition and to section 5.3.2.6 for its analysis of effect on trade between Member States. The analysis in those sections shows that for a restriction by object that may affect trade between Member States, the Commission does not have to prove an appreciable restriction of

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2025 Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643,paragraph 34.

2026 Matrix claims that the Commission fails to address from a factual perspective that entry and litigation were likely given that Matrix was not a potential competitor and given the costs, risks and uncertainty for Matrix in engaging in such litigation (Matrix's reply to the Statement of Objections, paragraph 5.8, ID8835, p. 62). However, it suffices to say that the Commission has proved that Matrix was a potential competitor given its ability and intention to enter the market within a short period of time (see section 5.3.1.2). The Commission does not deny that engaging in litigation is a source of risk and uncertainty but such course of action was a possibility that Matrix could have made use of if it wanted to pursue the project in which it had invested significant time and resources.

2027 Servier claims in its reply to the Statement of Objections that the Commission attempts to imply that Servier forced Matrix to conclude the settlement whereas it was Matrix which joined the negotiations in London following an invitation from Niche (paragraphs 535 and 540, ID10114, p. 223 and 225). However, it is irrelevant for the Commission who started the negotiations as the final outcome of the negotiations was the conclusion of an agreement between the two parties. In addition, Servier itself states that it had an interest in settling with Matrix to prevent the latter's DMF being licensed to third parties (see paragraph (622)). Servier cannot therefore pretend that the conclusion of the settlement agreement is mainly a consequence of Matrix coming to London after having been invited by Niche.

competition, but that in any case the Matrix Settlement Agreement did restrict competition to an appreciable degree.

5.3.2 The Matrix Settlement Agreement is a reverse payment settlement which restricts competition by effect under Article 101(1) of the Treaty

(1482) The previous section concluded that the Matrix Settlement Agreement was a restriction of competition by its very nature. Although in these circumstances, and according to the case law, it is unnecessary to analyse the effects of the agreement, the Commission will nonetheless, for the sake of completeness, show in the present section that the agreement was also likely to cause restrictive effects on competition between Servier and Matrix and on competition between Servier and other generic companies to which perindopril would have been supplied by Niche based on a MA licence. For the general framework for assessment of restrictive effects, reference is made to section 5.1.7 above.

(1483) To determine if the Matrix Settlement Agreement was likely to entail restrictive effects on competition, the following elements need to be considered: (i) Servier's market position, (ii) whether Matrix was a potential competitor of the originator company, (iii) the content of the agreement (significant reverse payment changes the incentives of the generic party to accept the exclusive clauses of the agreement), and (iv) competition that would have existed in the absence of the agreement. The latter point will focus on the competitive behaviour that Matrix would have been likely to engage in, absent the agreement, and on the other relevant sources of competition to Servier thereby demonstrating the importance of Matrix as a competitive threat to Servier.

(1484) The findings of this "effects analysis" are limited to the perindopril formulations markets where Servier has been, in the preceding analysis, found to hold significant market power (i.e. France, the Netherlands, Poland and the UK). For points (i) to (iii), the analysis in this section will rely on the preceding conclusions of the present Decision. Thus, the present section will focus in more detail on point (iv).

5.3.2.1 Servier's competitive position

(1485) In the framework of the dominance assessment under the standards of Article 102 of the Treaty, it was established that Servier held a dominant position on the final perindopril product market and on the upstream perindopril API technology market (see sections 6.5.2 and 7.3). According to the Horizontal Guidelines, these findings are directly transposable to the assessment of market power under Article 101(1) of the Treaty.[2028]

(1486) In the context of the Matrix Settlement Agreement, Servier had an interest in protecting its significant market power, as there had been no launch of generic perindopril and therefore its supra-competitive rents were intact. This also afforded the means to protect its market power: continued inflow of rents in the absence of price competition from generic companies provided the "deep pocket" to Servier from which it was able to finance rent sharing with generic companies in return for their withdrawal from competition.

[2028] *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, OJ C 11, 14/01/2011, point 42.

5.3.2.2 Matrix was a prominent potential competitor of Servier

(1487) Based on the facts in section 4.3.1 and according to the assessment in section 5.3.1.2, the Commission has concluded that Matrix was a prominent potential competitor to Servier on the EU markets for perindopril at the time the settlement with Servier was concluded.

(1488) In fact, the efforts and investments made by Matrix since the beginning of the perindopril project (together with Niche) show the intentions of the company to enter the EU perindopril markets. More importantly, Matrix would have been able to enter the market within a short time if it was not for the settlement agreement.

5.3.2.3 Content of the Matrix Settlement Agreement

(1489) The terms of the settlement agreement with Servier have already been described in detail in section 5.3.1.3. Therefore a reference is made to the said section where it was concluded that, against a significant payment, Matrix accepted contractual limitations which disabled or hampered Matrix's ability and incentives to enter the EU markets in a timely and viable manner and restricted competition by object.

5.3.2.4 Competition that would have existed in the absence of the restrictive agreement and the importance of Matrix in view of the remaining competition

(1490) This section will examine the competition that would have existed in the absence of the restrictive provisions of the Matrix Settlement Agreement. The section will focus on the competitive behaviour that Matrix would have been likely to engage in, absent the agreement, and on the other relevant sources of competition to Servier thereby demonstrating the importance of Matrix as a competitive threat to Servier.

(1491) In the absence of the restrictive provisions of the Matrix Settlement Agreement, Matrix would have remained a competitive threat as a potential generic entrant with perindopril in the UK and in other markets. The following points are important in this regard.

(1492) First, in the absence of the non-challenge obligation, Matrix would represent a potential litigation threat to Servier. Although Matrix and Servier were not in litigation in any national courts in the EU, Matrix was actively assisting Niche in the proceedings before the English court which took place between June 2004 and February 2005. Moreover, on 7 February 2005, Servier wrote a letter to Matrix claiming that Matrix was infringing Servier's patents and threatening to commence infringement proceedings.[2029] In the absence of the settlement agreement, it was likely that Servier would indeed have initiated such proceedings against Matrix because it clearly perceived Matrix as a competitive threat to its position through the product developed with Niche. Matrix could have also initiated litigation, a possibility of which it was deprived.[2030]

(1493) Secondly, in the absence of the non-compete obligation, Matrix would have remained a threat due to its advanced development of perindopril. Absent the

[2029] See paragraph (571).

[2030] In this respect, Servier's argument as to the absence of any proof that Matrix would as of itself engage in litigation in the EU (see Servier's reply to the Statement of Objections, paragraph 633, ID10114, p. 252) is dismissed. Absent the agreement, Matrix could decide to clear the way with regards to Servier's patents if it decided to pursue the perindopril project with a partner other than Niche/Unichem, or could also engage a litigation on the '947 together with its partner Niche, had it not settled with Servier.

agreement, Matrix would have retained the competitive ability and incentives to pursue commercial strategies independently of Servier, taking into account the patent situation. Matrix also admitted that it did not, at any point, consider abandoning its research and development efforts for perindopril erbumine API prior to the settlement with Servier.[2031] On the assumption that Niche/Unichem settled with Servier, and Matrix did not, the Commission considers that Matrix would likely have found an alternative partner for the API it was developing and would have been a serious threat to Servier's perindopril position.[2032] Matrix could easily have found a partner amongst the different generic companies seeking to enter the perindopril market.[2033] Given the scarcity of API sources, it is likely that those companies would have attempted to enter into an arrangement with Matrix because it was a source of viable perindopril API.[2034]

(1494) In addition, if Matrix had not settled with Servier, it is reasonable to assume that it would have continued to assist companies with regulatory processes in different Member States. Indeed, Servier accused Matrix in October 2005 of continuing to assist companies in this regard. Matrix denied this, pointing out that it could not provide such assistance under the settlement agreement and that, even if those companies were to get approval, Matrix would not provide them with API.[2035] It is reasonable to assume that, in the absence of those restrictions on its behaviour, Matrix would have provided assistance to those companies in order to bring perindopril to the market.

(1495) Therefore, absent the agreement and its restrictive provisions, Matrix would have remained a prominent potential competitor to Servier through its advanced product development and its support to Niche in the infringement proceedings before the English courts, if that litigation had continued. Even in the case of a settlement between Niche and Servier, Matrix would have remained a competitive threat.[2036] In its reply to the Statement of Objections, Servier claims that the Matrix Settlement Agreement had no appreciable effects on competition given that Matrix was not a

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2031 ID2579, p. 7. See also paragraphs (625)-(627) which show that Matrix was in principle willing to continue the development of perindopril but could not do so due to the need to comply with the settlement agreement.

2032 This is contested by Matrix (reply to Statement of Objections, ID8835, p. 7 and 53, paragraphs 1.14 and 4.28 respectively) which states that finding another marketing partner would not be a viable option (see also paragraph (615) of this decision) – finding such partner would have been difficult and entering into such partnership would not ensure a timely route to market (delay of 12 to 48 months) and would have created considerable risk and exposure to damages. The Commission reiterates that it was likely that Matrix would have found an alternative partner and would continue to exert competitive pressure on Servier given the scarcity of other perindopril API sources at the time of the settlement agreement. In addition clause 15 of the development agreement between Niche and Matrix provides that *"should the agreement be terminated for any reason, a period of […]* will be given to allow both companies to obtain an MRP Licence, plus a Licence in any EU country"* (ID1709, p. 42). This meant that it may have taken Matrix an even shorter time than claimed to enter. Finally, there was also the very likely hypothesis of Niche not entering into an agreement with Servier absent a settlement concluded in parallel between Servier and Matrix.

2033 Teva was certainly aware that Matrix was Niche's API supplier (see ID0346, p. 39) and had already had contacts with Niche before the settlement agreement in order to discuss the licensing of perindopril (see paragraphs (451)-(452)).

2034 See section 4.2.3.

2035 See section 4.3.1.2.2.

2036 Matrix argues that if Niche settled, Matrix would simply have to walk away and no entry would take place (Matrix's reply to the Statement of Objections, paragraph 1.28, ID8835, p.10). This is however unlikely for the reasons explained above (see paragraph (1493)).

competitive threat, its product was not advanced, it was unlikely that Matrix would enter at risk and no consequences would arise from withdrawal from the beta patent opposition. In addition, Servier claims that the Commission has not proven that restrictive effects were reasonably likely in every Member State of the EU.[2037] With respect to the latter point, it suffices to say that the agreement with Matrix was global (US excepted). Given that the restrictions applied to all Member States, Matrix was blocked from entering in the whole EU as a result of the settlement agreement and could not exert any competitive pressure on Servier with its development of generic perindopril.

(1496) Given the removal of a potential source of generic competition to Servier, the subsisting market structure at the time of the conclusion of the agreement will be examined, in particular by identifying other relevant sources of competition and whether they could be perceived as capable of sufficiently constraining Servier to offset the likely effects of the agreement. The analysis will focus on generic competition which was by far the most important source of constraint on Servier's prices and volumes for perindopril.[2038]

(1497) In June 2005, discussions between Krka and Ivax refer to the fact that *"Krka feel there is a strong likelihood that Servier will attempt to buyout all API manufacturers (I have not advised them of our source except to say it is not Matrix, who were bought out with Niche)"*.[2039]

(1498) It was important for Servier to remove the API manufacturers who are the source of the active ingredient necessary for the final product. Hence, Matrix's removal was of importance for Servier in order to block any perindopril API manufacturer from reaching the market.

(1499) As indicated in section 5.1.7.3, there was no generic perindopril on the market at the time the agreement was concluded and no effective entry took place until May 2009, with only a few exceptions such as the UK and the Netherlands. A few companies had tried or were trying to develop a viable API (see section 7.3.3.1). After acquisitions of [company name]*'s and Azad's perindopril API technologies by Servier, there were no further generic companies except Niche/Unichem, together with Matrix, which could have entered the market in the short term.

(1500) In addition, and as stated in paragraph (1245), in early 2005 there was only Niche which was engaged in litigation with Servier before a national court. Although Matrix was not directly taking patent related measures, it provided assistance to Niche in the English proceedings with Servier the subject-matter of which was Matrix's process for production of perindopril. It can thus be considered as having taken patent-related measures to launch its product.

(1501) The close generic competitors to the settling parties were limited to Teva, Apotex, Krka and Lupin. While Servier had already expected the first generic entry, in all likelihood by Niche/Unichem and Matrix, to occur by 2005,[2040] the first unsuccessful attempt by Apotex only followed in the second half of 2006, while Teva, Krka and Lupin respectively concluded settlement agreements with Servier.

2037 Servier's reply to the Statement of Objections, sections 7.3.2 and 7.3.3., ID10114, p. 250-256.

2038 See section 6.5.1.2.6.

2039 See paragraph (414).

2040 ID0105, p. 184 - 186.

(1502) Thus, other relevant sources of competition at the time of conclusion of the settlement agreement between Matrix and Servier had not reached a sufficiently advanced stage of development of the perindopril product. In addition, generic companies were possibly aware of the risk that similar agreements could be concluded by Servier to remove further imminent generic threats.

5.3.2.5 Conclusion – the Matrix Settlement Agreement was likely to entail restrictive effects for competition

(1503) The above analysis establishes that Servier held significant market power in the market for perindopril formulations and the upstream market for perindopril API technology, in which Matrix was active as a potential competitor. As the incumbent facing no price related constraints, and thus charging supra-competitive prices, Servier had the commercial interest and the financial means to offer significant inducements for close potential competitors to withdraw from competition. Thus, by inducing Matrix with a payment of GBP 11.8 million to accept the restrictive terms of the Settlement Agreement, Servier effectively removed Matrix from competition on perindopril. Matrix was no longer able to introduce patent challenges against Servier as a key avenue for viable generic entry, and was also not able to enter at risk had it decided to proceed in this way.

(1504) The Matrix Settlement Agreement thus reduced competition between the parties to the agreement. Matrix could no longer compete with Servier the way it would have in the absence of the agreement with its existing development. The agreement also affected competition between Servier and other generic companies as Matrix was the source of perindopril API for the generic companies with whom Niche had contracted.

(1505) In the period of conclusion of the Matrix Settlement Agreement, the agreement's likely effects on competition were appreciable, as Matrix was an important, and one of the first, sources of competition to Servier's perindopril. It was likely ready to launch perindopril (together with Niche) within a short time after concluding the settlement agreement and thus to also supply other generic operators. Moreover, Niche/Unichem and Matrix did maintain a time lead over all other generic challengers. In addition, there was considerable uncertainty as to whether the remaining sources would subsequently also reach an agreement with, or be otherwise blocked by Servier. The removal of Matrix thus likely affected the overall competitive structure concerning perindopril.

(1506) On the basis of the foregoing considerations, the Commission finds that the Matrix Settlement Agreement was such as to appreciably restrict potential competition among Servier and generic companies and barred "*real concrete possibilities*" for Servier and Matrix to compete among themselves or "*for a new competitor to penetrate the relevant market and compete with the undertakings already established*".[2041] By removing the possibility of launch at risk with Niche's/Matrix's product and the possibility of a patent challenge by Matrix, the Matrix Settlement Agreement appreciably increased the likelihood that Servier's significant market power would remain uncontested for a longer period of time and that consumers would forego a significant reduction of prices that would ensue from timely and effective generic entry.

[2041] Joined Judgments of 15 September 1998, *European Night Services and Others v Commission*, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198, paragraph 137.

5.3.2.6 Effects on trade within the meaning of Article 101(1) of the Treaty

(1507) Article 101(1) of the Treaty only applies to agreements and concerted practices "*which may affect trade between Member States*". This criterion has three basic elements.[2042]

(1508) First, "*trade between Member States*" must be affected. The concept of trade covers all forms of economic activity including establishment. According to settled case law[2043] an agreement that has an impact on the competitive structure in more than one Member State is by its very nature capable of affecting trade between Member States. Trade between Member States may be affected also in cases where the relevant market is national.[2044]

(1509) Second, it is sufficient that the practice "may" affect trade, i.e. that it is sufficiently probable that the practices are capable, based on an objective assessment (as well as subjective elements, if any), of having an effect on the patterns of trade, or on the competitive structure.

(1510) Third, the effect on trade of the agreement must be appreciable. This element requires that the effect on trade between Member States must not be insignificant and it is assessed primarily with reference to the position of the undertaking(s) on the market for the products concerned.

(1511) By discontinuing Matrix's efforts to viably enter the market, either on its own or through a cooperation partner, the economic activities in which Matrix was engaging in several Member States were affected. The suspension of the development agreement between Matrix and Niche had an effect both on the structure of the market (removal of an advanced perindopril development project) as well as on trade as some of Niche's customers which had obtained marketing authorisation after the conclusion of the Settlement Agreements could not be supplied with the product. The example of the significant price decrease following the annulment of the '947 patent in the UK illustrates the actual and potential effect on the competitive structure in the Member States (see paragraph (2529)).

(1512) By removing Matrix as a potential competitor to Servier across the EU, the Matrix Settlement Agreement actually or at least potentially, affected trade between Member States. In view of the magnitude of perindopril sales in the Member States concerned the actual or potential impact on trade can be said to be appreciable.[2045]

5.3.3 Conclusion – the Matrix Settlement Agreement restricts competition within the meaning of Article 101(1) of the Treaty

(1513) The above analysis has demonstrated that the Matrix Settlement Agreement consisted of a payment by Servier to Matrix for withdrawal as a close potential competitor from the market which had as its object to restrict competition. Matrix discontinued all activities needed for a viable and timely generic entry, which would

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2042 *Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81–96, point 18.

2043 Joined Judgment of 8 October 1996, *Compagnie maritime belge transports and Others v Commission*, T-24/93, T-25/93, T-26/93 and T-28/93, ECR, EU:T:1996:139, paragraph 203; Joined Judgment in *Commercial Solvents v Commission*, 7/73 and 6/73, EU:C:1974:18, paragraph 32

2044 *Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81–96, points 19-22.

2045 See paragraph (2129).

challenge Servier's market position, and in return received a significant payment, which effectively amounts to rent sharing. The Matrix Settlement Agreement thus constitutes a restriction of competition by object in terms of Article 101(1) of the Treaty which was also likely to produce restrictive effects on competition.

(1514) The parties' claims under Article 101(3) of the Treaty are analysed in section 5.7.

5.4 Assessment of the Teva Settlement Agreement

(1515) The present section sets out the assessment of the Settlement and Exclusive Purchasing Agreement concluded between Servier and Teva on 13 June 2006, as subsequently amended and implemented (the "Teva Settlement Agreement" or the "Settlement Agreement"),[2046] pursuant to Article 101 of the Treaty.

(1516) Under the Teva Settlement Agreement, Teva agreed to refrain from selling any perindopril (erbumine) not supplied by Servier in the UK[2047] and from challenging Servier's patents, in return for the payment by Servier of GBP 5 million. In addition, Teva agreed to purchase perindopril for distribution in the UK exclusively from Servier from 1 August 2006, and for a period of three years. Liquidated damages were agreed in case of non-supply by Servier of its perindopril product to Teva. In this respect, Teva waived its right to terminate the Settlement Agreement in case of non-supply by Servier. In return for the actual non-supply during 11 months, Teva received compensation of GBP 5.5 million from Servier. This led to an aggregated payment of GBP 10.5 million from Servier to Teva.

(1517) The analysis that follows will look at the terms of the agreement and the manner in which it was implemented by the parties. This is important as the settlement gave Servier the possibility not to supply Teva on the initially foreseen distribution day and Servier made use of this possibility. Consequently, Teva could not terminate the agreement with Servier and was bound by the non-compete obligation, which in turn led to the payment of liquidated damages.

(1518) Hence, in a first step, the assessment of the Teva Settlement Agreement as a restriction by object under Article 101(1) of the Treaty is carried out. Secondly, and even though it is not necessary to examine the effects of an agreement when it is established that its object is to restrict competition, for the sake of completeness, an analysis of the Teva Settlement Agreement as a restriction by effect is undertaken.[2048]

5.4.1 The Teva Settlement Agreement is a reverse payment settlement which restricts competition by object under Article 101(1) of the Treaty

(1519) In the following sections, the Commission will, first, describe the specific legal and economic context of the Teva Settlement Agreement. Second, it will be established that Teva and Servier were potential competitors at the time of their settlement

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2046 The Settlement and Exclusive Purchasing Agreement concluded between Servier and Teva is a single contract containing the provisions governing the settlement of the dispute and the provisions relating to the distribution of Servier's perindopril by Teva in the UK. It was first amended on 23 February 2007 in order to introduce conditions under which Teva could eventually enter the market. The second amendment was signed on 1 August 2008 in order to change the floor price of perindopril purchased by Teva.

2047 See section 7.4.1.3.2.2. for the exact scope of this obligation.

2048 Judgment in *T-Mobile Netherlands and others*, C-8/08, EU:C:2009:343, paragraphs 28-30; and Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 55.

agreement. Third, the restrictive terms of the settlement agreement will be assessed. Fourth, the parties' intentions will be described. Fifth, a concluding section will summarise the assessment of the Teva Settlement Agreement as a restriction by object.

5.4.1.1 Introduction

(1520) The general economic and legal context for the assessment of reverse payment patent settlements has been set out in section 5.1. In addition, the general factual background to the Teva Settlement Agreement has been set out in section 4.3.2.

(1521) Based on the facts, the specific legal and economic context of the Teva Settlement Agreement can be summarised as follows.

(1522) At the time the agreement was concluded, there was no generic perindopril on the market. Servier had concluded agreements with [company name]*, Azad, Niche/Unichem and Matrix in relation to perindopril which led to their exit from the market for perindopril API and/or formulations.[2049] In the UK, Servier held the monopoly of sales of perindopril since 1990 and this was its most important product at the time of the conclusion of the settlement agreement with Teva. In 2006, Servier's reported EBIT profit amounted to EUR [eight digit figure][2050] from the sales of perindopril in the UK alone. Thus, every month without generic entry represented on average EUR [seven digit figure] of profits for Servier during 2006.

(1523) Teva's product development was in an advanced stage. Together with Hetero (for the API) and Alembic (for the final formulations), Teva had developed and manufactured perindopril. Although it was delayed in its MA process, at the time of the conclusion of the Settlement Agreement, Teva expected to receive a MA from the UK authorities within a short period of time and launch its generic perindopril or the generic perindopril that would have been supplied by Krka (see section 4.3.2.2.2).

(1524) In terms of patent disputes between the parties, Teva was one of the ten opponents of Servier's '947 patent before the EPO. In June 2005, it considered that it had in this respect (alongside Krka) better arguments than other opponents.[2051] Moreover, Teva (at the time, Ivax) had, in August 2005, requested the revocation of the '947 patent before the High Court. These UK proceedings were stayed pending the outcome of the EPO opposition procedure. During the stay, Servier undertook not to commence proceedings against Teva if the latter were to launch a generic perindopril in the alpha form provided that it did not infringe any other Servier patents.[2052] As to the process patents, Servier and Teva had since January 2006 exchanged a series of drafts discussing the (non)infringing nature of the product that Teva would import (based on the Hetero API).[2053] Servier claimed that Teva's product would infringe Servier's process patents (in particular the '339 patent) which Teva denied (and considered in addition invalidity arguments against that patent). Instead of launching

2049 See section 5.1.7.3.
2050 ID1158.
2051 See paragraph (680).
2052 See paragraphs (681) to (685).
2053 See paragraphs (703) and (709).

legal proceedings on this matter, Teva and Servier concluded the Settlement Agreement.[2054]

(1525) The Opposition Division was expected to hand down its ruling at the end of July 2006. According to Servier, it was necessary for it to find a generic partner with whom to launch in the UK in case the market turned generic.[2055] In particular, in case of annulment of the patent or a launch at risk without Servier being granted an injunction, its agreement with Teva would have allowed the latter to launch a generic perindopril earlier than with its own generic version.[2056] However, it was unclear during the negotiation of the settlement agreement how many other companies would be able to enter the UK market after the EPO Opposition Division's decision or even earlier. Moreover, Teva's launch as an authorised generic was described by Servier as a *"nuclear weapon"*[2057] and the fact that Teva was in the hands of Servier shows that supply would only take place if Servier's other generic threats could not be stopped from entering. As Servier's puts it, it needed a partner for generic products with whom to enter the generic market but only *"if necessary"*.[2058]

(1526) Therefore, Teva was amongst the main generic threats (if not the main generic threat) in the UK to Servier's most important product at the time. As will be shown below, Servier agreed with Teva that the latter would not enter the market and compete with Servier's perindopril. Crucially, this was done in return for the transfer of a very significant inducement from Servier to Teva. This kind of arrangement is a restriction of competition by its very nature.

5.4.1.2 Teva and Servier as actual or potential competitors

(1527) In order to determine whether Article 101(1) of the Treaty can apply to the Teva Settlement Agreement, it needs to be assessed whether Teva and Servier were actual or potential competitors. In this context, it needs to be underlined that a potential competitor does not have to have a readily marketable product as long as the company is able to enter within a "short period of time".[2059]

(1528) At the time of the conclusion of the Teva Settlement Agreement, Teva had not yet received a MA and had not launched generic perindopril on the UK market. However, the Commission considers that Teva was a potential competitor to Servier for the following reasons.

2054 According to Teva, a number of documents show that it faced an imminent risk of injunction and infringement liability had it not concluded the settlement agreement (reply to Statement of Objections, paragraphs 214-220, ID8495, p. 50-52). The threat of an injunction by Servier is acknowledged by the Commission (e.g. at paragraphs (678), (706) and (709)). However, the chances of success of this injunction cannot be predicted – for example, a document from May 2006 shows that Teva internally considered that an injunction against Krka will almost certainly be granted *"but possibly not with [Teva's product]"* (see paragraph (693)). In addition, Servier submits that Teva's disclosure of its process description to Servier was part of their efforts to clear the way with respect to the process patents (reply to Statement of Objections, paragraphs 864-865, ID10114, p. 311). Teva was also looking for evidence that entry at risk will not cause a collapse in the prices of the originator. This shows that Teva was taking steps to avoid an injunction. See further details in paragraph (1638).

2055 See reply to the Statement of Objections, paragraphs 669-671, ID10114, p. 261-262.

2056 Reply to the Statement of Objections, paragraph 675, ID10114, p. 263.

2057 See paragraph (759).

2058 Reply to the Statement of Objections, section 8.1.2.1, ID10114, p. 261.

2059 A period of up to three years according to point 10 of the Horizontal Guidelines. See also Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 189 where the General Court stated that the potential entry must "*take place with sufficient speed to form a constraint*".

(1529) In order to produce perindopril, Teva/Ivax had concluded on 24 September 2003 an agreement with Hetero for the supply of perindopril API and a manufacturing and supply agreement was signed on 22 December 2005 with Alembic for the final product. In a situation where there was a general lack of API sources (in view of the patent situation and Servier's conduct vis-à-vis other sources of API (see paragraphs (671) and (672)), Ivax/Teva secured an exclusive supply relationship with Hetero as the source of API. On this basis, it was able to develop perindopril formulations with Alembic. Consequently, at the time of signing the settlement agreement, Teva had already a stock of perindopril bound for the UK which was valued at over GBP 1 million. This stock had to be destroyed pursuant to the terms of the agreement. In submissions to the Commission, Teva points to the fact that its own product […]*. Nonetheless, nothing at the time of the agreement suggests that Teva's product was […]* and that it would have refrained from launching its own product for this reason. Teva was actually actively pursuing the grant of a MA in the UK and had only one "hurdle" to clear before a possible grant.

(1530) In its reply to the Statement of Objections, Teva claims that it confronted […]* on which the Commission remained silent.[2060] Teva refers to […]* and the shorter shelf life of the product (21 to 24 months, depending on dosage, instead of three years).[2061] Servier also argues in its reply to the Statement of Objections that Teva had a product […]* which was […]* due to its packaging.[2062] However, Servier submits no explicit evidence on […]* dating from the time of the agreement or earlier to illustrate its argument. As to the shelf life of the product, Teva cannot claim that a shelf life of 24 months was […]*, as Servier's perindopril erbumine had the same shelf life and Teva itself considered in 2008 that this was "perfectly acceptable" for pharmaceutical products.[2063] As regards the size of the box or the fact that foil pouches instead of blisters had to be used, the reason for this type of packaging appears to be […]* of the product in conditions of humidity.[2064] Teva does not explain how this would have affected […]* its product in the UK. It refers, first, to the minutes of a project team meeting of Ivax on 19 May 2005 where this issue is mentioned. However, when read in its context, the minutes of this meeting do not reveal any […]* on the part of Ivax as to […]* the product for this reason.[2065] The witness statement of [employee name of Teva]* submitted together with Teva's reply to the Statement of Objections only refers to […]*.[2066] It should also be noted that in January 2006 when Teva merged with Ivax, Teva decided to retain the perindopril project started by Ivax, which included […]*, and scrapped its own project which was at the time based on API from Lupin (which did not have the same […]*). It is reasonable to conclude from

2060 Reply to the Statement of Objections, paragraphs 150-155, ID8495, p. 39-40. See also Teva's reply to the letter of facts, ID10250, p. 15-16.

2061 Reply to the Statement of Objections, paragraph 148, ID8495, p. 38.

2062 ID10114, paragraphs 702-706, p. 272-273. See also Servier's reply to the letter of facts, ID10289, p. 134.

2063 See paragraph (226). The 2 mg dosage had a shorter shelf-life of 12 months.

2064 Servier had different types of blisters, depending on the climatic region. In fact, Servier cited […]* of its perindopril erbumine as one of the reasons for switching to the arginine salt, as […]* in humid conditions meant that Servier could use the same packaging for all climatic conditions, including tropical regions (see paragraph (227)).

2065 See Teva's reply to the Statement of Objections, paragraph 151, ID8495, p. 39 referring to ID0345, p. 29.

2066 Annex 1 to Teva's reply to the Statement of Objections, paragraph 14, ID8496, p. 3.

this that Teva did not see insurmountable difficulties affecting […]* the product.[2067] Teva also seems to point to the impact that its packaging had on its production cost.[2068] Nonetheless, the evidence from around the time of the negotiation of the agreement with Servier does not suggest that Teva ever considered abandoning the launch of its product […]*. Quite to the contrary, Teva was making estimates on entry scenarios at the end of April 2006 (see paragraph (687)) and was still considering the different options of entry in May 2006, including its own product (see paragraph (689)). Further, the Commission considers that the correspondence addressed to Hetero in October 2007 (cited by Teva at paragraph 152 of its reply to the Statement of Objections)[2069] has to be read with caution. At this time, Teva was being supplied by Servier, and the exclusive purchasing obligation to which Teva had agreed (all of Teva's requirements of perindopril erbumine had to be sourced from Servier) in the settlement agreement does not appear to have been disclosed to Hetero. Moreover, the fact that Teva did not launch its product in the UK after the termination of the agreement with Servier in 2009,[2070] is not sufficient to call into question the above conclusion. The market situation had changed compared to the 2006-2007 period. The '947 patent had been annulled and many generics had entered the market. The price of perindopril had gone down considerably. It is possible that the Krka product may have been seen as more advantageous for the UK in that situation (and Teva did not explain the reasons behind this decision), but this does not show that the Hetero product would not have been viable at the time the agreement with Servier was concluded. In addition, Teva also markets the Hetero product in other Member States.[2071] Based on the above, Teva had at the time of the agreement a real and concrete possibility of entering the market with the Hetero product. Teva had estimated that its entry would be profitable if it entered with that product, even if one or more competitors were already on the market. Teva had manufactured stock to be ready for launch, and never thought of abandoning its own project.

(1531) As to the MA process, Teva argues that it faced major delays in obtaining a MA, in particular due to Servier's active lobbying and that the significance of these delays were not properly acknowledged by the Commission. It states that the MHRA had raised bioequivalence concerns and Teva (while negotiating with Servier) had no reasonable expectation of receiving approval before the end of 2006.[2072] Servier argues that Teva had difficulties obtaining a MA and that these regulatory delays made it impossible to predict when and if Teva would ultimately be able to enter the

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2067 The witness statement of [employee name of Teva]* refers in general to the need to secure a "*preferred supplier status*" (Annex 1 to Teva's reply to the Statement of Objections, paragraph 7, ID8496, p. 2). It should be noted, in this regard, that Servier explained in the reply to the Statement of Objections that Teva was at the time of the agreement, the leader in the UK market for generics, with significant resources, experience and good reputation (Servier's reply to the Statement of Objections, paragraph 671, ID10114, p. 261-262).

2068 Teva's reply to the Statement of Objections, paragraph 153, ID8495, p .39.

2069 ID0350, p. 1055.

2070 Teva's reply to the Statement of Objections, paragraph 155, ID8495, p.40. Teva nonetheless continued working with Hetero for other member states.

2071 See paragraph (820).

2072 Reply to Statement of Objections, paragraphs 158, 163-181, ID8495, p. 40 and f. See also Teva's reply to the letter of facts, paragraphs 17-19, ID10250, p. 5 reiterating Teva's claim that MHRA approval in or after September 2006 would not have permitted entry by Teva within the first wave of generic competition and that the regulatory delays were a key factor in its decision to enter into the settlement agreement.

market. Servier also argues that the Commission was biased and incorrect in the description of Teva's regulatory situation.[2073] However, as can be seen from paragraphs (674) and (675), the Commission has acknowledged the regulatory difficulties faced by Teva at the time. Teva cannot speak of major delays in the MA process even if Teva's experiencing delays could have had an impact on it being first to launch (in case other companies entered). However, the sales and profits estimates it had made at the end of April 2006 based on different scenarios (no competitor, one competitor, more than one competitor) show that Teva had taken into account the possibility that it will not be the first generic entrant and had not given up on marketing its product for this reason.[2074] The fact that the regulatory approval process was delayed in comparison with the initially set target date does not mean that Teva was not a potential competitor. As stated by the General Court, "[*t*]*he mere fact it takes longer than planned to enter the market does not mean that such entry will not take place*".[2075] In addition, Teva's claim that it did not expect to receive its MA by the end of 2006 at the earliest, is not supported by the contemporaneous documents relied on by Teva.[2076] These documents, in particular a document from 8 May 2006, mention a timeline of seven weeks to four months which would lead to a grant date in early September 2006 at the latest. Hence, at the time of the agreement, the MA process was delayed but it was still expected within a "short period of time" (according to the case law and Guidelines cited in footnote 2059).

(1532) Furthermore, Teva was in advanced negotiations with Krka as a potential supplier of the final product for distribution in the UK. Contemporaneous documents suggest that the product supplied by Krka did not have […]* as Teva's own product.[2077] Towards mid-May 2006 an agreement with Krka (who had received MA for the UK in May 2006) was still seen by Teva as an *"excellent option"*[2078] although concerns existed regarding its process.[2079] There were also discussions about entering the market with the Krka product in other Member States where Krka was considered as the only alternative.[2080] Although there were concerns over the possible infringement of the '340 patent by Krka, Servier cannot claim that there was a *"major risk of infringement"*.[2081] Teva argues that it decided to abandon Krka's offer as it was convinced that had it entered the market with this product it would have faced considerable infringement risk and would have had to bear the risk of liability.[2082]

2073 Reply to the Statement of Objections, paragraphs 691-699, ID10114, p. 268-272.

2074 See paragraph (687)

2075 See judgment of 3 April 2003, *BaByliss v Commission*, T-114/02, ECR, EU:T:2003:100, paragraph 102.

2076 Reply to Statement of Objections, paragraphs 170-177, ID8495, p. 42-45.

2077 See paragraph (670).

2078 See paragraph (695).

2079 See paragraph (693) also cited in Teva's reply to the letter of facts, paragraph 47, ID10250, p.10.

2080 See paragraph (695).

2081 See reply to the Statement of Objections, paragraph 711, ID10114, p. 274-275 (see also Servier's reply to the letter of facts according to which there was a genuine risk of infringement, not only a "possibility", which was so significant as for Teva to discontinue the negotiations with Krka. Servier also explains that Krka was aware of the infringement risks (ID10289, p. 127-131). However, the fact that Servier may have claimed infringement does in no way mean that the product was actually infringing. In addition, even if an injunction had been granted against Teva based on Krka's product, this does not mean that Servier would have been able to prove infringement at trial.

2082 Teva's reply to the Statement of Objections, ID8495, p. 60-61. See also Teva's reply to the letter of facts (paragraphs 41-51, ID10250, p. 9-11) mentioning a "serious risk of infringement" and "a major IP risk". As noted in paragraph (1532), uncertainty existed as to the possible infringement of the process patents by Krka. However, this should also be put into the perspective of the parallel negotiations with Servier

However, Teva cannot claim it was convinced that it would face a considerable infringement risk since the situation was summarised (post-settlement agreement) as follows: *"legal advice was that there may be patent issues"* (emphasis added)[2083] which suggests a possibility, not a certainty. Moreover, in communications dating from May 2006 it was stated that *"Krka's product could be found to infringe the '340 process patent"*[2084] and this is clearly not the same as Teva's being convinced of an infringement by Krka. There was therefore uncertainty as to Krka's process and divergent views on the risks of infringement (see paragraphs (693), (694) and (697).[2085]

(1533) Moreover, turning again to Teva's own product, nothing in the contemporaneous documents suggests that market entry by Teva would not have been economically viable. Quite the opposite, bearing in mind the costs reported by Teva regarding the development of perindopril (see paragraph (1598)) and the sales figures and profits which Teva expected to make in the first year after entry according to the contemporaneous documents (see paragraph (687)), its entry onto the market would have been quite profitable, even if not as much as the "*pile of cash*" that Teva would receive under the agreement with Servier.

(1534) In addition, despite submissions during the investigation stating the high risk of patent infringement if it launched its own product, internal documents of Teva predating the agreement with Servier indicate that Teva appeared confident that the Hetero/Alembic product did not infringe Servier's process patents and that the '947 patent was invalid (see paragraphs (677) to (681)).

(1535) In this context, as explained (see paragraph (681)) on 9 August 2005, Ivax (before its merger with Teva) had, as the first patent challenger in the UK, requested the revocation of the '947 patent before the High Court as it believed the '947 patent was anticipated in the prior art, and thus invalid. This action together with the opposition procedure filed at the EPO (for which Teva considered it had better arguments than others[2086]) indicate Teva's belief that the '947 patent was invalid, as it undertook action against it as the first challenger to the '947 patent before a national court.[2087]

– Teva informed Krka on 18 May 2006 of its wish to discontinue their relationship, and sent a letter of intent to Servier the following day.

2083 ID0078, p. 164.

2084 See paragraph (693).

2085 In its reply to the letter of facts, Teva claims that Krka's email stating that *"the UK is clear"* (see paragraph (697)) only reflects the negotiation posture that Krka adopted when Teva indicated that it is not willing to enter into a supply agreement (paragraph 45, ID10250, p. 10). First, Teva's decision to end the negotiations took place the day after this Krka statement and this indicates that it was not intended to persuade Teva to change its mind. In any event, the Commission has recognised that uncertainty existed over the possible infringement risk – Teva considered that it may be successfully injuncted in case it launched Krka's product, but was at the same time making a choice between Servier and Krka depending on the "offer" that would be made by Servier. Hence, these facts should not be forgotten in the overall context of the end of negotiations with Krka and the parallel negotiation of a deal with Servier.

2086 See paragraph (680)

2087 In its reply to the Statement of Objections, Servier claims that the Commission has closed its eyes on the doubts that Teva had in succeeding in the EPO opposition and which led it to choose to conclude an agreement with Servier in the following days (ID10114, p.301, paragraph 824). However, the email correspondence on which Servier bases its claim and where Teva explains its uncertainty about the outcome of the EPO decision has not been cited by the Commission given that it is an email of 11-12 June 2006. At that time Teva had already made its decision to sign with Servier for the UK market.

(1536) Concerning the process patents (on which Servier threatened to sue Teva on the basis of an infringement of at least one claim of the '339 patent during April/May 2006), Teva/Ivax visited Hetero's plant to check that the process was being carried out according to the process description. Teva/Ivax received in November 2005 and February 2006 expert, patent attorney and counsel opinions which concluded that while *"some risk of infringement"* remained with respect to the '339 patent, the Hetero/Alembic product would avoid infringement of Servier's '339, '340 and '341 process patents.[2088] Even in May 2006, only one month before the settlement agreement, Teva stated that it believed its product did not infringe the process patents.[2089] Another comment during the Heads of Agreement's negotiations is even more explicit: *"[Teva] clearly believe that the patents are not infringed and invalid"*.[2090] Given the documents at hand, the witness statement provided by Teva with its reply to the Statement of Objections stating that *"we were not sufficiently confident in the strength of our non-infringement case to rely solely upon it"*[2091] seems inconsistent with the different sets of opinions which analysed in detail the interpretation of the claims of the process patents in comparison with the Hetero process.[2092] In addition, Teva argues that the infringement and injunction risks evolved over time and cites the report of a patent attorney from February 2006 that refers to "some risk of infringement" in relation to the '339 patent.[2093] What Teva forgets to add is that the same opinion concluded that Teva would *"avoid infringement"* according to the construction of claim 1 of the patent and that on the balance of probabilities, a court in the UK would reach the same conclusion.[2094]

(1537) In addition, Teva (Ivax) was the only generic company out of the addressees of the present Decision to which Servier had given an undertaking that it would not sue or seek financial relief other than a reasonable royalty if Teva were to launch a product containing the alpha polymorph provided all other Servier patents were not infringed. This undertaking given by Servier meant that Teva could have launched its product once it had obtained a marketing authorisation although the possible threat of being sued or injuncted on other relevant patents remained.[2095]

The agreement that was actually discussed in this correspondence related to a pan-European agreement with Servier which was ultimately not concluded.

2088 See paragraph(677).

2089 See paragraph (677) and (713).

2090 See paragraph (731).

2091 Witness statement provided by [name of Teva counsel]*, Annex II to Teva's reply to the Statement of Objections, paragraph 22, ID8497, p. 5. The witness statement of [employee name of Teva]* speaks of serious infringement risks, see Annex I to Teva's reply to the Statement of Objections, paragraph 22, ID8496, p. 5.

2092 See paragraph (677)

2093 Teva's reply to the letter of facts, paragraph 25, ID10250, p. 6. See also Servier's reply to the letter of facts which speaks of the existence of a genuine infringement risk with respect to the '339 patent (ID10289, p.122).

2094 See paragraph (677).

2095 In its reply to the Statement of Objections, Teva argues that nothing in Teva's internal documentation suggests that Teva perceived Servier's undertakings as allowing its early entry as the sole generic entrant and that on the contrary, it constantly considered the infringement risk that it anticipated in relation to the '947 patent (ID8495, p. 57, paragraphs 248-249, see also reply to the letter of facts, ID10250, p. 11-12). However, the email cited by Teva (ID0350, p. 1132) appears to relate to countries other than the UK since it speaks of "options" there may be with Servier, i.e. options with respect to countries other than the UK on which negotiations were going on (see also ID0350, p. 1134 which discusses launch in other countries, particularly Germany, the Netherlands and France). Moreover, the '947 was never discussed in the UK between Servier and Teva during 2006 – the dispute related

(1538) Teva appears to argue that lawfully permitted entry would only take place once the '947 patent was annulled.[2096] It is worth recalling in this respect that under the regulatory framework governing the marketing authorisation of medicinal products in the EEA described in section 3.2., the authorities responsible for authorising the placing on the market of medicines cannot take into account the patent status of the originator medicine when deciding on the grant of a MA to a generic company. Thus, once the generic has received a MA, it is legally entitled to market the product, despite the fact that it may subsequently be required, e.g. by a court order, to cease marketing, if it infringes the originator's patent. Teva was far advanced with its application for a MA in the UK at the time of the deal with Servier. Although Teva was experiencing certain delays in the MA procedure, contemporaneous documents speak of only one "hurdle" to clear before the MA was granted (see paragraph (675)).[2097] Accordingly, Teva obtained the MA for its generic perindopril on 12 December 2006,[2098] only a few months after concluding the Teva Settlement Agreement. Teva argues that the Commission inaccurately described it as a prominent potential competitor whereas it had no MA and no prospect of obtaining one in the appropriate timeframe to assess potential competition. Teva further argues that what constitutes a short of period of time to form a constraint on the incumbent depends on the specific facts of the case and that in this case such a period should be limited to a few weeks only (entry by the summer of 2006), as Teva's business decision to enter the market was largely dependent on its ability to be among the first entrants.[2099] The test proposed by Teva cannot be accepted. In light of the circumstances of the case and the case-law referred to in section 5.1 there is no reason to limit the period that is relevant for assessing potential competition to a few weeks only. First, Teva had been making preparations for market entry for the last three years and these entry steps constitute an element showing it was a potential competitor, despite the fact that its MA was delayed. Second, at the time of the agreement, Teva's MA was expected by September 2006, within a period of a few weeks. Although it could not be predicted with certainty ex ante, there was still a real and concrete possibility that Teva could be the first or among the first generic entrants. Although Krka had obtained its MA in May 2006, by June 2006 when the settlement agreement was concluded, Krka had not entered the market. Apotex had not yet received its MA and Teva was aware of the fact that the required bioequivalence data "*could be an issue for all* [companies applying for a MA]".[2100] Thus, there was a possibility that Apotex's MA would also be delayed. Third, Teva received MA in December 2006 and had it not been for the agreement with Servier, Teva would have been lawfully permitted to enter the market and may have been successful in entering provided it was not injuncted. At that time, both Apotex and

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exclusively to the process patents (*"if our differences continue with the process patent […]"*, see paragraph (705)).

2096 Teva's reply to the letter of facts, paragraph 21, ID10250, p.6.

2097 In submissions to the Commission, Teva argues that it suspected that submissions made by Servier to the UK Medicines Agency regarding the evaluation of the equivalence between generic and originator were behind the request by the Agency for further studies which was the cause of the delay. By contrast with Teva, Krka was granted MA in the UK in May 2006 without the same studies.

2098 See paragraph (676).

2099 Reply to the Statement of Objections, paragraphs 45, 404 and 421 in particular, ID8495, p. 15, 88 and 91. Teva also speaks of a period of three months as the relevant time for first-wave entry (reply to Statement of Objections, paragraph 25, ID8495, p. 12).

2100 See Annex 5.1 provided with Teva's reply to the Statement of Objections, ID9298, p.7 disclosing ID0078, p.45.

Krka had been enjoined. Fourth, as regards Teva's arguments on its business decision to enter, it should be pointed out that contemporaneously. Teva made estimates for entry based on different scenarios (no competitor, one competitor, multiple competitors) showing that Teva considered that its entry strategy would still be viable even if more than one competitor was on the market. Therefore, such a "commercially sensible" test cannot be upheld based on the legal and economic context prevailing at the time of the agreement. There had been no launch of generic perindopril at the time of the agreement (June 2006). Even if the '947 patent had been annulled and other generic companies entered the market Teva could have been in the first wave of entrants (see paragraph (1613)). Moreover, Teva is an "important generic company" with significant resources and experience on the UK market and was the only generic company to be on the top ten of pharmaceutical companies in the UK according to Servier.[2101] Hence, Teva had the required ability to see its perindopril project through to the end, even if there were delays.

(1539) Teva also argues that a generic company that faces a realistic and bona-fide prospect of infringement cannot be construed as a potential competitor.[2102] This argument is dealt with in the general assessment of potential competition which indicates that the presence of patents is not an obstacle to the finding of potential competition (see paragraphs (1164) and (1168)).

(1540) Based on the above, the Commission concludes that Teva was a prominent potential competitor of Servier in the production and supply of generic perindopril on the UK market at the time the Settlement Agreement was concluded.[2103] The elements presented in the above paragraphs indicate that Teva had the ability and the intention to enter the market within a short period of time and was actively exploiting the possibilities to enter, either with its own product (the Hetero/Alembic product) or with the product that would have been supplied by Krka. Servier's claim that Teva was unable, *de jure* and *de facto*, to enter the perindopril market with its own product is clearly unfounded.[2104] Teva's entry was not a mere hypothesis in May-June 2006 as evidenced by the several points made above. Quite to the contrary, Teva was taking measures aiming at entry within a short time notwithstanding the delays that did not allow it to enter immediately and compete with Servier.

2101 Servier's reply to the Statement of Objections, paragraph 671, ID10114, p.261-262.

2102 Teva's reply to the Statement of Objections, paragraph 405, ID8495, p.89.

2103 The Commission cannot accept Teva's claim that the agreement with Servier should be seen as a vertical agreement between a supplier and a distributor because Teva's relationship with Servier was not a horizontal one. According to Teva, the agreement did not have the object to restrict competition but was intended to enable Teva to enter the market in a commercially relevant timeframe (see Teva's reply to Statement of Objections, paragraphs 469-472, ID8495, p. 100-101). The agreement was concluded in the context of a patent dispute between Servier and Teva. The upfront payment, together with the payment of liquidated damages by Servier in case of non-supply were part of an inducement designed to keep Teva out of the perindopril market. As established in this section, Teva was a potential competitor and according to Servier, a leader on the UK generics market which expected to capture 40% of the market shortly upon entry (Servier's reply to the Statement of Objections, paragraph 671, ID10114, p. 262). The existence of a supply relationship between Servier and Teva is not sufficient to turn the agreement into a vertical agreement (see also Vertical Restraints Guidelines on this point). Servier explained, and as discussed below, that the purpose of the supply relationship was also to enable Servier to participate in the generics market through the sales made by Teva, if the '947 patent was annulled and other generics entered the market, as Servier expected Teva to capture the majority of the sales. As regards whether the agreement enabled Teva to enter the market early, see below.

2104 See reply to the Statement of Objections, paragraph 836, ID10114, p. 304.

5.4.1.3 Terms of the Teva Settlement Agreement

5.4.1.3.1 An agreement between undertakings

(1541) Teva and Servier concluded a written legally enforceable contract with obligations for both parties which, in view of the case law mentioned in section 5.2.1.3.1, clearly qualifies as an agreement. Given that these companies offer goods or services on a given market, they can be considered as undertakings within the meaning of Article 101 of the Treaty. Hence, the Teva Settlement Agreement is an agreement between undertakings within the terms of Article 101 of the Treaty.

5.4.1.3.2 Restrictions on competition disabling or hampering Teva's ability to enter the market in a timely and viable manner

(1542) Before the settlement agreement was concluded, Teva was free to continue its commercial activities to enter the market in a timely and viable manner. The Settlement Agreement contains two key restrictions of this ability to compete, namely (i) a non-challenge obligation, and (ii) a non-compete obligation (the latter going beyond the scope of Servier's patents). These restrictions were obtained in exchange for an inducement in the form of a very significant reverse payment from Servier to Teva.

(1543) The subsequent analysis aims to establish whether the Teva Settlement Agreement, viewed as a whole, can be seen as a restriction of competition by eliminating Teva as a potential competitor for the period foreseen in the agreement itself.

5.4.1.3.2.1 The non-challenge obligation

(1544) The non-challenge obligation whereby Teva committed not to *"revoke, challenge or otherwise invalidate"* the '947 or the '339, '340 and '341 patents for the duration of the agreement,[2105] is contained in clause 2.4 of the settlement agreement.[2106] It relates to Teva's obligation not to challenge these patents in the UK whether directly or indirectly (i.e. through third parties).[2107]

(1545) In fact, Teva (at that time Ivax) had already launched proceedings in the UK contesting the validity of the '947 patent, but these proceedings had been stayed in October 2005 following an application made by Servier. Teva agreed to the stay in exchange for a number of undertakings given by Servier, most notably an undertaking not to injunct Teva if the latter were to enter the UK market with a product infringing the '947 patent during the period of the stay.[2108] As the Teva Settlement Agreement was concluded within this period, Teva could enter the market without fear of being sued by Servier for infringing the '947 patent.[2109] As regards the process patents, it is worth recalling that there was no actual litigation between Servier and Teva but only an exchange of correspondence on this matter.[2110]

2105 The duration of the agreement was set to 3 years with the possibility of a renewal (Clause 8.1).

2106 See paragraph (743).

2107 Teva argues that the fact that the non-challenge clause barred Teva from challenging the process patents' validity is irrelevant as their validity was not questionable (Teva's reply to the Statement of Objections, footnote 277, ID8495, p. 115). However, in case infringement proceedings were initiated against Teva, the latter was considering attacking the validity of the '339 patent (see paragraph (678)) and this has not been contested by Teva in its reply to the letter of facts (see ID10250, p. 14).

2108 See paragraph (682).

2109 Regarding Teva's claim that there was ambiguity on the entity that could benefit from the Servier undertakings and on the duration of these, see paragraph (686).

2110 See paragraph (1524).

(1546) Therefore, the non-challenge clause was clear as regards the process patents and the '947 patent. It is true that with the non-challenge clause Teva did not undertake to withdraw its EPO opposition to the '947 patent. However, this clause had two main consequences. First, it prevented Teva from establishing its technology for the production of perindopril, or the technology of its supplying partner, as *de iure* non-infringing. Second, the non-challenge obligation prevented the possibility of an objective legal review of patent validity in the UK, disabling the possible benefit for Teva and other generic producers of obtaining a final adjudication on the validity of the patent (whether the '947 or the process patents). With respect to the '947 patent in particular, the agreement restricted Teva's ability to directly challenge this patent in the period between the EPO's final determination and the end of the agreement.

(1547) Teva claims that competition rules do not oblige generic companies to devote resources to litigate in the public interest the validity of patents granted by a patent office, such as the EPO. A similar claim has been made by Servier.[2111] Teva states that generic firms are free to abstain from engaging in a costly patent challenge or to withdraw an on-going action, to allow a patent to expire or to complete infringement proceedings. Therefore, Teva concludes that it cannot be assumed that in the absence of the agreement, Teva would have litigated with Servier and invalidated the patents.[2112] In this respect, the decision not to challenge Servier's patents was the result of an agreement made possible by the payment offered by Servier to Teva, and whose object was to shield Servier's patents from the threat of litigation which would have opened up the possibility that such patents may be found invalid or not infringed.[2113]

(1548) To conclude, the non-challenge clause granted Servier complete certainty that Teva would not represent a competitive threat through its challenge to Servier's patent position for the duration of the agreement. Though Teva alleges that its entry onto the market was blocked by Servier's patents, it should be observed that through the non-challenge clause Teva agreed not to challenge those patents and, therefore, not to try to overcome these patents in view of its entry onto the market.

5.4.1.3.2.2 The non-compete obligation

(1549) Clause 2.3 of the Teva Settlement Agreement provides that: *"Until the earliest of termination or expiration of this Agreement or the expiration of all of Servier's […] rights under the Patents, Teva shall not, and shall procure that its Affiliates shall not, in the United Kingdom either make, have made, keep, import, supply or offer to supply or dispose of generic Perindopril manufactured in accordance with the Process Description or infringe the Patents in each case by themselves or in collaboration with any third party"*. From the reference in this clause to the 'Process Description' (the confidential process description sent by Teva's solicitors to Servier's solicitors on 23 March 2006) and the 'Patents'[2114] it can be concluded that Teva would not be prevented from selling in the UK a product manufactured through a

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2111 Servier's reply to the Statement of Objections, paragraph 741, ID10114, p. 281.

2112 See paragraph (795).

2113 See paragraph (1120) citing Judgment in *Windsurfing International / Commission*, C-193/83, EU:C:1986:75, paragraph 92. See also Judgment *T-Mobile Netherlands and others*, C-8/08, EU:C:2009:343, paragraph 43: *"an exchange of information between competitors is tainted with an anticompetitive object if the exchange is capable of removing uncertainties concerning the intended conduct of the participating undertakings"*.

2114 See paragraph (743).

different process to that described on 23 March 2006 provided it was not covered by Servier's alpha crystalline form patent and process patents in force at the time. This would include a product covered by a new salt (e.g. arginine), or a crystalline form of erbumine other than the alpha form, or an amorphous form, provided in each case that the process patents were not infringed.

(1550) Clause 2.3 does not relate to perindopril as an active moiety as such, but to a specific crystalline form (alpha) of a specific salt (tertbutylamine, also known as erbumine) of perindopril. In other words, the non-compete clause relates to the perindopril as developed by Teva at the time of the settlement with Servier. This clause was limited to the duration of the agreement or the expiry of Servier's rights under the patents.

(1551) Thus, under clause 2.3, Teva remained free to develop other forms and salts of perindopril using non-infringing processes. However, its current development (Hetero/Alembic product) had to be put on hold, given its obligation to destroy its stock of perindopril within 30 days from the settlement agreement's conclusion (clause 2.2).[2115]

(1552) The Teva Settlement Agreement included in addition to clause 2.3 an exclusive purchasing obligation whereby Teva had to buy all its requirements of perindopril erbumine for distribution in the UK exclusively from Servier. Clause 3.1 stipulates*: "For the duration of this Agreement, Teva shall purchase all Teva and its Affiliates' requirements for Perindopril for supply or disposal in the United Kingdom exclusively from Servier or Servier's Affiliates"*. This meant that in fact Teva could not in any case supply other products based on perindopril erbumine (whether crystalline or amorphous form, whether manufactured in accordance with the process description or another process), whether manufactured by itself or by a third party (e.g. Krka). In addition, clause 3.8.3 stipulates that, in case of failure to supply the product to Teva, "*Servier shall […] pay Teva the Liquidated Damages in respect of that month and Teva and its Affiliates shall have no other right or remedy (including any right of termination) in respect of any failure by Servier to supply Product to Teva".*[2116] Hence, Teva could not sell its own product and had also no incentive to engage in a development of an alternative perindopril product given the combination of clauses 2.3 and 3.1., which went beyond the scope of Servier's patents. As both clauses affect Teva's ability to compete and/or to choose independently its source of perindopril for supply on the UK market, they should be analysed together as a single non-compete obligation.

(1553) Clause 3.1 had the following consequences. First, in case of non-supply by Servier, Teva was not entitled to sell non-infringing perindopril erbumine whether sourced from a third party, or of Teva's own make. In other words, whatever the patent situation of the possible alternative sources, Teva could only supply Servier's product, or receive compensation for the non-supply (liquidated damages of GBP 500,000 per month of default (see paragraph (744)). The fact that it could sell another salt of perindopril is irrelevant because: (i) no such other salt existed at the time and developing such salt would have taken some time (see section 7) and an internal Teva email shows its belief that at the time all products were in the alpha form, i.e. if the '947 EPO opposition is won by Servier, everyone will be *"shut out of the market"*, see paragraph (2688)); and (ii) there was no incentive for Teva to

[2115] See paragraph (743).

[2116] See paragraph (744).

develop or purchase from a third party a product using another salt (once one was developed) given that it was subject to the exclusive purchasing obligation with respect to perindopril erbumine.

(1554) Second, not only could Teva not substitute Servier's supplies with another source in case Servier defaulted, but Teva could not even terminate the agreement. The only remedy for Teva in the case of non-supply was its entitlement to the liquidated damages.

(1555) This interpretation is further corroborated by the following assessment made by Teva during the negotiating period: "*as long as you are still happy [employee name of Teva]* to be tied exclusively to Servier material for three years with only the 6.3 [clause allowing for termination by Teva if floor price cannot be agreed] get out, even after all the patents have been revoked or expired […]"*.[2117] Although this draft agreement of 31 May 2006 evolved in the following days, it shows that Teva understood the consequences of the liquidated damages provision, the wording of which did not change significantly thereafter. An even earlier legal assessment by Teva raised competition law concerns: it considered that if Teva was as a whole prevented *"from marketing Krka or any other product this could be anti-competitive"*.[2118]

(1556) Third, clause 3.1 would remain in force for the duration of the agreement even if the patents underlying the settlement were no longer in force.

(1557) The combination of the above prompts the conclusion that Teva could for the period of the agreement only source Servier's perindopril erbumine and that in practice Servier retained full discretion as to whether such supplies to Teva could take place: *"For the rest of the year, Servier will supply Perindopril [] or will pay compensation for non-supply"*.[2119] Hence, the combination of clauses 2.3 and 3.1 goes beyond the scope of Servier's patents as it prevented Teva from sourcing perindopril erbumine from any third party regardless of the patent situation of the non-Servier sources of perindopril. Such a non-compete obligation clearly went beyond the material and temporal scope of the claims of the patents to which the dispute between Teva and Servier related and closely corresponds to the statement in the Technology Transfer Guidelines which can be applied here by analogy: *"where it was clear to the parties that no blocking [patent] position exists […] the settlement is merely a means to restrict competition that existed in the absence of the agreement"*.[2120]

(1558) In the present case, Teva submits that the agreement was not restrictive but pro-competitive and that it perceived the settlement agreement as a supply arrangement allowing early market entry.[2121] Thus, even if a non-compete obligation was in place,

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2117 See paragraph (734).

2118 See paragraph (717).

2119 See paragraph (790).

2120 *Commission Notice, Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*, O.J. C 101 (27 April 2004) p. 2-42, point 205.

2121 See also section 5.7.4 In addition, Teva claims that the context of the agreement demonstrates that Teva's primary objective was pro-competitive. Teva was trying to secure a timely market entry and not to obtain money in exchange for a delayed entry (reply to the Statement of Objections, ID8495, p. 107-108). However, given the obligations to which it agreed under the settlement agreement, Teva's claim cannot be accepted. While negotiating, Teva accepted to settle only for *"significant sums"* and was aware before the non-supply by Servier that this was one of the likely scenarios that could take place. In such case, it was satisfied with the liquidated damages and the ensuing profits without any launch of a perindopril product.

no competition problems would arise as at the same time, the agreement allowed Teva to enter the market with an authorised generic product before the expiry (or annulment) of the relevant patent, in particular the '947 patent.[2122] In addition, Teva argues that the terms of the supply agreement were designed to allow effective and timely supply of the products at a reasonable price.[2123] Servier also claims that the agreement was pro-competitive and cites in this respect documents showing that Servier was determined to supply Teva in case of an EPO revocation of the '947 patent or an injunction not granted against third parties, in which case Teva could enter before the expiry or annulment of the '947 patent.[2124]

(1559) While the grant of a non-supply option is contested by Teva,[2125] the facts speak for themselves. Servier had the possibility to "choose" the behaviour it wanted to adopt, i.e. supply or not supply, and this was clear to Teva - documents from June and July 2006 (i.e. before the actual non-supply took place) confirm this point (see in particular paragraphs (735) and (785)). Hence, Servier's decision not to supply was not in breach of the agreement given that the agreement allowed it not to supply Teva and pay damages instead. This meant that from the date of conclusion of the settlement agreement, Teva did not have any incentive to engage in the development of an alternative product given that under the agreement it would be compensated with liquidated damages and would not need to make any effort to sell perindopril.

(1560) Therefore, no early entry option was foreseen by the agreement. As aforesaid, the supply of perindopril was essentially left at Servier's discretion, as Teva did not have a right to any remedies, other than the liquidated damages in case Servier did not supply the product to it. Although the agreement foresaw the 1 August 2006 as the starting date of the distribution, Servier could elect not to supply Teva and to pay the liquidated damages instead *(e.g. "we have a supply agreement starting in August or a GBP 0.5m per month compensation for not supplying"*).[2126] In this case, Teva did not have any right to source perindopril from third party suppliers, even if their perindopril did not infringe Servier's patents, and it could not terminate the agreement either. Thus, Teva could only receive liquidated damages.[2127] In these

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2122 See paragraphs (786) and (794).

2123 Clause 3.4 provided the quantity of products to be supplied on a monthly basis from 1 August 2006 on, with no obligation for Servier to fulfil orders in excess of these quantitates. Clauses 4.1 to 4.5 addressed the logistic and regulatory issues to permit Teva to supply the product under its own name and livery, after a transitional period where Teva would obtain its own marketing authorisation.

2124 Servier's reply to the Statement of Objections, paragraphs 772-777, ID10114, p. 288-290.

2125 Teva's reply to the Statement of Objections, paragraphs 337-353, 375, 522-528, ID8495, p. 76-78, 83, 110-111. See also reply to the letter of facts, ID10250, p. 16-18. While it appears to be the case that Teva was preparing to be supplied on 1 August 2006, this is logical behaviour given that this was one of the available options at hand to Servier. This does not contradict the Commission's statement that no breach was committed by Servier after the EPO Opposition Division's decision - Servier had the possibility of not supplying and Teva had no other remedy but liquidated damages in such case.

2126 See paragraph (735). See also paragraph (785).

2127 See also Servier's reply to the Statement of Objections where it claims that the liquidated damages were not a *"*mere alternative method of performing the contract, but a pre-determined compensation mechanism"* (paragraph 761, ID10114, p. 286). However, it is reasonable to assume that a contract featuring liquidated damages will also contain a termination clause – such clause was expressly excluded in the present case. Therefore, while liquidated damages may be "common place" in English contractual agreements (see Servier's reply to the letter of facts, ID10289, p. 132-133), the explicit exclusion of any right to termination from the present agreement led to Servier having the possibility to either supply or pay damages. Teva did not have any option but to receive liquidated damages in case of non-supply.

circumstances, it cannot be concluded that the agreement provided for an early entry for Teva, as Teva did not have any enforceable right to obtain supplies from Servier and it could not sell its own perindopril or that manufactured by third parties instead. Furthermore, the amendment to the Teva Settlement Agreement makes it plain that Teva will not enter the market while Servier's patents were still in force (see below). Moreover, Teva itself realised that the agreement would result in a *"delay to us [Teva] in entering the market"*.[2128]

(1561) In addition, according to contemporaneous documents Servier internally considered engaging Teva (and another generic company) as authorised generics a key element to defend market shares only in case the '947 was annulled: "*If the judgment is in favour of the generic companies then the following day, Friday 28 July, there will be one or more generic copies of Perindopril freely available in the market. A key element of our strategy has been to supply the generic Perindopril market ourselves through our partners [generic company] and Teva, this product will be known as the 'friendly' generic. Our partners will capture the majority of Perindopril market share"*.[2129] This document makes it plain that the said strategy (market entry by generic company and Teva) would only kick in if the '947 were to be annulled.

(1562) Thus, Teva's argument that the settlement was an early entry agreement cannot be upheld.

(1563) It is noteworthy that the first delivery date had been fixed for the 1 August 2006, i.e. a few days after the date on which the decision of the EPO Opposition Division on the '947 patent was expected (27 July 2006). Servier explained[2130] in this respect: *"*The date of 1 August 2006 was set **by mutual agreement between the parties** to allow them to take into account the decision of the EPO, expected on 27 July 2006. In the event of an EPO decision against Servier, the latter would have supplied Teva to allow it to start marketing the generic effectively as from 1 August 2006. The SEPA [i.e. the Teva Settlement] also provided for a deadline of ten working days for Servier to supply Teva, following which the former would be liable to penalties, which left Servier time to try and obtain an injunction from the British courts in case the EPO confirmed the validity of the patent"* (emphasis added).

(1564) This confirms that the agreement was structured so as to provide mechanisms for the following options: (i) immediate supplies to Teva in case the '947 patent was revoked by the EPO to gain a first mover advantage amongst the generics, or (ii) no supplies to Teva if the '947 was upheld and independent generics (such as Apotex and Krka) were effectively kept off the market.

(1565) An early entry in case the '947 patent was upheld was not amongst these options, which was explicitly confirmed by Servier: *"*Anyone familiar with the pharmaceutical sector naturally knew that, having won the case before the EPO and the UK courts, Servier was obviously not going to ruin its investments by giving rights to third party generic manufacturers through an 'early entry' without compensation and for a long duration"*.[2131]

2128 See paragraph (714).
2129 See paragraph (758).
2130 See paragraph (750).
2131 See paragraph (751).

(1566) This is in line with Servier's internal documents which considered entry with authorised generics as a *"nuclear weapon": "be prepared (registration, production)", "but launch only in case of absolute necessity"*.[2132]

(1567) Moreover, already in the course of the negotiations, Teva was aware of the impact of the liquidated damages provision, on which Servier reportedly insisted (a statement which is refuted by Servier),[2133] especially in view of Teva's own contrasting proposal to be entitled to third party supplies in case of Servier's default.[2134] Therefore, Teva's claim that it had not anticipated Servier's behaviour, i.e. non-supply on 1 August, cannot be upheld[2135] since such behaviour was allowed under the agreement and was one of possible scenarios which could take place. Teva adds that Servier's decision could not be anticipated "with certainty"[2136] – this is not contradicted by the Commission's reasoning in this Decision since Servier had a choice to supply or not – hence the non-supply was an option, yet uncertain, but one which Teva as an experienced company in the pharmaceutical sector must have at least envisaged. As Servier puts: *"*it was natural that Servier would want to give itself the possibility of not supplying Teva in the event of confirmation of its patent"*[2137] and this is something that would have been obvious also to Teva at the very least because of the supply date that was fixed for 1 August 2006, a few days after the EPO's Opposition Division decision (in comparison with the initial request of Teva to be supplied already in June 2006).[2138] In particular, once the actual non-supply was explicitly recognised, Teva stated that it did not *"anticipate marketing this product in the near future"*.[2139] The exclusive purchasing obligation was later evaluated by Teva as follows: "*some elements of the agreement were not ideal from a commercial perspective ie Servier insisted on the option of a compensatory ('Liquidated Damages') payment if they were unable to supply us with actual product*".[2140]

(1568) The implicit "no early entry" arrangement which emerges from the circumstances relating to the negotiation and implementation of the agreement but was not rendered explicit in the Teva Settlement Agreement was however formalised in Amendment N° 1 to the Teva Settlement Agreement, concluded on 23 February 2007. This amendment confirmed the non-supply by Servier and

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2132 See paragraph (759).

2133 See reply to the Statement of Objections, paragraph 760, ID10114, p.286 – *"*Teva wanted to obtain a guarantee from Servier, hence the insertion of the liquidated damages clause in the agreement"*.

2134 In paragraph 354 of its reply to the Statement of Objections, Teva claims that when they were introduced by Servier in the third draft agreement, the liquidated damages were genuinely perceived as a compensation mechanism that provides an effective remedy and specifies Teva's damages claim if Servier were to breach its supply obligation (ID8495, p. 78, see also reply to the letter of facts, ID10250, p. 18). Given this statement, the Commission fails to understand Teva's previous argument that this clause was imposed upon it (see paragraph (733) and that it could not negotiate an alternative proposal due to timing issues and Servier's bargaining power. If this provision was a compensation mechanism (and a standard clause under English law, as alleged by Teva), it is unclear why Teva would need to negotiate an alternative to this proposal and why Servier would allegedly have it imposed on Teva.

2135 ID8495, p. 82.

2136 Teva's reply to the Statement of Objections, paragraph 376-383, ID8495, p. 83-84.

2137 Servier's reply to the Statement of Objections, paragraph 841, ID10114, p. 306.

2138 Annex 1 to Teva's reply to the Statement of Objections (witness statement of [employee name of Teva]*), paragraph 20, ID8496, p. 4.

2139 See paragraph (761).

2140 See paragraph (792).

introduced the concept of "First Distribution Date" before which Teva *"shall have no right to market, sell or distribute the Products"*. The First Distribution Date was defined as the earliest of the following events to occur: (i) date as notified by Servier to Teva, (ii) revocation or expiry of the '947 patent or (iii) independent generic entry by Apotex.[2141] Moreover, Teva signed on 30 May 2007 a declaration whereby it undertook not to supply or offer to supply any perindopril until the lifting of any injunctions ordered in the Apotex proceedings.[2142]

(1569) In accordance with the conditions of Amendment N°1, Teva entered the market in the UK in July 2007, right after the annulment of the '947 patent and the lifting of the injunction against Apotex.[2143]

(1570) All of the above elements present a strong and coherent body of evidence that the exclusive purchasing obligation of the Teva Settlement Agreement was not intended to facilitate Teva's early entry, but, quite the opposite, to control Teva's market behaviour, by ensuring that Teva would not supply perindopril in the UK when this would be detrimental to Servier's interests. At the same time, the agreement made it possible to convert Teva from an important source of competitive pressure into an authorised generic, a tool to confront generics once Servier's patent protection would be lost. This is summarised in Teva's response to the Statement of Objections: *"[after obtaining an injunction against Apotex] Servier no longer had an interest in allowing Teva to enter the market with its product […] as Servier could effectively bar generic entry until the end of the patent litigation […] or the patent expiry date, several years later"*.[2144] In addition, a document from July 2006 envisaging an EU-wide agreement between Servier and Teva draws inspiration from the UK case and lists the main terms, one of which being *"generic perindopril to be provided to Teva in each country* ***at a time decided by Servier****"* (emphasis added).[2145]

(1571) Teva also argues that the exclusive purchasing obligation should be analysed under the Vertical Restraints Guidelines given that Servier's and Teva's agreement was of a vertical nature.[2146] A similar claim has been made by Servier which considers that the exclusive purchasing obligation is not forbidden by the Vertical Restraints Regulation.[2147] As stated previously, the agreement between Teva and Servier (and

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2141 See section 4.3.2.6.3 According to Servier, the Amendment was purely descriptive and reflected the reality of the market following the legal procedures against Apotex and Krka (reply to the Statement of Objections, ID10114, p. 298, paragraph 814). Actually, the Amendment as said above in paragraph (772) is just an explicit confirmation of Teva's non-supply until entry by Apotex or invalidation of the '947 patent.

2142 See paragraph (775).

2143 See paragraphs (776)-(778).

2144 ID8495, p. 85, paragraph 391.

2145 See paragraph (813). Teva claims that this is an internal Servier document not shared with Teva and which does not reflect Teva's perception (reply to the letter of facts, ID10250, p. 18). However, this document enables to make a comparison with the agreement which was signed between Teva and Servier for the UK – that Servier would have the possibility to decide when to start supplying without breaching the agreement but only by paying liquidated damages.

2146 Commission notice of 19 May 2010: *Guidelines on vertical restraints*, OJ C 130, 19.05.2010, p. 1 ("Vertical Restraints Guidelines"); Reply to the Statement of Objections, paragraph 574-575, ID8495, p. 119. See also Teva's reply to the letter of facts, ID10250, p. 19.

2147 Reply to the Statement of Objections, paragraph 749, ID10114, p. 283,. An analysis under the Regulation on vertical restraints was also deemed necessary by Servier in respect of the non-challenge obligation (ID10114, p. 280).

therefore the terms of this agreement) is not analysed under the Vertical Restraints Guidelines for a number of reasons (see footnote 2103).

(1572) Last but not least it is worth noting that the assessment set out by the Commission was shared by the High Court, which had to assess the Teva Settlement Agreement in its judgment of 9 October 2008 in relation to a damages action brought by Apotex against Servier.[2148]

(1573) The court explained, inter alia, its interpretation of the terms of the Teva Settlement Agreement: *"Because the agreement bound [Teva] not to sell perindopril manufactured other than by Servier, but did not bind Servier to supply perindopril to [Teva], it gave Servier the right to exclude [Teva] from the market. Servier obtained this right by agreeing to pay [Teva] £5 million, and further to pay £500,000 per month for each month of non-supply (irrespective of the amount of perindopril that [Teva] would have ordered in that month). Servier was initially preparing to supply [Teva] in anticipation of the revocation of patent 947 on the 27th of July 2006. But then in August 2006 Servier exercised the option not to supply, and continued to do so throughout the period for which the injunction against Apotex was in force. Servier thus paid [Teva] approximately GBP 10 million* ***to keep it out of the market****"* (emphasis added).

(1574) In view of the foregoing, the Commission concludes that the non-compete obligation ensured that Teva could under no circumstances, and regardless of the potential source, sell perindopril in the UK for the duration of the agreement. In case of Servier's failure to supply, Teva was unable to terminate the agreement and/or to sell (possibly non-infringing) own or third party perindopril. Instead, it received a lump sum payment and liquidated damages during the period starting with the conclusion of the Settlement Agreement until the beginning of the actual supply (June 2006 to July 2007).

5.4.1.3.3 Financial or other considerations for the restriction

(1575) The assessment of the Teva Settlement Agreement as a restriction of competition by object requires an identification of the value transfers to Servier and/or Teva. The aim of the assessment is to establish whether there was a net value transfer from Servier to Teva and to quantify that value transfer with a view to establishing its importance.

(1576) This section is divided into three sub-sections. First, the Commission will assess the precise purpose of the net value transfer and what was gained by Servier from this compensation. Second, this section will verify whether the value transferred by Servier was justifiable as remuneration for the costs incurred by Teva. Third, the significance of the quantum transferred by Servier to Teva will be assessed.

5.4.1.3.3.1 Assessment of the precise purpose of the net value transfer and the value gained by Servier from this compensation

(1577) In the framework of the Teva Settlement Agreement, Servier agreed to pay Teva GBP 5 million, as an upfront payment.

(1578) The Teva Settlement Agreement also foresaw, as indicated, that Servier would supply Teva a defined quantity of perindopril formulations to be distributed in the UK under Teva's livery or pay compensation in the form of liquidated damages in

[2148] See paragraph (810).

case of non-supply. Servier opted not to supply Teva on the initially foreseen distribution date and instead paid Teva liquidated damages totalling GBP 5.5 million for the period August 2006 – July 2007.[2149] Servier states that the liquidated damages clause should not be taken into consideration in the assessment of the net value transfer, given that Servier made no choice and the circumstances determined the actual result, i.e. non supply.[2150] This argument cannot be accepted given that the liquidated damages were agreed in advance, in the context of an exclusive purchasing obligation excluding the possibility of terminating the agreement. Hence, in case of non-supply Teva's entry with perindopril was made impossible since the latter was *"in the hands of Servier"*.

(1579) Having regard to the combination of the provisions on exclusive purchasing, liquidated damages and the exclusion of termination rights, the Teva Settlement Agreement - as implemented by Servier and Teva - cannot be understood as unilateral performance by Servier in breach of the agreement, but as exercising an option in accordance with the provisions previously agreed by both parties: "*We [Teva] place orders with them, they [Servier] default and we raise a default invoice"*.[2151] The liquidated damages thus fall squarely within the agreement, and should also be taken into account for the assessment of the net value transfer, the overall payment in the framework of the agreement amounting thus to GBP 10.5 million. According to the general methodology for the assessment of net value transfers as laid out in section 5.1.4.2 , the value transfer falls into the category of a one-way transfer, where only a payment from Servier to Teva took place.

(1580) First, as to the initial payment of GBP 5 million, it was justified in the Teva Settlement Agreement as a "*contribution towards the costs incurred by Teva in preparing to enter into the (Settlement) Agreement*", which also included *"without limitation"* the costs for the "*termination of its existing supply arrangements for the United Kingdom*" (clause 10.1).[2152]

(1581) It is necessary to assess what is meant by *"costs incurred by Teva in preparing to enter into the agreement […]"*.

(1582) As explicitly stated in clause 10.1, Teva's costs refer, at least partly, to the termination of its supply arrangements for the UK. Teva also committed to destroy its existing stock of perindopril (clause 2.2.) intended for sale in the UK, which may have involved some costs encompassed within this clause.[2153]

(1583) Teva claimed[2154] that the amount of GBP 5 million was not based on a precise quantitative evaluation of costs but reflected the outcome of commercial negotiations, based on the parties' perceived bargaining powers and Teva's efforts to achieve the best supply agreement. Contemporaneous evidence shows that during the initial stages of the negotiations Teva had requested GBP [5–10]* million.[2155] Servier was prepared to contribute towards the cost of litigation incurred by Teva and the cost of doing business with Servier but it initially offered the amount of GBP [0–5]* million, seen as unacceptable by Teva.

2149 See, for example, paragraph (810).

2150 Servier's reply to the Statement of Objections, paragraph 787, ID10114, p.292.

2151 See paragraph (782).

2152 See paragraph (747).

2153 See paragraph (743).

2154 See paragraph (794).

2155 See paragraph (711).

(1584) Teva explained[2156] that the lump sum was negotiated in order to compensate, in addition to the litigation costs, the costs of terminating the Hetero/Alembic arrangements and destroying the existing stocks of the products. Teva also argued that the lump sum was a *"premium to ensure the commercial attractiveness of Servier's supply offer versus in particular Krka's offer"*. Teva adds that *"the lump sum payment was negotiated between Teva and Servier as part of a bona-fide commercial arrangement the main objective of which was the supply of the product to Teva. The lump sum was not agreed upon in compensation for the delayed entry"*.[2157]

(1585) The latter statement is somewhat at odds with the contemporaneous considerations of the parties. The letter of intent which preceded the agreement made a clear link between the payment to Teva and its acceptance of the non-compete clause *("in consideration for Teva's […] agreement to desist […] from importing and marketing in the UK generic perindopril manufactured pursuant to the process description […], Servier shall pay to Teva a non refundable one off payment of GBP 5m …"* (see paragraph (724)). This link was later removed and does not appear in the final version of the agreement but is relevant to show that Teva was aware of the link between the payment and the non-compete obligation. In an exchange of emails from May 2006, Teva's Director of Legal Affairs for the UK and Ireland noted that *"as the payment is not linked (in the agreement) to the patent settlement this should be fine from a legal perspective […]"*.[2158] The need to provide a legal coverage for the initial payment is therefore evident. Moreover, when having to decide whether to conclude a deal with Krka or Servier, Teva was explicit: *"best case, we get a product from Krka […]. Next best we get a pile of money from Servier"*.[2159] In addition, in a document from early 2007, Teva commented that "*part of the £5m compensation payment received may relate to a non-compete aspect of the contract, since the contractual terms of the supply agreement prevent Teva launching its own generic product or seeking alternative suppliers in the UK"*.[2160]

(1586) Next, it needs to be considered whether Servier gained any marketable value or commercial benefit from compensating Teva for said costs. The plain answer appears to be that the costs incurred by Teva as a result of preparing to enter into the settlement agreement were worthless for Servier. Teva argues that Servier gained a clear commercial benefit unrelated to Teva being off the market since it avoided litigation costs or possible damages if an injunction was followed by invalidation.[2161] As to avoided litigation costs, reference is made to section 5.7 and to the fact that not only Servier but also Teva avoided litigation costs. As to possible damages, there was no certainty of an injunction being granted on the process patents since Apotex was injuncted on the basis of the '947 patent, which was not an issue for Teva given the Servier undertakings. Servier claims that the important benefit that it gained through the conclusion of the supply agreement is not taken into account by the

2156 See paragraph (796).

2157 This argument has also been made by Teva in its reply to the Statement of Objections, for example at paragraph 599 (ID8495, p.123).

2158 See paragraph (730).

2159 See paragraph (699).

2160 See paragraph (789).

2161 Reply to the Statement of Objections, paragraphs 588-595, ID8495, p. 121-122.

Commission.[2162] The compensation cannot however be considered to have any marketable value or commercial benefit (see below).

(1587) In fact, Servier received no other commercial benefit from the destruction of stock and/or discontinuation of supply arrangements by Teva but for the reinforcement of the non-challenge and non-compete provisions. The destruction of the stock of perindopril in possession of Teva and the rupture of its supply arrangements guaranteed that the generic product would not be put on the market.

(1588) Turning to the liquidated damages, they represent Servier's commitment to pay for the option of not supplying Teva as per the terms of the Settlement Agreement, including Amendment N°1. Therefore the payment of liquidated damages is not a legitimate compensation for the breach of the agreement, but a payment for Teva's non-compete commitment. This is confirmed by the way the negotiations between the parties proceeded on this point. Initially Teva proposed the possibility to be supplied by a third party in case of Servier's failure to supply. Ultimately, and reportedly on Servier's insistence, Teva accepted an absolute purchasing exclusivity even in case of non-supply.[2163] In exchange, the liquidated damages clause was introduced and it led to the payment of GBP 5.5 million by Servier to Teva. This, too, should therefore be considered as a payment for Teva's acceptance of the restrictive provisions.[2164]

(1589) In reply to a Commission request to clarify what value transfers flowed from Teva to Servier, Teva points to the terms of the agreement stipulating the obligation of Servier to supply and the consequent obligation of Teva to purchase perindopril.[2165] However, as stated these obligations were not implemented during the year that followed the conclusion of the agreement. Therefore they did not represent any benefit to Servier for that period of time.

(1590) In particular, Teva was in a position to understand from the negotiation history and the content of the agreement that the transaction did not relate to any performance by Teva transferring marketable value to Servier. Moreover, Teva essentially confirmed ex post that the lump sum payment induced Teva to agree to the Teva Settlement Agreement as opposed to pursuing its perindopril launch project independently from Servier, either through its own perindopril development or through supplies by third parties, in particular Krka (*"premium […] to ensure the commercial attractiveness of Servier's supply offer versus, in particular, Krka's offer").*[2166] In this respect, Servier claims that the payment was not an inducement to conclude an anticompetitive

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2162 Reply to the Statement of Objections, ID10114, p.297-298, paragraphs 810-811.

2163 See paragraph (733).

2164 According to Teva, the liquidated damages were an efficient means of identifying the remedy to which Teva would likely have been entitled in the case of a breach of Servier's supply obligation - they reflected the likely outcome of a UK court ruling had Teva sued Servier for breaching, its obligation to supply, based on Teva's expected gain and should therefore not be taken into account for the net value transfer assessment (reply to the Statement of Objections, ID8495, p. 123-124). First, in Teva's reply to the Statement of Objections, the profits were calculated in comparison with the liquidated damages of GBP 500,000 per month whereas it should have added to this the lump sum payment of GBP 5 million in order to compare what Servier's payments represented vis-à-vis its expected profits. Second, had it not been for the non-termination clause, Teva could have been able to exit the contract and look for supply elsewhere.

2165 Teva's reply to the Commission's RFI of 15 April 2011, ID4556, p. 10.

2166 See paragraph (796).

settlement agreement.[2167] However, it is reasonable to assume that Teva would not have concluded the same agreement or would have concluded it on different terms, had it not been for the lump sum payment. Concretely, it appears from the negotiation history that Teva required a certain amount of compensation before deciding to conclude an agreement with Servier and the importance of the settlement sum is demonstrated in section 5.4.1.3.3.3.

(1591) In the light of the above, it is concluded that the payment from Servier to Teva totalling GBP 10.5 million can be understood as a net value transfer.

5.4.1.3.3.2 Settlement payment as possible remuneration for settlement specific costs

(1592) For the sake of completeness, the below analysis will show that the net value transfer by far exceeded any costs for Teva stemming from the settlement.

(1593) As noted, Teva explains that the lump sum was negotiated in order to compensate in addition to the litigation costs, the costs of terminating the Hetero/Alembic arrangements and destroying the existing stocks of the products. It is noted that such explanations directly contradict other Teva statements which acknowledge, in tempore non suspecto, that the payment was an incentive to "*both cease its plans to launch a generic product in the UK and enter into a supply agreement with Servier*" (emphasis added).[2168]

(1594) It should be noted that no specific amounts have been reported by Teva ex post for the different costs alleged to have been compensated by the lump sum (except possible litigation costs).

(1595) However, it must be borne in mind that Teva continued its arrangements with Alembic and Hetero for the commercialisation of perindopril in other Member States.[2169]

(1596) With regard to the destruction of Teva's perindopril to be sold in the UK, contemporaneous evidence reports[2170] that *"Perindopril that is 'at risk' has a value of GBP [0–2 million]*. This is all product packed in UK packaging. Some of this is held in [company name]* (GBP [0–1 million]*) and some is held by [company name]*, our contract manufacturer in [non-EEA jurisdiction]* (GBP [0–1 million]*)"*. This coincides with the figure reported in a memo[2171] from Teva UK dated 16 January 2007 which informs that after writing off the available stock the resulting net amount stemming from the payment was GBP [0–5]* million: this suggests that writing off stock amounted to GBP [0–5]* million.

(1597) Other costs directly related to the Teva Settlement Agreement are primarily the actual sums submitted by Teva for prior litigation undertaken by Ivax in the UK against Servier's '947 patent.[2172] The costs of less than EUR 100,000 were for external advice.

(1598) It could also be argued that the payment reflects a compensation for Teva's development costs. However, the development costs reported by Teva concerning

2167 Reply to the Statement of Objections, paragraph 784-785, ID10114, p. 292.

2168 See paragraph (788).

2169 See paragraph (820).

2170 See paragraph (783).

2171 See paragraph (782).

2172 See paragraph (797). The cost of Teva's opposition to the '947 patent before the EPO are irrelevant, as the Teva Settlement Agreement did not concern these proceedings.

direct R&D and regulatory expenses incurred between 2003 and 2009 amount in total to some EUR [0.5 – 1.5] million.

(1599) If – to the benefit of Teva– one were to add up Teva's reported incurred costs of stock destruction, litigation and development, the total amount of less than GBP [1.6-2.6] million would represent less than 40% of the initial lump sum and less than a fifth of Servier's total payments to Teva (GBP 10.5 million). However, no deduction from the net value transfer described in the previous subsection is made by the Commission given that Servier did not receive any marketable value in return.

5.4.1.3.3.3 Assessment of quantum

(1600) It is central to the assessment of the Teva Settlement Agreement that the amount of the net value transfer was very significant and induced Teva to conclude the agreement. The quantum of the net value, and its significance to the parties, is assessed below.

(1601) Concerning the magnitude of the payment, Servier stated, according to Teva's contemporaneous minutes of negotiation meetings, that the "*value of settlement depends on the strength of [Teva's] patent case*".[2173] Moreover, Teva's possibility to get supplies from Krka was leveraged by Teva to obtain more "value" from the Teva Settlement Agreement: "*It was the risk of us doing a deal with Krka that accelerated the deal and added more value from Servier's original position with us"*.[2174]

(1602) [Employee name and function with Teva]*, commented that the settlement resulted in *"a good deal as it will bring us the amount of profits that we had set ourselves as a goal for Q1 and the rest of the year in the work plan, despite the uncertainty around our own file"*.[2175] An internal Teva presentation is also revealing on the magnitude of the transfer: *"The profits resulting from settlements are high. […] <u>big lump sum</u> for Perindopril"* (emphasis added).[2176]

(1603) Thus, the Commission finds it instructive to compare the sums of money transferred by Servier to Teva with the levels of profits which were contemporaneously expected by each of the parties in the alternative scenario of generic market entry.

(1604) Regarding Teva, it received from Servier a one-off payment of GBP 5 million and 11 monthly payments of GBP 0.5 million each for settling the dispute and refraining from entering the perindopril market in the UK. Shortly before the settlement, Teva expected to earn in the first year of its market presence an EBIT[2177] profit in the range of GBP [0–5]* million to GBP [5–10]* million depending on three different market scenarios. It also expected that soon after its entry the price of perindopril would substantially decrease which would obviously lead to lower profits in the periods to follow. In an internal email of 28 April 2006, the following scenarios were set out:[2178]

"If we are able to launch in May (ie MA is granted mid to end May) and we take three different assumption sets […].*

Scenario: Sales in Q2 EBIT in Q2

2173 .See paragraph (707).
2174 See paragraph (737).
2175 See paragraph (736).
2176 See paragraph (784).
2177 EBIT refers to "earnings before interest and taxes".
2178 See paragraph (687).

Best	*[5–10]* m*	*[0–5]* m*
Medium	*[0–5]* m*	*[0–5]* m*
Worst	*[0–5]* m*	*[0–5]* m*

The figures for the rest of the year then assume […].*

Scenario	*Sales Full Year*	*EBIT Full Year*
Best	*[10–15]* m*	*[5–10]* m*
Medium	*[5–10]* m*	*[5–10]* m*
Worst	*[5–10]* m*	*[0–5]* m"*

(1605) The Commission notes that the amounts transferred to Teva by Servier (in total GBP 10.5 million) even after discounting for the value of destroyed stocks of the generic product (GBP [0–5]* million)[2179] were well above the EBIT profit of GBP [5–10]* million that Teva expected to make during "EBIT Full Year" under its best scenario. The Commission also notes that the monthly payment of GBP 0.5 million compensating Teva for non-supply by Servier was higher than the monthly EBIT profit that Teva assumed in its projection of profits for the periods after Q2.

(1606) Regarding Servier, in its reply to the Commission's RFI, it reported an EBIT profit of EUR [eight digit figure] (GBP [eight digit figure]) from the sales of perindopril in the UK in 2006.[2180] This figure is equivalent to an average monthly EBIT profit of GBP [seven digit figure] during that year. Taking into account the price discounts expected by Teva and a more than likely loss of considerable quantities to generic entrants, Servier was confronted with the risk of an abrupt drop in its profits generated by perindopril. In this respect, as evidenced by internal contemporaneous documents, Servier had no illusion that *"[t]he uptake of generic perindopril is likely to be rapid and driven by the need for the NHS to contain costs. Payers will endorse the use of cheaper generic ACEi"*.[2181] By entering into the settlement agreement with Teva, Servier sacrificed a fraction of its UK profits in exchange for securing a continuous monthly EBIT of around GBP [seven digit figure] (GBP [seven digit figure] minus the payment of GBP 0.5 million in damages to Teva).

(1607) In view of the foregoing, the Commission considers that both Servier and Teva understood that they were better off in concluding the settlement than in the alternative scenario of generic entry and resulting competition on the UK market.

5.4.1.3.3.4 Conclusion on the financial consideration

(1608) In the light of the above, it is concluded that the settlement agreement involved a net value transfer for the amount of GBP 10.5 million without any value transferred in return to Servier during the investigated period. As indicated, the purpose of the transfer was clearly linked to Teva's limitations on entry, and represented a rent

2179 For the sake of clarity, it is noted that the assessment of quantum was undertaken from the internal perspective of each party and should be distinguished from the assessment of the net value transfer from Servier to Teva. The quantum assessment includes costs that were internalised within the company (e.g. destruction of existing stock).

2180 Based on the data underlying section 6.4.5.3.

2181 ID0360, p. 74.

sharing arrangement between Servier and Teva in return for the obligations limiting Teva's ability and incentives to compete.

5.4.1.4 The parties' intentions

(1609) The intentions of the parties can be an additional indication of the object of a given agreement. A description of, respectively, Teva's and Servier's intentions follows.

5.4.1.4.1 Teva's intentions

(1610) Concerning the purpose of the settlement agreement and the underlying payment, the statement of Teva's Head of Global Accounting in July 2006 is explicit regarding Teva's awareness of the impact of the agreement on Teva's ability and incentives to compete: "*My understanding is that the economic effect of the agreement is that Teva is being paid an amount of GBP 5m in order to both cease its plans to launch a generic product in the UK and enter into a supply agreement with Servier.[…] The GBP 5m should be viewed primarily as an incentive to enter into the contract*" (emphasis added).[2182]

(1611) In addition, during the negotiation of the settlement agreement, Teva made it clear to Servier that *"any settlement will have to be for significant sums"* illustrating that the payment was essential in case both parties agree to settle.[2183]

(1612) Unsurprisingly, and unlike in the letter of intent, the drafters of the Teva Settlement Agreement were careful not to mention a specific link between the payment and the settlement: *"as the payment is not linked (in the agreement) to the patent settlement this should be fine from a legal perspective […]"*.[2184]

(1613) Already in the course of the negotiations, Teva was aware of the implications of the exclusive purchasing obligation, on which Servier reportedly insisted, especially in view of Teva's own contrasting proposal to be entitled to third party supplies in case of Servier's default. Teva also agreed not to have other rights or remedies including the right of termination in case of non-supply. The intention of implementing the agreement in a restrictive way that would prevent Teva from an "early" entry was thus built into the terms of the agreement itself, to which Teva agreed.

(1614) In the days between the EPO Opposition Division decision on 27 July 2006 and 1 August 2006, by when Teva was supposed to receive first supplies of perindopril as per Clause 3.4, Teva was aware that Servier would exercise the non-supply option. On 31 July 2006, Teva internally announced that it was "*not hopeful of any stock arriving in the future*" and that "*Teva [had] no stock of Perindopril and [did] not anticipate marketing this product in the near future*".[2185] In reply to the Statement of Objections, Teva argues that timing of entry was a critical factor in its decision to enter the settlement agreement because of its objective to secure a first mover advantage. Had it not entered the agreement with Servier, it would have lost the first mover advantage.[2186] This argument cannot be accepted. First, as explained in

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2182 See paragraph (788). This email shows that even a person who was not involved in the negotiations understood the contract in the same way as the Commission.

2183 See paragraph (708).

2184 See paragraph (730).

2185 See paragraph (761).

2186 ID8495, p. 12-13, p. 32 and f. (paragraphs 23-31, paragraph 123 and f.)– the claim of a first mover advantage was also developed by Servier in its reply to the Statement of Objections, section 8.1.5.1, ID10114, p. 300-302.

paragraph (1530), the Commission does not accept Teva's argument that the Hetero/Alembic product was only viable if Teva had managed to enter the market as the first generic entrant or in the first wave of entrants. In addition, that the first mover advantage would have been lost was not clear at the time of the agreement. At that time, there was no generic perindopril on the market in the UK. Although Krka had already obtained MA in May 2006, by June Krka had not entered the market and Apotex had not yet received MA. There was thus uncertainty over the timing of any potential entry. There was also the possibility that the EPO will reject the oppositions against the '947 patent, which *"will shut everyone out of the market"* according to Teva's predictions.[2187] In this case, Teva could have secured a first mover advantage, given its advanced regulatory position, its advanced development of perindopril and the globally positive expert opinions on non-infringement of the process patents and the undertaking given by Servier on the '947 patent. There was uncertainty as to the outcome of the expected EPO decision at the time of the Teva Settlement Agreement - had the EPO ruled in favour of the opponents and revoked the patent in July 2006, entry by other generic companies could have taken place and Teva may have lost the possibility to be the first on the market. However, this cannot justify entering into an anticompetitive agreement under which Teva agreed to restrictions on its market entry in return for payments. As explained in the period after the compound patent expires, there is often a "race" between generics to be the first to enter the market and take the competitive advantage that comes with a 'first mover' status.[2188] Such a race (and the risk of losing it) are an expression of the dynamic competition that exists between generics (and with the originator), of which both Servier and Teva were acutely aware, and which was replaced with the certainty of no entry in return for payments. Moreover, Teva may not have been able to take advantage of a first mover status if it entered the market under the agreement with Servier. As explained in paragraph (1618) Servier would only have supplied Teva if the '947 patent was annulled or if another generic entered the market and Servier was unable to obtain an injunction. Thus, by the time Teva entered, another generic would have already entered or such entry may have been imminent. In addition, the agreement restricted the possibilities for Teva to take advantage of a first mover status, as Servier was not obliged to fulfil orders in excess of the quantities specified in clause 3.4 of the agreement. As Lupin observed after learning about the settlement agreement, apparently based on information from within Teva *'the transfer price and the restriction on number of packs they can sell significantly reduces their competitiveness'*.[2189] Thus, had the agreement allowed Teva to enter as the first generic entrant (which was not the case), it is unclear if Teva would have been able to take advantage of the first mover status, as its position vis-à-vis the supply of perindopril was not the same as one in which it had entered the market independently of Servier. Even if the Settlement Agreement provided for increased quantities of product at the beginning of the supply period (clause 3.4), it should be observed that comparing the situation of Teva with that of Apotex (who entered the market at risk in August 2006) Teva will not have been in the same position as Apotex to take advantage of the first mover status.[2190] Thus the settlement agreement replaced the

2187 See paragraph (2688).

2188 See paragraph (1183).

2189 See paragraph (1023).

2190 Thus, Apotex sold GBP 4 million worth of perindopril in the period 28 July to 8 August 2006 before withdrawing due to the injunction granted to Servier (see paragraph (177)). As it was explained in the subsequent damages claim by Apotex against Servier regarding the quantification of the damages

risks of competition with a certainty for Servier of no independent competition from an advanced potential competitor, and ensured, for Teva, that it will draw compensation for ensuring such certainty, without the risks of competition.

(1615) In the period following the settlement agreement which coincided with the conclusion of the Amendment N°1, it seems that Teva was hoping for a settlement between Servier and Apotex as it was cognisant of the fact that the annulment of the '947 patent would open the market to everybody: *"this would be a good result for us (…)? If the settlement keeps other generics off the market in the UK then we keep our present arrangement with Servier"*.[2191] This quote is explicit in relation to Teva's intentions when it concluded the settlement with Servier. It also shows that for Teva receiving payment under the settlement was at least as advantageous an option (if not more) to a competitive scenario.

(1616) In light of the above, it can be concluded that Teva opted for a patent settlement in exchange for a substantial sum of money,[2192] in a situation in which Teva had real and concrete possibilities to enter the market, either with its own product or with the product that could have been supplied by Krka.

5.4.1.4.2 Servier's intentions

(1617) Turning to Servier's intentions, it can be inferred from the following facts that the settlement agreement was designed to restrict competition in exchange for a share of Servier's monopoly rents.

(1618) As mentioned already, Servier effectively exercised its option not to supply Teva as of August 2006, when it was also granted an interim injunction against Apotex. Teva in turn exercised its rights under the provisions on Liquidated Damages. The following excerpt from Teva's internal communications shows that Servier's intention to prevent generic erosion with the way the Teva Settlement Agreement was structured was successful:

"In our Q306 memorandum on review we commented that part of the £5m compensation payment received may relate to a non-compete aspect of the contract, since the contractual terms of the supply agreement prevent Teva launching its own generic product or seeking alternative suppliers in the UK. We have subsequently discussed this issue with management and further reviewed the supply agreement and make the following points:

(a) Based on discussions with local management it is expected that Teva's competitors will launch their generic equivalent during April 2007. Subsequent to

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suffered by Apotex for being prevented from marketing its product, a generic can expect to sell large quantities in the first few days after an entry at risk.

2191 See paragraph (773).

2192 In its reply to the Statement of Objections, Teva claims that its primary objective when negotiating with Servier was to secure a non-infringing supply source and not to receive payments in consideration for delayed entry (paragraphs 516 and 521), ID8495, p. 109-110). On this point, the Statement of Objections does not object to the fact that Teva wished to receive supply in addition to a "settlement sum". However, the supply discussions were always connected to the patent settlement agreement restraining Teva's ability and incentives to compete. In any event, Teva already knew before the conclusion of the settlement agreement that an agreement with Servier would entail a delayed entry (see paragraph (714)). The actual terms of the agreement show that its main objective was to receive monetary payments instead of pursuing its ability and incentives to compete – as a result of the agreement, it could neither enter by itself, nor was it guaranteed to enter with Servier's product in August 2006.

this it is expected that Servier will supply Perindopril to Teva under the contract (Servier are currently enjoying exclusivity and the decision not to supply Teva has prevented price erosion/competition in the market); […]".[2193]

This Teva document is also corroborated by Servier's own ex post statements indicating that Servier had the intention to supply Teva only in case of a revocation of the '947 by the EPO in July 2006 or of an unsuccessful injunction against third parties.[2194] Servier goes on to say that it would have been *"suicidal"* for it to enter with Teva's authorised generic product in case of a confirmation of the '947 patent.[2195] Another document shows that authorised generics were a nuclear weapon to be launched *"only in case of absolute necessity"* (see paragraph (759)).

(1619) In addition, an internal undated document entitled "United Kingdom Operational Audit"[2196] casts some light on the contemporaneous evaluation by Servier and, in particular, on the exclusive purchasing agreement with Teva and the reasons behind the arrangements: *"To protect market share against generics, an exclusive purchasing agreement for Perindopril was concluded with TEVA UK in 2006 for three years. A one-off payment of 5 million GBP was fixed for the implementation of contract. Consequently to a first favourable injunction of the court, generics have been fortunately momentarily removed from the market. As per contract, the Company is now required to pay damages of 500' 000 GBP for each month Servier does not supply TEVA with Perindopril. The cost generated by the agreement in 2005- 2006 amounts therefore to 6 million GBP (5 million * 2 months damages fees)*" (emphasis added).[2197]

(1620) In this respect Servier explains that its intentions when concluding the agreement were to ensure it had a strong distribution partner in the context of a market turning generic and to avoid a lengthy and costly procedure.[2198] Servier also argues that the settlement of the dispute was accessory to its main objective, i.e. the supply of Teva.[2199] However, these justifications are not convincing - settling the dispute was essential to Servier which was ready to discuss business with Teva only after the dispute was settled (and Teva was thereby removed from competition). This is evidenced in particular by documents quoted in paragraphs (725) and (708)*("if we can settle the dispute, we are prepared to […]"* and *"settlement […] for significant sums"*) and by documents which show that the settlement was always discussed together with the supply agreement (see email of 24 March 2006 at paragraph (707) – *"Patent settlement – supply agreement"*, and email of 28 April 2006 at paragraph (710) – a deal which included *"a […] settlement […] followed by a supply agreement").*

(1621) Finally, Servier's internal presentation entitled *"Coversyl: Defense against generics"* referred to the Teva Settlement Agreement which is telling on Servier's considerations to conclude the settlement agreement.[2200]

2193 See paragraph (789).

2194 Servier's reply to the Statement of Objections, paragraph 777, ID10114, p. 290.

2195 Servier's reply to the Statement of Objections, paragraph 782, ID10114, p. 291.

2196 Servier has not been able to trace back the date of this document collected at Servier's premises during the inspection but estimates that it could date from 2007.

2197 See paragraph (801).

2198 See reply to the Statement of Objections, paragraphs 827-829, ID10114, p. 302.

2199 Reply to the Statement of Objections, paragraph 673, ID10114, p. 262.

2200 See paragraph (111).

5.4.1.5 Conclusion – the Teva Settlement Agreement restricts competition by object

(1622) In summary, the Teva Settlement Agreement is an agreement between undertakings whereby Teva limited its ability to compete through the non-challenge and non-compete obligations. In exchange for these commitments, Teva received an initial payment of GBP 5 million and liquidated damages totalling GBP 5.5 million for the 11 months of non-supply. These amounts represent a substantial sum of money which served as a significant inducement to refrain from competing on the perindopril market.

(1623) As explained in the general assessment framework 5.1, patent settlement agreements can properly be based on an assessment of e.g. (i) the validity of the patent(s) at issue and/or (ii) the strength of the infringement case, without objections being made from a competition law perspective. However, it is a violation of Article 101(1) of the Treaty for one competitor to pay another competitor to stay out of a market. As indicated, every operator should determine independently the policy which it intends to adopt on the market.[2201] Paying a competitor to stay out the market does not become acceptable just because it is subsumed in a patent settlement agreement. As the Court recalled in *Bayer v Süllhöffer*, Article 101 of the Treaty does not make a distinction between agreements whose purpose is to settle litigation and those concluded with other aims in mind.[2202]

(1624) In the present case, the Commission's view based on the evidence described in this section is that the payment to a potential competitor of a significant amount of money is the central and essential consideration for the conclusion of the agreement.[2203] Teva's comment on a meeting with Servier in March 2006 that *"any settlement will have to be for significant sums"*[2204] shows that the significance of the inducement was essential to the conclusion of the settlement. Therefore, if such a reverse payment were not deemed necessary to reach the same negotiating outcome, it is reasonable to assume that Servier would behave as any profit maximising economic operator and not pay out such a significant amount of cash. By the same token, Teva would thus have either insisted on more favourable settlement terms, for example with possibility to be able to sell perindopril in case Servier did not supply it, or would have pursued its efforts to enter the market independently, either with its own product or with the one that would have been supplied by Krka.

(1625) Both parties to the settlement, Servier and Teva, were better off in agreeing the settlement that in the alternative scenario of generic entry and resulting competition. It is also evident that the mutually beneficial arrangement was only possible at the expense of the perindopril customers and consumers who as a consequence were required to continue paying higher prices than in the scenario of competitive entry. In economic terms, the Teva Settlement Agreement must be considered as a classic rent sharing agreement by which the interests of the counterparties are aligned.

(1626) Finally, at the time of conclusion of the settlement agreement, both parties' intentions were clear as evidenced by a number of facts assessed above (section 5.4.1.4). First, the generic company decided to forego the competitive commercial incentives (in its

2201 Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 34.

2202 See paragraph (1122).

2203 While the parties clearly retained their views on the dispute, the respective strengths of their cases no longer dominated the outcome. Rather, the payment became the decisive factor.

2204 See paragraph (708).

own words, to put themselves into "*the hands of Servier*") in exchange for *"a big lump sum"*. Second, Servier's main intention was to protect its market share, as evidenced by the terms of the agreement and in particular the extensive non-compete obligation as well as by the internal evaluation of the agreement.

(1627) Given the above assessment of the agreement concluded between Servier and Teva, the Teva Settlement Agreement should be considered as a restriction of competition by object. The Commission refers to sections 5.1 (and in particular to paragraph (1112)) and 5.4.1 for its considerations on the appreciable degree to which the agreement in question restricted competition and to section 5.4.2.6 for its analysis of effect on trade between Member States. The analysis in those sections shows that for a restriction by object that may affect trade between Member States, the Commission does not have to prove an appreciable restriction of competition, but that in any case the Teva Settlement Agreement did restrict competition to an appreciable degree.

5.4.2 The Teva Settlement Agreement is a reverse payment settlement which restricts competition by effect pursuant to Article 101(1) of the Treaty

(1628) The previous section concluded that the Teva Settlement Agreement was a restriction of competition by its very nature. Although in these circumstances, and according to the case law, it is unnecessary to analyse the effects of the agreement, the Commission will nonetheless, for the sake of completeness, show in the present section that the agreement was also likely to cause restrictive effects on competition between Servier and Teva. For the general framework for assessment of restrictive effects, reference is made to section 5.1.7 above.

(1629) To determine if the Teva Settlement Agreement was likely to entail restrictive effects on competition, the following elements need to be considered: (i) Servier's market position, (ii) whether Teva was a potential competitor of the originator company, (iii) the content of agreement (significant reverse payment changes the incentives of the generic party to accept the exclusive clauses of the agreement), and (iv) competition that would have existed in the absence of the agreement. The latter point will focus on the competitive behaviour that Teva would have been likely to engage in, absent the agreement, and on the other relevant sources of competition to Servier thereby demonstrating the importance of Teva as a competitive threat.

(1630) For points (i) to (iii), the analysis in this section will rely on the preceding conclusions of the present Decision, which will be shortly summarised for ease of reference. Thus, the present section will focus in more detail on point (iv).

(1631) The findings of this analysis are limited to the geographic scope of the Teva Settlement Agreement which covers the UK territory and where, in the preceding analysis, Servier has been found to hold significant market power (see paragraph (2593) and section 7.3.5).

5.4.2.1 Servier's competitive position

(1632) In the framework of the dominance assessment under the standards of Article 102 of the Treaty, it was established that Servier held significant market power on the final perindopril product market and the upstream perindopril API technology market (see sections 6.5 and 7.3). According to the Horizontal Guidelines, these findings are

directly transposable to the assessment of market power under Article 101(1) of the Treaty.[2205]

(1633) In the context of the Teva Settlement Agreement, Servier had an interest in protecting its market power, as there had been no launch of generic perindopril and therefore its supra-competitive rents were intact and thus not competed away. This also afforded the means to protect its market power: continued inflow of rents in the absence of price competition from generics provided the "deep pocket" to Servier from which it was able to finance rent sharing with generic companies in return for their withdrawal from competition. To illustrate the significant financial incentive from the originator company, one can compare the transfer of GBP 10.5 million pursuant to the Teva Settlement Agreement to the GBP [5–10]* million that Teva was expecting to earn in the UK[2206] in a medium competitive scenario with its own perindopril for the year 2006.[2207] For the same period of time, Teva had estimated in the best scenario profits of GBP [5–10]* million. Therefore, the upfront payment of GBP 5 million followed by the monthly payments of GBP 0.5 million in all likelihood exceeded the profits Teva would have made under any competitive scenario during the 11 months when Teva was prevented from entering the perindopril market. Furthermore, Teva celebrated the conclusion of the settlement with Servier in a number of documents as financially very attractive. For 2006 it is commented "*A significant feature of the year has been the other income received of GBP 6.5 m re the Perindopril supply agreement with Servier. Without this income the legal loss would have been GBP [5–10 million]* (2005 loss of GBP [0–5 million]*)*".[2208]

5.4.2.2 Teva was a prominent potential competitor of Servier

(1634) Based on the facts in section 4.3.2 and according to the assessment in section 5.4.1.2, it was possible to conclude that Teva was a prominent potential competitor to Servier in the production and supply of perindopril on the UK market at the time the settlement with Servier was concluded. Teva not only had the intention but crucially, it had the ability to enter the UK market and compete with Servier within a short period of time.

5.4.2.3 Content of the Teva Settlement Agreement

(1635) The terms of the settlement agreement have already been described in detail in section 5.4.1.3. Therefore, a reference is made to that section where it was concluded that, against significant reverse payment, Teva accepted contractual limitations which disabled or hampered Teva's ability and incentives to enter the market in a timely and viable manner and restricted competition by object.

5.4.2.4 Competition that would have existed in the absence of the Teva Settlement Agreement and the importance of Teva in view of the remaining competition

(1636) This section will examine the competition that would have existed in the absence of the restrictive provisions of the Teva Settlement Agreement. It will focus on the competitive behaviour that Teva would have been likely to engage in, absent the

2205 *Guidelines of the applicability of Article 101 of the Treaty of the Functioning of the European Union to horizontal co-operation agreements*, OJ 2011/C 11/01, point 42.

2206 See paragraph (687).

2207 To reach these estimations, Teva considered different scenarios (depending in particular on the number of potential competitors) assuming that marketing authorisation was granted in the UK.

2208 See paragraph (782).

agreement, and on the other relevant sources of competition to Servier thereby demonstrating the importance of Teva as a competitive threat to Servier.

(1637) In the absence of the restrictive provisions of the Teva Settlement Agreement, Teva which was very close to obtaining its MA and had the possibility to launch a product containing the alpha polymorph, would have remained a competitive threat as a potential generic entrant with perindopril in the UK and would have likely entered the market.

(1638) First, in the absence of the non-challenge obligation, Teva could have cleared the way to its product by litigation on the process patents – Teva could in such case either be sued by Servier or launch a revocation action. Teva would have then become an even stronger competitive threat for Servier than it was at the time of the conclusion of the agreement when no actual litigation on these patents existed. It could have also decided to enter at risk given that it contemporaneously considered that there was a realistic chance that its product did not infringe the process patents (no injunction had been granted on the basis of these patents against any parties and Teva benefited from an undertaking on the '947 following the stay of a revocation action launched in 2005 based on a counsel opinion indicating strong arguments of the '947 patent's invalidity).[2209]

(1639) In its reply to the Statement of Objections, Servier claims that the Commission (i) seems to imply that Teva would have launched an invalidity action against the process patents and (ii) does not demonstrate that it would have been involved in an infringement action with a successful outcome for Teva.[2210] However, the previous paragraph lists the likely actions that were open to Teva. First, an invalidity action was not excluded since Teva considered possible attacks on the '339 patent in the course of 2006 (see paragraph (678)). Second, Teva could have defended itself if an action for infringement was initiated with arguments of non-infringement or invalidity. A certain outcome in such litigation cannot however be demonstrated by the Commission ex ante. The Commission has only mentioned Teva's belief in the non infringement. The only patent which Servier invoked against Teva was the '339 patent, a patent on which Teva had received a number of opinions, the latest of which concluded that that infringement would be avoided. No threat of infringement had been made in relation to the '340 and '341 patents.[2211]

(1640) Second, in the absence of the non-compete obligation, Teva would have been free to enter the market, either with the product developed by Hetero/Alembic after the grant of the MA or with the product that would have been supplied by Krka (if this was the source that was chosen, notwithstanding the risks attached) provided no injunctions were applied for and granted.[2212] Teva was actively pursuing the grant of its MA which was at an advanced stage according to contemporaneous evidence. It could have therefore entered at risk after obtaining regulatory approval, taking advantage

2209 See paragraph (681).

2210 Servier's reply to the Statement of Objections, paragraphs 857-858, ID10114, p.309-310.

2211 See paragraphs (677)-(678).

2212 Servier claims that the counterfactual does not include the possibility of Teva obtaining supply from Krka (Servier's reply to the Statement of Objections, paragraph 873-876, ID10114, p. 313-314). However, Teva itself listed launch at risk with Krka's product as a possible counterfactual in the present case (see Teva's reply to the Statement of Objections, paragraph 655, ID8495, p. 132-133). In addition, the fact that Teva rejected Krka's offer a few days before signing the binding heads of agreement with Servier does not suggest that it would have acted in the same way if it was not in negotiations with Servier.

of the undertaking given by Servier in October 2005 not to seek an injunction or claim damages if Ivax entered the market with a product infringing the '947 patent provided all other Servier patents were not infringed. Teva was the only generic company to be in this situation which placed it in a unique position vis-à-vis other generic competitors developing a product in the alpha form (like Apotex, for example, who was injuncted by Servier following its entry in the UK).

(1641) Servier claims that Teva would not have entered at risk, given that (i) there was a risk that a confirmation decision of the '947 by the EPO in 2009 would make Teva exit the market, and that (ii) Teva had begun to clear the way on the process patents which shows that it had no intentions to enter at risk.[2213] However, launch at risk in the UK was a possibility that Teva was considering – it speaks several times of the risk of being injuncted (see paragraphs (689), (715) and (718)) and this is implicitly confirmed by Teva.[2214] It was also looking for evidence on the absence of a collapse in price after limited/temporary generic entry[2215] which suggests the same.[2216] Finally, the fact that Teva had begun to clear the way (as alleged by Servier) is consistent with Teva's likelihood of launching at risk, contrary to Servier's allegations. In fact, given that the process description was sent to Servier in March 2006 and that Servier did not sue Teva, it was likely that in the case of an application for an injunction, Teva could have resisted such injunction based on the exchange of correspondence with Servier on the process patents.[2217] Servier also claims that in case of launch at risk, Servier would have immediately applied for an injunction on the basis of the process patents,[2218] an injunction which would have likely been granted on the basis of the status quo, i.e. the Apotex injunction. In such case, Teva would not have been able to enter before the end of the main litigation.[2219] However, it is impossible to prejudge on the outcome of an application for an injunction on the process patents (Apotex was injuncted on the basis of the '947 patent) and in addition, Teva had taken steps to clear the way by disclosing the process description to Servier. Moreover, Servier's argument is misleading given that

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2213 Reply to the Statement of Objections, paragraphs 861-866, ID10114, p. 310-311. Servier also claims that Teva did not consider entering at risk in France and the Netherlands which shows Teva's wish not to launch at risk (reply to the Statement of Objections, paragraphs 867, ID10114, p. 311-312). This argument however pertains to Member States that are not covered by the present assessment concerning the UK market only.

2214 Teva explained in its reply to the letter of facts that it considered all possible options to enter, the surest of which being the agreement with Servier (ID10250, p. 15).

2215 See paragraph (678).

2216 Teva argues in its reply to the letter of facts that this document reflects Teva's careful assessment of the litigation risk and its options to enter the market. It adds that the document does not support the assertion that Teva could have launched at risk absent the agreement (ID10250, p. 14). Servier argues that there is no evidence that Teva was committed to launch at risk (ID10289, p. 124). The Commission notes that Teva was considering such a route to the market and this is implicitly confirmed by Teva in its reply to the letter of facts (ID10250 p. 14-15). Teva also mentioned in the document assuming three different scenarios of launch that if launch takes place in May, this would be prior to any legal action from Servier (see paragraph (687)), so it appears that entry at risk could have taken place once the MA was granted.

2217 See also in reply to Teva's argument on the threat of an injunction footnote 2054.

2218 Servier claims that the process patents were blocking Teva's entry and that Servier's expert was convinced of the infringement by Teva of the '339 patent (Servier's reply to the Statement of Objections, paragraph 862, ID10114, p. 311). Reference is made in this regard to paragraph (1536) which shows a different perception of the (non)infringement of the process patents by Teva – there was a dispute between the parties on this point.

2219 Reply to the Statement of Objections, paragraph 870-871, ID10114, p. 312-313.

it tries to show that Teva was unable to actually enter the market before the Apotex judgment in 2007 whereas the Commission has demonstrated the likelihood of anticompetitive effects.

(1642) Hence, absent the agreement and its restrictive provisions, Teva could therefore enjoy the benefit of the undertaking given to Ivax and enter the market ahead of expiry or revocation of the '947 patent with an alpha-containing product once it had obtained its marketing authorisation, provided that it was not successfully injuncted on the process patents or that it had prevailed at trial. Alternatively, Teva could have entered the market with the Krka product, had it chosen this path and assumed the risks attached to it, provided no injunction would ensue. The contemporaneous documents show that Teva expected its entry onto the market to be profitable. Indeed, at the time of the conclusion of the patent settlement agreement, no other generic had entered the UK market, so Teva would have been in a very favourable position to compete with Servier. With the benefit of hindsight, if Teva had entered the market in December 2006 when its MA was actually granted, there would have been still no generic competitor on the UK market.[2220]

(1643) Given the removal of Teva as a potential source of competition, the subsisting market structure at the time of the conclusion of the agreement will be examined, in particular by identifying other relevant sources of competition and whether they could be perceived as capable of sufficiently constraining Servier to offset the effects of the agreement. The analysis will focus on generic competition which was by far the most important source of constraint on Servier's prices and volumes for perindopril.[2221]

(1644) The aforementioned Servier anti-generic strategy document identified the main sources of competition Servier was facing in June 2006. Apart from Teva and Krka, Servier mentioned[2222] Glenmark, Apotex and [name of Lupin business partner]* (which was in fact sourcing its API from Lupin).

(1645) This assessment of competitive landscape largely coincides with the one made by Teva in an internal email from April 2006: *"[…] Krka is our first competitor. We do not know how far Apotex are in their development other than they have had a dossier in for some time and that it is based on Glenmark API"*.[2223]

2220 Teva argues that the agreement was not likely restrictive of competition compared to the relevant counterfactual which consisted of two alternative courses of action: either (i) wait for other companies to pursue infringement proceedings or wait for patent expiry, or (ii) launch at risk with the Krka product (since its own product was not ready) and be enjoined given Krka's likely infringement of Servier's patents. Neither action would have accelerated or facilitated Teva's entry compared to the agreement with Servier (Teva's reply to the Statement of Objections, paragraphs 653-656, ID8495, p. 132-133). On these points, it is noted first that there was no certainty an injunction would have been granted against Krka. Second, Teva could have entered with its own product once it had obtained a marketing authorisation, especially in view of the Servier undertaking on the '947 and its internal assessment of the likelihood of (non)infringement of the process patents (for details, see paragraphs (1536) and (1537)). The fact that it had not yet obtained a MA for its product and therefore not ready to be placed on the market in June 2006 does not prevent the possibility of entry later, and before any other generic competition.

2221 See section 6.5.1.2.6.

2222 Another generic company, also mentioned in the report, did not have an own perindopril product and concluded a distribution agreement with Servier. See section 4.1.2.5.1.

2223 ID0346, p. 24.

(1646) It is recalled that, at the time of the Teva Settlement Agreement, the '947 patent was still in force in all countries where it was granted, including the UK. The sources of competition to Servier, as identified in the Commission's market investigation, were thus limited to those operators with an advanced development which were willing to accept the risks of patent litigation (clearing the way by (non)infringement and/or invalidity claims, launch at risk etc.) or sought to launch a potentially non-infringing form of perindopril.

(1647) The first group of operators were thus generic companies with an advanced perindopril development which had initiated or were about to initiate invalidity actions against the '947 patent in the UK or were involved in infringement actions with Servier. These companies were Krka (whom Teva considered not only as a possible supplier, but also as its "*first competitor*"), Teva, Apotex and Lupin (for further information on the stage of development of each of these companies, see section 5.1.7.3).

(1648) The second group consisted of a few generic operators developing non-infringing forms of perindopril. At the time of the Teva Settlement Agreement, only Sandoz and Cipla had advanced projects for perindopril possibly avoiding any of Servier's patents, including the '947 patent (for further information on the stage of development of each of these companies, see section 5.1.7.3).

(1649) The above strongly suggests that, from the perspective of both Teva's and Servier's perception of the competitive structure prior to the conclusion of the agreement, as well of the Commission's market investigation, Apotex and Krka appeared to represent the most important competitive threat to Servier in addition to Teva. Glenmark's development was less advanced at the time. Accordingly, Glenmark did not have a MA and was not actively pursuing an entry strategy through a challenge to the validity of key Servier patents (the '947 and the process patents). It was thus not a direct threat to Servier.

(1650) Sandoz's advanced development of non-infringing perindopril was another threat to Servier's significant market power, although not as imminent, as it appeared to lag more than a year behind Teva. Cipla's project was considered by Servier to be likely to infringe its patents, and Cipla did not take any measures to clear the situation.[2224] Thus, Cipla did not constitute a direct threat to Servier at the time of the Teva Settlement Agreement.

(1651) To conclude, apart from Teva, there were only four other direct generic threats to Servier with advanced perindopril development, either about to contest the validity of the '947 patent (Apotex, Krka and Lupin), or with non-infringing forms of perindopril (Sandoz). In a situation where there had been no actual generic entry at the time of the Teva Settlement Agreement and where there were only a very limited number of companies with prospects of a viable launch in view of the persisting barriers to entry (in particular patent and regulatory compliance), the removal of a single competitor significantly reduced the likelihood of a timely and effective generic entry (and therefore increased the probability that generic entry would be delayed to the detriment of consumers). Teva argues that contrary to the Commission's view, a limited number of potential competitors were sufficient to avoid any possible restrictive effects on competition. It supports its claim by stating that Amendment N°1 provided that Teva would be able to enter the market as soon

[2224] See paragraph (1261).

as Servier's '947 patent would be revoked or annulled and hence a single competitor successfully challenging this patent was enough to permit Teva's entry at the earliest possible date.[2225] However Teva was prior to the agreement with Servier in a specific situation given the undertaking it benefitted from in respect of the '947. Moreover, given that Teva was a prominent potential competitor it was one of the threats to Servier's patent position which could have succeeded in this enterprise, given its reasonable assessment of the non-infringement of the process patents. Hence, its elimination significantly reduced the likelihood of timely and effective generic entry.

(1652) In addition, one needs to recall Servier's expected/prospective actions to confront generic entry, which posed an additional source of uncertainty as regards the likely behaviour of the remaining potential sources of competition.

(1653) Thus, the Teva Settlement Agreement was part of a consistent series of "amicable" solutions between, on the one side, Servier, and on the other, Servier's close generic rivals, whereby agreements involving a significant financial transfer to generic operators (either reverse payment patent settlements or acquisitions of API technology) at the same time removed the latter from competing with Servier. Given Servier's overall defensive strategy against generics, but also that the market generally suspected that Servier would try to buy out all possible sources of competition,[2226] and that Servier had already concluded a patent settlement agreement with Niche/Unichem and Matrix, there was a strong possibility that Servier would attempt to reach similar agreements with Krka, Lupin, Apotex and/or Sandoz (see section 5.1.7.3 for further information).

(1654) Servier actually concluded patent settlements with Krka and Lupin shortly after the Teva Settlement Agreement, as described below. Servier also attempted to reach a settlement with Apotex, although unsuccessfully.[2227] Teva was even hoping for such a settlement between Servier and Apotex, as can be derived from an internal communication of 27 February 2007. Regarding a potential settlement between Servier and Apotex it is noted: *"this would be a good result for us (...)? If the settlement keeps other generics off the market in the UK then we keep our present arrangement with Servier. (...) I have asked Alia to keep an eye on the court lists to see if this case gets withdrawn"*.[2228]

(1655) Thus, even for the four remaining sources of competition identified above, there was at the time of the Teva Settlement Agreement, a strong possibility that Servier would try to reach an agreement with them or otherwise remove them from competition.

5.4.2.5 Conclusion – the Teva Settlement Agreement was likely to entail restrictive effects for competition

(1656) The above analysis established that Servier held significant market power in the market for perindopril formulations and the upstream market for perindopril API technology. As the incumbent facing no price related constraints, and thus charging supra-competitive prices, Servier had the commercial interest and the financial

2225 Reply to the Statement of Objections, ID8495, p.135.

2226 "*The position with Perindopril is very complicated in terms of patents-particularly process patents which affect API manufacturers. This is partly why everyone is late (once an API manufacturer has got round the process patents Servier has bought the company, sourcing API has been very difficult*", (Teva quote from October 2005). See paragraph (142).

2227 See paragraphs (179) and (191).

2228 See paragraph (773).

means to offer significant inducements for close potential competitors to withdraw from competition. Thus, by inducing Teva with an upfront payment of GBP 5 million plus a monthly GBP 0.5 million in case of failure to supply as compared to Teva's best scenario of expected profits of GBP [5–10]* million for 2006 in the UK, Servier effectively induced Teva to withdraw from competition on perindopril. Teva was no longer able to pursue any patent challenges against Servier in the UK as a key avenue for a viable generic entry, and was also not able to enter at risk.

(1657) The Teva Settlement Agreement thus reduced competition between the parties to the agreement, Servier and Teva. Teva could no longer compete with Servier the way it would have in the absence of the agreement with its product in advanced stage of development or with the product developed by Krka.

(1658) In the period of conclusion of the Teva Settlement Agreement, the likely effects of the agreement on competition were appreciable, as Teva was an important source of competition to Servier. It was (and still is) one of the biggest generic companies in the world,[2229] who had sunk considerable resources and time into bringing a viable perindopril product to the market. In May 2006, Teva was nearly ready to launch perindopril, as it had only one step to clear to gain MA for the product it had developed with Hetero/Alembic. In addition, Teva was in a unique position as the patent invalidity proceedings launched by Ivax had been stayed and, moreover, Servier had given an undertaking not to injunct it or seek damages if it were to enter the market with a product infringing the '947 patent during the period of the stay. Given that there were only four other potential sources of competition posing a comparable competitive threat (advanced product development and/or actively addressing patent situation by invalidity actions or non-infringing product) who were nevertheless in a different situation to Teva, and that Servier had a strategy to neutralise all the competitive threats, the removal of Teva as a potential competitor was likely to delay generic entry into the UK perindopril market and to have restrictive effects on competition.

(1659) On the basis of the foregoing considerations, the Commission finds that the Teva Settlement Agreement was such as to appreciably restrict potential competition among Servier and generic companies and barred "*real concrete possibilities*" for Servier and Teva to compete among themselves or "*for a new competitor to penetrate the relevant market and compete with the undertakings already established*".[2230] By discontinuing Teva's patent challenge and removing the possibility of launch at risk with Teva's product or a third party product, the Teva Settlement Agreement appreciably increased the likelihood that Servier's significant market power would remain uncontested for a longer period of time, thereby avoiding the significant reduction of prices that would have ensued from timely and effective generic entry.

2229 According to Servier, Teva was the only generic company to be on the top 10 of pharmaceutical companies in the UK in 2006, see Servier's reply to the Statement of Objections, paragraph 671, ID10114, p. 262.

2230 Joined Judgments of 15 September 1998, *European Night Services and Others v Commission*, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198, paragraph 137.

5.4.2.6 Effect on trade within the meaning of Article 101(1) of the Treaty

(1660) Article 101(1) of the Treaty only applies to agreements and practices *"which may affect trade between Member States"*. This criterion has three basic elements.[2231]

(1661) First, *"trade between Member States"* must be affected. The concept of trade covers all forms of economic activity, including establishment. According to settled case law[2232] an agreement that has an impact on the competitive structure in more than one Member State is by its very nature capable of affecting trade between Member States. Trade between Member States may also be affected in cases where the relevant market is national.[2233]

(1662) Second, it is sufficient that the practice *"may"* affect trade, i.e. that it is sufficiently probable that the practices are capable, based on an objective assessment (as well as subjective elements, if any), of having an effect on the patterns of trade, or on the competitive structure.

(1663) Third, the effect on trade of the agreement must be appreciable. This element requires that the effect on trade between Member States must not be insignificant and it is assessed primarily with reference to the position of the undertakings on the market for the products concerned.

(1664) The Teva Settlement Agreement has, by removing Teva as a potential competitor to Servier, delayed or attempted to delay market entry of generic perindopril in the UK.

(1665) It is settled case law that an agreement which extends over the whole territory of a Member State has, by its very nature, the effect of reinforcing the partitioning of markets on a national basis, thereby holding up the economic interpenetration which the TFEU is designed to bring about.[2234]

(1666) In addition, Teva was prevented from selling in the UK the product it had developed at the time with Hetero and any other non-infringing form of perindopril erbumine, be it its own or sourced from a third party, affecting potential supplies from other Member States. As indicated, Teva had been in negotiations with Krka to distribute Krka's perindopril product in the UK. This option was ruled out when Teva entered into intense negotiations of the settlement agreement with Servier.

(1667) Therefore, the Teva Settlement Agreement has removed Teva as a potential competitor to Servier in the UK and, actually or at least potentially, affected trade between Member States.

2231 *Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81–96, point 18.

2232 Joined Judgment of 8 October 1996, *Compagnie maritime belge transports and Others v Commission*, T-24/93, T-25/93, T-26/93 and T-28/93, ECR, EU:T:1996:139, paragraph 203; Joined Judgment in *Commercial Solvents v Commission*, 7/73 and 6/73, EU:C:1974:18, paragraph 23.

2233 *Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81–96, points 19-22.

2234 Judgment in *Wouters and Others*, C-309/99, EU:C:2002:98, paragraph 95. See also Judgment in *Erste Group Bank and Others v Commission*,,C-125/07 P, EU:C:2009:576, Judgment in *Raiffeisen Zentralbank Österreich v Commission*, C-133/07 P, EU:C:2007:648, Judgment in *Bank Austria Creditanstalt v Commission* C-135/07 P, EU:C:2007:648 and Judgment in *Österreichische Volksbanken v Commission* C-137/07 P, EU:C:2007:648, paragraph 38 and following.

5.4.3 Conclusion – the Teva Settlement Agreement restricts competition within the meaning Article 101(1) of the Treaty

(1668) The above analysis has demonstrated that the Teva Settlement Agreement involved payments by Servier to Teva for withdrawal as a close potential competitor from the market which had as its object to restrict competition. Teva was prevented from a viable and timely generic entry, which would challenge Servier's market position, and in return received a significant payment, which effectively amounts to rent sharing. The Teva Settlement Agreement thus constitutes a restriction of competition by object in terms of Article 101(1) of the Treaty which was also likely to produce restrictive effects on competition.

(1669) The parties' claims under Article 101(3) of the Treaty are analysed in section 5.7.

5.5 Assessment of the Krka agreements

(1670) This section sets out the assessment of the Settlement Agreement concluded between Servier and Krka on 27 October 2006, and the related Licence Agreement (also signed on 27 October 2006), as well as the Assignment and Licence Agreement ("ALA") concluded between the same parties on 5 January 2007 (together also referred to as "the Krka agreements"), pursuant to Article 101(1) of the Treaty. This Decision will find that Krka and Servier infringed Article 101(1) of the Treaty in the 18/20 Member States where Krka (i) committed to withdraw from competition with Servier with its existing product in exchange for a licence in the remaining seven Member States, and thereby dividing and allocating the EU markets between Servier and Krka, and (ii) stopped competing as a source of existing perindopril technology by transferring its technology to Servier for EUR 30 million. For the avoidance of doubt, this decision finds no infringement on the sole basis that Servier and Krka entered in a licence agreement in respect of the seven countries concerned. Nor should this Decision be construed as finding that a licence agreement, as part of a patent settlement agreement, constitutes in itself and irrespective of the level of the license fee agreed a transfer of value going beyond the normal value attached to a licence agreement by a licensee, to the effect that such a licence would as such be analysed as a value transfer resulting in the patent settlement falling foul of Article 101 of the Treaty. However, where all the conditions of the test set out at paragraph (1154) are met, and in particular where a significant inducement which substantially reduced the incentives of the generic to independently pursue its efforts to enter the market can be substantiated, Article 101 of the Treaty applies.

(1671) The legal assessment in this chapter will take into account the economic and legal context leading up to the agreement's conclusion as it appears from the facts described in this Decision. This analysis will, in particular, consider whether Servier and Krka were at least potential competitors at the time when they concluded the agreement. In a second step, it will be examined if the Settlement Agreement and the related Licence Agreement restrict competition by their very object. Third, the Assignment and Licence Agreement will be examined to establish whether it had the object of imposing further restrictions on Krka as a source of competition to Servier, and formed with the Settlement and the Licence Agreement formed a single continuous infringement. Fourth, for the sake of completeness, an analysis of restrictive effects of these agreements is carried out for France, the Netherlands, and the UK. Specific arguments of the parties relating to this analysis will be taken up in the assessment of these agreements. The parties' arguments pertaining to analysis under Article 101(3) of the Treaty are analysed in section 5.7.

5.5.1 Introduction – economic and legal context

(1672) The specific legal and economic context of the agreements between Servier and Krka can be summarised as follows.[2235]

(1673) At the time the agreements were concluded (end of October 2006 and beginning of January 2007), there was no generic perindopril in the Western European markets, but Krka had launched its generic perindopril at risk in a number of Central and Eastern European markets (Czech Republic, Hungary, Lithuania, Poland, Slovenia). Perindopril was Servier's most important product at the time. Servier held the monopoly of sales of perindopril since 1988/1989, owing to the patent protecting the product. Servier's sales of perindopril in the year of the settlement agreement (i.e. 2006) on the top 13 EU markets had generated an EBIT profit of EUR [nine digit figure] million.[2236] Moreover, Servier's profits from perindopril were still growing and reached EUR [nine digit figure] in 2007. Section 6.5 shows that Servier's perindopril enjoyed significant market power in that period, and Servier put in motion a strategy to protect itself against generic competition (see section 4.1.2).

(1674) After Servier's settlement agreements with Niche/Unichem and Matrix, Krka remained the most advanced competitor. Krka had initiated perindopril development in 2003 and received the first marketing authorisation already in 2005, with many more granted in the course of 2006 to Krka as the first generic company, or at least one of the very few (including the UK, France, the Netherlands, and Poland). As mentioned above, Krka launched its perindopril in a number of Central and Eastern European markets (hereafter CEE markets), which it considered to represent its key markets with the strongest market presence, and highest profits. Krka was also preparing for launch in Western European markets and was discussing a number of partnerships with other generic companies, including Teva, Ratiopharm and Stada. Teva considered supplies from Krka as an "*excellent option*"[2237] and moreover recognised that the settlement payment under its Settlement Agreement with Servier was *a "premium to ensure the commercial attractiveness of Servier's supply offer versus in particular Krka's offer".*[2238]

(1675) Krka's generic perindopril was in alpha crystalline form covered by the '947 patent. In terms of legal disputes between the parties, Krka was one of the remaining opponents to Servier's '947 patent before the EPO. After the '947 patent was, to Krka's surprise and "*shock*",[2239] confirmed on the intermediate level by EPO's Opposition Division in July 2006, Servier did start to enforce this patent with respect to generic perindopril of Apotex and Krka.[2240] According to Krka's reply to the Statement of Objections, following the EPO Opposition Division decision, the risks of litigation and damages (in case of sales at risk) became an "insurmountable barrier" and Krka decided to cease all activities on perindopril erbumine in the alpha

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2235 The general economic and legal context for the assessment of reverse payment patent settlements has been set out in section 5.1. In addition, the general factual background to the agreements between Servier and Krka has been set out in section 4.3.3.

2236 See section 6.4.5.3.

2237 See paragraph (695).

2238 See paragraph (796).

2239 In a contemporaneous document, Krka stated it was *"in shock after such an unfavourable outcome with respect to the polymorph alpha litigation"* following the EPO Opposition Division's decision (July 2006) and concluded that the Opposition Division was biased against generics. See paragraph (895).

2240 See section 4.1.2.4.

form.[2241] Yet, Krka in fact continued to sell generic perindopril where it was already present on the market (for example, Servier's application for interim relief was rejected by a Hungarian court in October 2006), and launched invalidity claims before the High Court over the validity and (non)infringement of Servier's '947 and '340 patents.

(1676) Therefore, even against the set-back of the intermediate decision in the EPO opposition procedure, Krka remained amongst the main generic threats to Servier's most important product at the time, both in Western Europe, where Krka had received first marketing authorisations and was challenging the '947 patent in the UK, and in CEE markets, in most of which Krka was already present with generic perindopril.

(1677) As will be shown below, Servier agreed with Krka that Krka obtained a sole licence in the seven CEE markets,[2242] as Krka's core markets, where a *de facto* duopoly of Servier and Krka was maintained. In return, Krka withdrew from its generic challenges in 18/20[2243] mostly Western European markets (also referred to "18/20 markets", or "restricted markets" for the purpose of the assessment of the Krka Settlement Agreement). This geographically limited sole licence induced Krka into an arrangement akin to market sharing, whereby in 7 markets Krka was allowed onto the market alongside Servier, which however would keep the remaining 18/20 markets to itself. In the specific context of this case, considering the non-challenge and non-compete obligations, but also the parties' intentions, this arrangement could amount to a restriction of competition by its very nature.

(1678) Two months later, Servier purchased from Krka patent applications for competing technologies to produce perindopril for EUR 30 million. Krka considered that Servier feared that this technology could otherwise be assigned or licensed to other competitors.[2244] While certain indications point towards the existence of the link between the Settlement Agreement and the EUR 30 million payment by Servier,[2245] this decision does not reach a conclusion to this effect, and the assessment of these agreements is not premised on the existence of such a link.

(1679) As explained in section 5.1, litigation on contested patents is an essential element of the competitive process between originator and generic companies. Whilst companies should be free to settle their disputes on the merits of the patent case, it is essential that the ultimate outcome of the settlement, in particular restrictions imposed, is not distorted by elements outside the merits of the patent case, such as an economic inducement from the originator to the generic company to share markets. This is all the more the case where potential restrictions of competition are compounded by additional transactions eliminating the remaining competitive threat from possible third party use of Krka's technology.

2241 Krka's reply to the Statement of Objections, paragraphs 40, 48, ID8742, p. 24, 29-30.

2242 Czech Republic, Hungary, Latvia, Lithuania, Poland, Slovakia, Slovenia.

2243 This comprises all other Member States. The accession of Romania and Bulgaria to the EU occurred on 1 January 2007, 2 months after the Krka Settlement Agreement was concluded, which increased from 18 to 20 the number of markets not covered by the licence.

2244 See paragraph (946).

2245 See paragraph (1798).

5.5.2 Krka and Servier as actual or potential competitors

(1680) In order to examine whether the prohibition in Article 101(1) of the Treaty applies to the Settlement Agreement, the Licence Agreement and the Assignment and Licence Agreements, it must first be shown that Krka and Servier were actual or potential competitors.[2246]

(1681) Krka was by far the first generic competitor to challenge Servier's incumbent position for the supply of perindopril and to actually launch generic perindopril. Prior to the conclusion of the Settlement Agreement and the Licence Agreement, Servier and Krka were actual competitors in the supply of perindopril in a number of national markets, i.e. Czech Republic, Hungary, Lithuania, Poland and Slovenia.[2247]

(1682) In other EU markets, Krka had not yet launched its generic product. The Commission finds that Krka was a potential competitor (directly or through third party distributors) in these markets for the following reasons, as (i) Krka's product was ready to launch, (ii) the patent barriers were not insurmountable, (iii) Krka had a number of cooperation partners for several EU markets and (iv) was endeavouring to enter the markets.[2248]

(i) Krka's product was ready for launch

(1683) First, Krka developed workable and efficient processes for the production of generic perindopril API and formulations, for which patent applications were filed, and which complied with the very strict standards of the European Pharmacopoeia monography for perindopril, which has, amongst others, also been acknowledged internally by Servier.[2249] Krka was the first company to launch generic perindopril (in 5 CEE Member States). It was also the first company, or at least amongst the first companies, to receive a marketing authorisation for generic perindopril in a number of Western European Member States already in 2006, either directly or through a regulatory dossier licensee[2250] (in May 2006 in the UK, October 2006 in France and the Netherlands). This demonstrates that it had a readily available and marketable product (depending on the patent situation).

(ii) Patent barriers were not insurmountable even after the decision of the EPO Opposition Division

(1684) Second, as explained in general terms in section 5.1, the mere existence of Servier's patents, and unilateral claims that these patents were infringed, is not sufficient to claim that there was no real concrete possibility for Krka to enter the market.[2251]

The '947 patent

(1685) Krka's internal documents prior to the EPO Opposition Division of 27 July 2006, which upheld the '947 patent on an intermediate basis (also "Opposition Decision"), confirm that Krka was convinced of its annulment case.[2252] There is ample evidence of Krka's genuine doubt as to the validity or infringement of Servier's '340 and

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2246 The general framework for the Commission's assessment is laid out in section 5.1.3.

2247 See paragraph (907).

2248 Certain of the parties' arguments are also addressed in paragraphs (1825)-(1834).

2249 See paragraph (862). These patent applications were the sold to Servier by virtue of the Assignment and Licence Agreement on 5 January 2007.

2250 See Table 9.

2251 Servier's reply to the Statement of Objections, paragraph 967, ID10114, p. 335.

2252 See, for example, paragraphs (830), (844), (851), (873), (874) and (895).

'947 patents. Krka considered that its particular strength was, besides having a developed product, in its invalidation actions (against the '947 patent) where Krka believed to have a strategic advantage due to its superior evidence.[2253] For example, Krka's patent attorneys considered the '947 patent as "*not valid in view of the available prior art and likely cancelled or restricted during opposition proceedings*".[2254] Krka was also aware, for example, of Stada's view that "*Krka's nullity suit [was] among all the others the most promising one*".[2255] Krka deemed that if it concluded an agreement with Servier, this would eliminate Krka as the sole remaining opponent (after Niche had settled) with material evidence of prior art concerning the '947 patent.[2256]

(1686) Krka essentially contends that, following the Opposition Decision which confirmed, on an intermediary basis, the validity of the '947 patent, it no longer exercised a competitive constraint on Servier and thus did not constitute a potential competitor. According to Krka and Servier, the risks of litigation and damages (in case of sales at risk) related to its perindopril covered by the '947 patent, became an "insurmountable barrier", prompting Krka's decision to cease all activities on perindopril erbumine in the alpha form.[2257] This claim is in the Commission's view not borne out by the facts for the following reasons.

(1687) In support of its claim, Krka essentially relies on the minutes of internal meetings dated 13 and 14 September 2006 which report that all activities on the alpha form perindopril are to be ceased in view of the Opposition Decision, and R&D work on a novel form of perindopril is to be initiated.[2258] However, this was an operational meeting within the R&D department, and during which neither litigation nor marketing issues were discussed, much less decided. Unlike the strategy email of 29 September 2005 from [employee name and function with Krka]*, to [employee function with Krka]*,[2259] these meetings did not consist in a comprehensive review of R&D, litigation and commercial strategies for perindopril, and there was no presence from high level management. The minutes of these meetings are neither confirmed nor corroborated by evidence of any decision taken at the highest level of the company and nothing suggests that the instructions to stop work on perindopril erbumine within the R&D team were of general nature and also concerned commercial and litigation strategies. Such an interpretation of the minutes would be inconsistent with both Krka's continued challenge to the '947 patent (counterclaims

2253 ID0046, p. 25.

2254 See paragraph (834).

2255 See paragraph (867).

2256 See paragraph (853).

2257 Krka's reply to the Statement of Objections, paragraphs 40, 48, ID8742, p. 24, 29-30. Servier's reply to the Statement of Objections, for example paragraph 954, ID10114, p. 332. Servier's inference that Krka was not a potential competitor in the wake of the Opposition Decision, a setback for Krka, is at odds with the fact that Servier was nonetheless willing to grant it a licence. Already in 2005, Servier and Krka were discussing a possible acquisition of the Krka technology and a licence for Krka to commercialise perindopril as of October 2008 (see paragraph (858) and footnote 2412). Although one could, based on the parties' claims, say that the negotiating context in 2005 was more favourable to Krka, no licence was granted to Krka then, while in October 2006, when Krka allegedly faced "insurmountable barriers" and would thus be expected to have inferior negotiating leverage, Servier reversed its position and granted Krka a licence.

2258 ID0046, p. 34-35, ID1245. Krka's reply to the Statement of Objections, for example paragraph 89, ID8742, p. 9, Krka's reply to the Letter of Facts, ID10202, p. 8-10, Servier's reply to the Letter of Facts, ID10289, p. 139-140.

2259 See section 4.3.3.2 and footnote 2385.

for invalidity of the '947 patents had been filed less than two weeks earlier), and with the commercialisation of the existing product where launched (in Hungary, it won against Servier's application for interim injunction in October 2006).[2260] The alluded decision to cease Krka's work concerning perindopril erbumine should thus be understood in its proper context, the operational roll-out of further R&D activities for a novel form of perindopril within the R&D department, to which the meeting was dedicated.

(1688) Consistently, Krka describes the decision as "*shocking*",[2261] "*dreadful*"[2262] and obviously biased.[2263] This in itself suggests that Krka did not accept the reasoning of the Opposition Decision. Although Krka "*had reasons to be somehow less convinced*"[2264] it also recognised that "*Servier apparently also had certain doubts as to the strengths of its litigation cases*".[2265] Even if it was no longer fully convinced of its case in the aftermath of the Opposition Decision,[2266] Krka was far from giving up

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2260 The minutes moreover show that Krka continued producing perindopril API, of which only a part was intended for R&D purposes. This suggest that not only the perindopril erbumine API, as used in Krka's existing product, continued to be produced, but that at least a part of it continued to be used for production of Krka's stocks of perindopril erbumine formulations.
In this context, Servier also refers to Krka's email to Ratiopharm, inquiring whether Ratiopharm would be willing to switch its cooperation from the alpha product to Krka's new perindopril form in development as allegedly showing that Krka abandoned its existing product (Servier's reply to the Statement of Objections, paragraph 1019, ID10114, p. 349, reply to the Letter of Facts, ID10289, p. 141-142, see also Krka's reply to the Letter of Facts, ID10202, p. 10-12). The email of 25 September 2006 does testify that Krka was canvassing the commercial interest to abandon the existing product and switch to the new product yet to be developed, but does not state that Krka had already taken a final decision to abandon perindopril erbumine. Ratiopharm was "*fairly irritated upon [Krka's] short term notice and your request to give a written commitment to your proposal based on the little informations you send in the mail within a day*", requested further information, and asked Krka "*not to withdraw completely from this product. As you know, it is still possible that the alfa-polymorph patent might get nullified next year, and then it should be much easier and faster to launch with the alpha polymorph. We are also still working on new nullity arguments for the polymorph patent".* In its reply of 26 September 2006, Krka explained that it was "*intensively working on alternative scenarious that would enable us to enter the market without a patent risk. In order to invest in the project once again we need to learn our partners' interest*". Yet, when in November 2006, Krka and Ratiopharm discussed the terms of a suspension agreement, Ratiopharm still insisted that it "*would like to include something stating that in case Servier is not further able to uphold the patent [Krka is] willing to supply the old product as well if with this product in such a situation market entry would be possible earlier".* (ID5656, p. 9) Krka was thus asked to supply perindopril erbumine in case this would, in view of on-going patent challenges, allow an earlier entry than Krka's new development. This was also reflected in the termination agreement (ID1294, point 5) as invoked by Servier. Accordingly, Ratiopharm indeed entered with Krka's "old" product once the '947 was annulled (ID1307, p. 99-100).

2261 Krka's reply to the Statement of Objections, paragraph 100, ID8742, p. 53 and paragraph (895).

2262 Krka's reply to the Statement of Objections, paragraph 101, ID8742, p. 54.

2263 See paragraph (895).

2264 Krka's reply to the Statement of Objections, paragraph 71, ID8742, p. 40.

2265 Krka's reply to the Statement of Objections, paragraph 91, ID8742, p. 50.

2266 Parties also claim that its arguments and evidence for the invalidity of the '947 patents were rejected by the Opposition Decision, and that therefore the Commission's position that Krka was certain to win was incorrect (Krka's reply to the Statement of Objections, paragraph 25, ID8742, p. 17, Servier's reply to the Letter of Facts, ID10324, p. 158-159). The Commission's assessment of potential competition does not encompass an assessment on the merits of the underlying patent, or patent litigation, and is not premised on the certainty that the generic companies would prevail in litigation. Instead, it seeks to establish if overcoming patent barriers, including through an invalidity action, represents a real concrete possibility in the case of Krka. This is, for example, also consistent with Servier's observations according to which Krka's invalidity action, even if it had certain weaknesses, made it obvious that

on the question of invalidity of the '947 patent. Krka's representative commented: "*[Krka is] still in shock after such an unfavourable outcome with respect to the polymorph alpha litigation. Especially what bothers us is that the trial was discriminative against generic industry and we shall not let them go just like that*".[2267] Also, Krka continued to enjoy support from its partners for its continued attempts to invalidate the '947 patent. Ratiopharm stated that Krka and Ratiopharm "*should try as much as possible to revoke this strange decision of the Opposition Division*".[2268] In reaction to Servier's infringement claim, Krka confronted Servier before the English court with a counterclaim for the invalidity of the '947 and '340 patents lodged in September 2006.[2269] If Krka had indeed considered to have no realistic chances of succeeding and decided to abandon the marketing of perindopril erbumine, as claimed, it could offer an undertaking to Servier to refrain from

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Krka considered to have had real chances to revoke the '947 patent (Servier's reply to the Statement of Objections, paragraph 906, ID10114, p. 321).
Likewise, Servier claims that there is no evidence that Krka was still convinced of its patent case following the Opposition Decision (Servier's reply to the Statement of Objections, paragraph 1018, ID10114, p. p. 349). The Commission repeats that it does not, and needs not to contend that Krka would certainly prevail in its patent challenges to the validity of the '947 patent. What matters is that Krka continued with its challenges, as shown below.

2267 See paragraph (895). Krka claims that this statement only alleged procedural irregularities and did not comment on the merit. As reference was also made to "irreparable damage to the generic industry and national health systems", this confirms, according to Krka, that this statement does not express Krka's intention to challenge the Opposition Decision (Krka's reply to the Letter of Facts, ID10289, p. 30-32). The Commission does not contest that the statement does not raise substantive patent law arguments. However, the statement does convey Krka's obvious discontent with the Opposition Decision and the intention not to "*let them go just like that*", which, in the context of legal proceedings, implied taking legal action. This is corroborated by Servier's interpretation that the statement shows that Krka and Ratiopharm received the Opposition Decision negatively, had an intention to appeal, which they actually did (Servier's reply to the Letter of Facts, ID10289, p. 161). Reference to irreparable harm cannot be reasonably understood as meaning that that decision could not be reversed, as claimed by Krka. What was irreparable were the delays to generic entry and delayed price reductions which could not be avoided even in the case the '947 were to be later annuled by the EPO Board of Appeals or in national patent litigation.

2268 See paragraphs (895)-(896). Moreover, Ratiopharm undertook, vis-à-vis Servier, not to enter the UK pending the conclusion of UK litigation between Servier and Krka (see paragraph (894). This shows that, while eventually abandoning plans to launch at risk pending the legal action, Ratiopharm continued to rely on Krka efforts to overcome the '947 patent. The parties claims that this is incorrect as (1) nothing suggests that Ratiopharm requested Krka to initiate invalidity actions against the '947 patent (Servier reply to the Letter of Facts, ID10324, p. 159-160); and (2) Ratiopharm decided not to launch the product as long as the '947 was upheld (Krka's reply to the Letter of Facts, ID10202, p. 29-30). The Commission first recalls that Ratiopharm's undertaking explicitly referred to "*the conclusion of Krka Proceedings*"; if the patents in suit were declared invalid and/or Krka's perindopril erbumine were held non-infringing, Servier would need to compensate Ratiopharm). Second, the fact that Ratiopharm abandoned plans to launch at risk while the '947 was valid is in no contradiction with its reliance on Krka's challenge to the validity of the same patent.

2269 See paragraph (902). Servier claims that Krka's might have used the UK invalidity counterclaims tactically in order to incite Servier to conclude a licence agreement (Servier's reply to the Statement of Objections, paragraphs 940-941, 1016-1017, ID10114, p. 328-329, 348-349). There is no contemporaneous evidence to confirm that this was Krka's sole or main motive. The same logic applies to Servier. Krka reports to have had initiated settlement discussions and reached a preliminary agreement even before Servier filed an action for infringement of the '947 patent and applied for interim relief. Moreover, a confidentiality agreement was signed end August 2006, a more than a month before the interim injunction was granted. Therefore, it appears that both Servier and Krka were defining their litigation tactics in a way not to weaken their position for the settlement avenue. Nothing suggests that, in the absence of a settlement prospect, Krka would not defend its commercial position the way it did.

marketing its perindopril in return for Servier's withdrawal of legal actions.[2270] To the contrary, Krka itself conceded that the settlement negotiations started not only because of the continued validity of the '947 patent, but also because Krka was seen as a "*serious threat*" to Servier, which reportedly "*believed that Krka had one of the best and most comprehensive evidence in the opposition before the EPO and in UK revocation"*.[2271]

(1689) The High Court Order, which granted to Servier an interim injunction against Krka and ordered a full trial, rejecting Krka's motion for summary judgment on the invalidity of the '947 patent, might be seen as an intermediate procedural success for Servier. Notwithstanding, its content could also be deemed as encouraging for Krka's case. Although the judge found that "*it was impossible to say that there is no issue to go to trial on the question of anticipation or obviousness of the Patent over 341*" and thus ordered a full trial, it also considered that Krka had "*a powerful base for the attack on the validity of the patent for lack of novelty or obviousness over 341*".[2272]

(1690) Krka's assessment of the patent situation was certainly influenced by the Opposition Decision, and the grant of the interim injunctions against Krka and Apotex in the UK. Yet, the above strongly suggests that, from an *ex ante* perspective, nothing precluded a real concrete possibility for Krka to invalidate the '947 patent in full trial.[2273] Krka's contribution to challenging the '947 patent would not necessarily be limited to the UK.[2274] A successful challenge in one jurisdiction could entail a series of challenges in other jurisdictions (where patent litigation was also significantly less costly than in the UK), such as Teva's annulment action in the Netherlands and the Czech Republic following the annulment of the '947 patent in the UK. It is recalled that Ratiopharm, Krka's partner, was considering litigation strategies not only for the UK, but also France, the Netherlands and other markets.[2275]

(1691) The evidence demonstrates that the invalidation of the '947 patent was perceived by Servier not as a marginal risk, but a real concrete possibility.[2276] According to Krka's contemporary documents on contacts with Servier in spring 2005, Servier had warned Krka not to enter prior to September 2008, when the process patents expired.[2277] Although this occurred already a year after the grant of the '947 patent which would run until 2021, it would appear that at the time, prior to the Opposition

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2270 See Krka's claim that it "*had to react and thus on 1 September 2006, launched a counter-action*". See Krka's reply to the Statement of Objections, paragraph 75, ID8742, p. 43.

2271 See paragraph (912).

2272 See paragraph (904).

2273 See paragraph (904). See also Servier's reply to the Statement of Objections, paragraphs 920 and 921, ID10114, p. 324. In its reply to the Letter of Facts, Krka points to the exposure to the risk of bearing own and Servier's litigation costs, which reportedly reached around EUR 4.7 million in the Krka and Niche litigations (ID10202, p. 33). The Commission observes that this position is not fully consistent with Krka's own actions – when Servier brought the patent infringement action, Krka did not seek to terminate litigation, but extended its scope by bringing invalidity counterclaims. The Commission also notes that Krka's EUR 4.7m cost estimate is overinflated, as it combines the combined cost of no less than three different litigations, including the Apotex one, which comprised four sets of proceedings (interim injunction, first instance, appeal, and action for damages) (see paragraph (609)).

2274 Servier's reply to the Statement of Objections, paragraph 1047, ID10114, p. 356.

2275 See paragraph (869).

2276 For the sake of clarity, the Commission reiterates that this does not exclude the possibility that Servier would prevail on the account of the validity/infringement of the '947 and/or '340 patent. See, for example, Servier' reply to the Statement of Objections, paragraph 982, ID10114, p. 339. See also footnote 1652.

2277 See paragraph (837).

Decision, Servier did not expect to enjoy such long protection from the '947 patent. Servier was aware of the aforementioned position of the UK court concerning the strength of Krka's arguments for invalidity. In addition, in the course of the Krka litigation, concerning the issue of prior art, Servier made representations that its perindopril's API was not tested for crystalline form structure before the priority date of the '947 patent. However, in the course of the Apotex litigation, Servier's witness admitted that this information was not accurate and that "*Servier did analyse the crystalline form of the active pharmaceutical ingredient (API) perindopril […] before the priority date of the patent*". In view of this, "*Servier […] made an admission that the API in Servier's perindopril product, marketed before the priority date of the Patent, is the alpha crystalline form claimed in the Patent"*[2278] (ID0371, p. 973), which entirely corroborated one of Krka's claims for invalidity. However, Servier later withdrew this admission. Finally, it appeared that at the time of the Krka settlement, Servier had not carried out the necessary experiments aimed at rebutting the claim that the '947 patent was anticipated in the prior art. When these experiments were eventually carried out only a couple of months later, Servier stated in March 2007 that "**we [Servier] anticipate an unfavourable decision for us*".[2279]

(i) The '340 patent

(1692) According to Servier, the Commission's assessment disregarded that Krka was equally exposed to the risk of infringement of Servier's process patents, and Servier's legal action before English courts also claimed infringement of the '340 patent protecting a manufacturing process.[2280] The Commission recalls that it is not necessary, and outside the Commission's remit, to determine whether Krka's product infringed Servier's patents. To properly assess the context in which the Krka Agreements were concluded, and conclude that Krka had a real concrete possibility to overcome Servier's process patents, the Commission took the following elements into account. First, Krka itself underlines that the process patents were not the main obstacle to entry: "*it was not the '339 patent, '340 patent or '341 patent but rather the '947 patent, which constituted the main obstacle to entering the perindopril market…*".[2281] No internal evidence by Krka was found to suggest that Krka, which had used both in-house and external patent advice on the question of process patents, had identified significant concerns of infringement of Servier's process patents. The DLA Piper letter, to which Servier refers, recognises that, concerning the '339, '340 and '341 patents, there are "*a number of differences in each case which should avoid any finding of infringement in the UK based on a literal construction. English law does not have a 'doctrine of equivalents'*". While the memo raises the possibility that Servier may claim infringement based on equivalence arguments, it contains no

2278 ID0371, p. 973.

2279 See paragraphs (179) and (191). Servier claims that the fact that it did not discontinue litigation as suggested in the document showed that it preserved the confidence that it could still win in litigation (Servier's reply to the Statement of Objections, paragraphs 233, 1027, ID10114, p. 130, 351), Servier however provides no proof to substantiate its attack on the relevance of this document, which was addressed by head of patent department to top managers in Servier. Moreover, Servier fails to explain why other motives could not equally well explain Servier's persistance in litigation (see for example email by Servier's head of patent to top Servier management advising that Servier stood virtually no chances with an appeal of the High Court decision, but that an appeal would nonetheless be helpful to prolong uncertainty in the market – paragraph (185).

2280 Servier's reply to the Statement of Objections, paragraphs 943 and 986-990, ID9070, p. 330 and 341-342.

2281 Krka's reply to the Letter of Facts, ID10202, p. 12-14.

assessment how likely it was for such arguments to be upheld.[2282] Second, Servier's analysis of Krka's perindopril in January 2006 recognised that the impurities profile of Krka product did not signal an infringement of Servier's patents. Neither in its replies to the requests for information nor in its reply to the Statement of Objections did Servier submit internal documentation which would supersede the earlier findings. Even after Krka disclosed its confidential process description,[2283] Servier's strategy document dated 19 June 2006 suggests that no process patent issues were perceived with Krka's perindopril.[2284] While the document finds that some generic companies were infringing process patents (at least Apotex and Glenmark), no such remark was tagged to Krka's perindopril. Third, even if in the course of negotiations of the agreement with Servier in May 2006 Teva abandoned Krka as a supplier for the UK, allegedly for a higher likelihood of process patent infringement than with Teva's own product,[2285] Teva nonetheless continued discussions with Krka for other markets where the same patents were in force.[2286]

(ii) Supplies at risk

(1693) The parties observe that neither Krka nor its commercial partners were minded to supply at risk following the Opposition Decision.[2287] However, it is mainly the ability to enter, and not the current intentions to enter that determines whether an operator exercises a competitive constraint on the incumbent. While supplies at risk

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2282 ID0297. Parties (see Servier's reply to the Letter of Facts, ID10289, page 142-143, Krka's reply to the Letter of Facts, ID10202, p. 12-14) also point to various parts of the memo which suggest that a judge could decide either way. These passages, however, do not make a distinction between the process patents and the '947 patent, which was considered the "*strongest patent Servier has against Krka*", and thus have limited relevance for the issue of process patents. Servier's claim that the latter quote suggests that other patents were also considered strong is without merit, as the only conclusion the quote allows is about the perception of the relative strength of the relevant patents.

2283 ID0297, p. 1.

2284 ID0105, p. 177-180. Servier claims that the process patent infringement was not reflected in the document for two reasons. First, Krka's process description was confidential, subject to Chinese walls provisions and could thus not be disclosed to [employee name of Servier]*. Second, Krka refused to provide product samples (Servier's Letter of Facts, ID10289, p. 164-165. In the Commission's views, these arguments are unconvincing. First, confidentiality provisions precluded the disclosure of the process, but not of the recommendations/legal assessment within the company. Second, concerning Krka's refusal to provide samples, the Commission recalls that Servier had already collected and analysed samples of Krka's product as early as January 2006. Krka's refusal therefore appears unlikely to hinder Servier's analysis.

2285 Teva considered that " *Krka's probability of winning is also considered high but not as high as with the Teva product. The probability of Servier getting an injunction on the basis of the process patents is considered very low*" ID10239, p. 646. Servier refers to Teva's notice to Krka informing it would terminate UK negotiations based on Teva's assessment of the ROS (reply to the Letter of Facts, ID10289, p. 144). The Commission notes that Krka's representative replied as follows: "*Being quite frank with you I don't believe that ROS issues are the main concern for Teva since the decision at your side was made even before additional questions have been raised and answered from our side*" (ID7707, p. 39).

2286 See paragraph (881) and ID10239, p. 648 Servier claims that Teva's continuation of negotiations with Krka for France, Germany, and the Netherlands provides no indication that Krka's product would not be infringing Servier's process patents in the United Kingdom, as judgments may diverge across jurisdictions (Servier's reply to the Letter of Facts, ID10289, p. 144). The Commission does not dispute that, but notes nonetheless that the document reflects Teva's willingness to take on the exposure to Servier's claims of process-patent infringement for these markets (in this respect, see footnote 2285 above).

2287 Servier's reply to the Statement of Objections, paragraph 935, ID10114, p. 327, Servier's reply to the Letter of Facts, ID10289, p. 165-166.

were indeed not Krka's principal option for the 18/20 markets immediately after the Opposition Decision and at the time of the settlement, it is incorrect to say both that this risk-averse stance was irreversible and that launches at risk by Krka and its partners were entirely ruled out even at that time. First, Krka did not withdraw from the five CEE markets following the Opposition Decision, but continued unabated to market at risk its generic perindopril, although it was facing uncertainty from on-going or possible future litigation (typically once pending patents were granted). Krka was moreover successful in having an interim injunction application rejected by a Hungarian court in October 2006. In the Western European markets, Krka was also supporting Ratiopharm's preparations for launch at risk in the Netherlands in August 2006, a plan seriously pursued by Ratiopharm[2288] but eventually abandoned due to delays by Krka.[2289] Second, even though after the attempt in the Netherlands Krka and others eventually ceased to consider entering at risk in the UK, France and other Western European markets in the aftermath of the Opposition Decision, this did not exclude a return to a more aggressive policy in case the circumstances changed. This, for example, happened in the Netherlands, where Apotex entered at risk following the favourable judgment of the English court revoking the UK part of the '947 patent in July 2007. There are several other indications that Krka, or its partners, were not *a priori* risk averse.[2290]

(iii) Krka had a number of cooperation partners and broad coverage of EU markets

(1694) This section will demonstrate that Krka's perindopril activities was not limited to the markets where it could rely on its own local networks (traditionally the CEE markets), but also intended to supply numerous Western European markets.

(1695) Krka had concluded, or negotiated, a number of agreements for the licence of the regulatory dossier and the supply of its perindopril in Western Member States to large generic companies (Ratiopharm,[2291] Stada and Teva[2292]). Krka and Servier argue that the 18/20 markets were not a priority for Krka, as they did not belong to Krka's "core" markets in Central and Eastern Europe, and there were no forecasts supporting that Krka had the capacity to launch major quantities of perindopril.[2293]

(1696) This is incorrect. Although Krka's direct local presence in Western Europe was limited compared to the CEE markets, Krka cooperated with the aforementioned

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2288 "*We took the risk to have the product listed on the dutch list (this is necessary to be able to market the product), which is already an patent infringement. Nevertheless we would have launched the product if it would have been available*", ID0045, p. 120. See paragraph (893). This is not in contradiction to Krka's claims that it was ultimately Ratiopharm which decided not to launch (Krka's reply to the Letter of Facts, ID10202, p. 35-36).

2289 In that period, Krka was already in discussions with Servier (see paragraph (898) - (901)), which could also have affected its incentives to fully support Ratiopharm's launch at risk.

2290 See paragraph (873): before the Opposition Decision, Krka mentioned the need to reflect on the reservations for potential damage claims in Finland and Denmark. Paragraph (881): Teva was considering its options in view of the (low) likelihood it would be injuncted with Krka's process in Germany, the Netherlands, and France, and the pending opposition procedure for the '947 patent.

2291 Krka claims that the Commission's assessment disregarded the effects of the Opposition Decision, which, for example, led Ratiopharm to withdraw its plans to launch in the UK, France, and elsewhere based on Krka product. (Krka's reply to the Statement of Objections, paragraph 149, ID8742, p. 76), However, Krka fails to mention that Ratiopharm affirmed that the two "*should try as much as possible to revoke this strange decision of the Opposition Division*"(see paragraphs(895) - (896)).

2292 See paragraphs (866) and (867).

2293 Krka's reply to the Statement of Objections, paragraph 162, ID8742, p. 83, Servier's reply to the Statement of Objections, paragraphs 1044-1046, ID10114, p. 355-356.

large scale distribution/licensing partners (for example, prior to the Opposition Division decision, Ratiopharm was planning launches in the UK, France, the Netherlands, and a number of smaller markets[2294]) and, accordingly, its marketing authorisation applications covered virtually the entire EU. In keeping with this, its envisaged API quantities for perindopril formulations in Western Europe exceeded the ones for CEE Member States manifold (140 kg API expected for key CEE markets and Russia, against 800 kg for Western European Member States).[2295]

(1697) In the aftermath of the Opposition Decision, an EU-wide launch was no longer an option, pending the appeal procedure. Servier is correct to claim that even if Krka's on-going national litigation (in the UK and Hungary) were successful, this would not affect the validity of the '947 patent in the other Member States.[2296] This said, it is plausible that either Krka or its local partners would initiate new litigation in other Member States, all the more if the '947 patent were revoked in an on-going trial (as was for example the case with Apotex and Teva, which started litigation in the Netherlands and the Czech Republic after the '947 patent was revoked in the UK).[2297]

(1698) Servier moreover contends that launch at risk was not possible in all the 18/20, mostly Western European, markets to which the Commission's objections related, as Krka had not applied for marketing authorisation in all of these markets (e.g. Spain and Sweden).[2298] The Commission observes that the use of decentralised/mutual recognition procedures makes it fairly expedient to apply for a marketing authorisation in a new market based on a marketing authorisation in another RMS.[2299] Krka had numerous licensing/distribution partners and, as evidence shows, it is fair to assume that Krka would be responsive to their initiatives to enter new markets.[2300] As the settlement prevented this possibility for Krka for the investigated period, the Commission is not in a position to verify this plausible hypothesis.

(iv) Intention to enter

2294 See ID5656, p. 57: " *The countries of interest are:*
2 mg: DK, FR, NL, UK
4 mg: BE, CH, CZ, DK, FI, FR, HU, IT, NL, PL, PT, SK, ES, UK
8 mg: CZ, DK, FR, NL, PT, UK, maybe more".
The parties claim that this information was rendered irrelevant by the Opposition Decision, which affected the generic companies means and incentives to enter the market (Servier's reply to the Letter of Facts, ID10289, p. 145, Krka's reply to the Letter of Facts, p. 16-19). This argument is addressed in paragraph (1697).

2295 See paragraph (839).

2296 Servier's reply to the Statement of Objections, paragraph 1047, ID10114, p. 356, and reply to the Letter of Facts, ID10289, p. 161-162.

2297 See Table 6. Servier argues that there were only a limited number of proceedings showing that to commence litigation in several jurisdictions was not viable, that the scenario in which Krka would commence litigation in other jurisdiction was purely theoretical, that parallel actions to EPO opposition procedures were not possible in Germany, and likely stayed in certain other jurisdictions, such as France and Spain, and that reference to later litigation conflicts with the Commission's proclaimed approach of ex ante assessment of facts (Servier's reply to the Letter of Facts, ID10289, p. 169-171). From an *ex ante* perspective, the Commission considers that the settlement could remain in force, wholly or partly, until 2021. During this extensive period of time, the market situation could modify significantly, amending the companies incentives to litigate significantly. Reference to actual Apotex and Teva litigations merely illustrates that this possibility is not purely theoretical.

2298 Servier's reply to the Statement of Objections, paragraphs 995-996, ID10114, p. 343-344.

2299 While Servier correctly observes that Krka did not ask for an Sweden, Krka did apply for a Spanish marketing authorisation (see, for example, ID4968, p. 8).

2300 See, for example, ID5656, p. 51.

(1699) There is abundant evidence that, before the Opposition Decision, Krka intended to launch perindopril in the UK and elsewhere in the 18/20 markets, mostly through cooperation partners.[2301] Moreover, even after the Opposition Decision, Krka appeared willing to support launches at risk by its generic partners, as exemplified by Ratiopharm's attempt to enter the Dutch market in August 2006. Krka, which was in patent litigation with Servier, also remained committed to supply its existing perindopril product in case the patent barriers were overcome. While Krka did start developing a non-alpha perindopril, Ratiopharm urged it to supply its existing, "old", perindopril product in case the '947 patent was invalidated.[2302] Indeed a number of Krka's distribution partners launched Krka's "old" perindopril once the '947 patent was invalidated in the respective markets.

(v) Intermediate conclusion – Krka was at least a potential competitor

(1700) Krka was an actual competitor to Servier in the supply of perindopril products in the Member States where it had already launched its generic perindopril (i.e. the Czech Republic, Hungary, Poland, Lithuania and Slovenia). In addition, Krka had received marketing authorisations in a number of Western European markets (with more to come). Krka's confidence in the invalidity of the '947 patent was somewhat reduced following the Opposition Decision, which it found surprising, and it also started developing a non-alpha form of perindopril. Contemporaneous facts show that Krka continued its challenge to the '947 patent: "[*Krka*] *shall not let them go just like that*".[2303] Krka not only filed invalidity counterclaims in the context of UK proceedings brought by Servier, but also succeeded in rejecting an application for interim relief in Hungary. Moreover, it was at least in principle willing to support Ratiopharm's attempt to launch at risk in the Netherlands. On balance, this suggests that Krka had a real concrete possibility to overcome in particular the remaining patent barriers for entry with its generic perindopril. The elements presented in the above paragraphs indicated that Krka had the ability and the intention to enter these restricted markets within a sufficiently short period of time, and was thus a potential competitor to Servier for the production of perindopril products in the 18/20 EU markets (including France, the Netherlands, and the UK).

5.5.3 The Settlement Agreement and Licence Agreement between Servier and Krka constitute a market sharing agreement which restricts competition by object under Article 101(1) of the Treaty

5.5.3.1 Introduction

(1701) The legal assessment in this chapter will, in accordance with well-established case-law of the Court of Justice,[2304] take into account the economic and legal context

2301 See for example, paragraphs (865) – (870) and (1698). Servier questions this, claiming that "**the declarations of Krka in June/July 2006 concerning its intention to enter the UK market seem to have been motivated by the desire to capitalise on the MA rather than to actually enter the market* " (Servier's reply to the Statement of Objections, paragraph 942, ID10114, p. 329). This is disproved by the fact that Krka had discussed and/or secured agreements with large generic partners, such as Ratiopharm and Teva, and Krka affirmed that"*in expecting revocation at the EPO, Krka has had a product on UK border – our threat for UK was a real and imminent one - trucks with Prenessa were on the way to UK and the product prepared for launch*". ID1307, p. 84.

2302 See footnote 2268.

2303 See paragraph (1688).

2304 See Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 58 and the jurisprudence cited therein. See also Joined judgments in *Football Association Premier League and Others*, C-403/08 and

leading up to the agreement's conclusion as it appears from the facts described in this Decision. This analysis will rely on the above conclusion that Servier and Krka were at least potential competitors at the time when they concluded the agreement. Firstly, it will be assessed whether there is a link between the Settlement Agreement and the Licence Agreement. In a second step, the actual content, implementation and objectives of the Settlement Agreement and the related Licence Agreement will be examined. This analysis will in particular identify Krka's commitments and examine the *quid pro quo* of the agreement. Finally, each party's subjective intentions regarding the agreement will be examined to see whether they match the analysis of the objective elements of the first two steps.

5.5.3.2 Establishing links between the Settlement Agreement and the Licence Agreement

(1702) The two agreements[2305] are technically separate agreements. However, regardless of their form, the two agreements are economically connected, and the conclusion of each of the agreements was interdependent on the conclusion of the other agreement.

(1703) The main elements for establishing a link between the Settlement Agreement and the Licence Agreement are as follows:

- Draft Licence Agreement dated 19 October 2006 shows that explicit references to Krka's generic perindopril development and launches, alongside with references to Servier's patent infringement claims and to litigation, were removed from the text.
- Both agreements bear the same date, relate to exactly the same subject matter, i.e. production and supply of generic perindopril by Krka.
- Krka explicitly acknowledges that it only settled with a view to obtaining a licence for the '947 patent to remain / launch on the seven CEE Member State markets.
- Clause V of the Settlement Agreement generally prohibits Krka from launching, supplying etc. perindopril in alpha form. However, it contains a derogation in case such supply is expressly authorised by Servier. This clause can thus be understood as the legal interface overbridging the general prohibition in the Settlement Agreement in view of the Licence Agreement.
- Both agreements appear to be drafted on the basis of the same standard template and were signed by the same representatives of both Krka and Servier who cannot ignore the existence of both contracts.

(1704) Based on these arguments, one can clearly infer that the two agreements are economically linked, and shall be henceforth referred to as the "Krka Settlement Agreement".

5.5.3.3 Terms of the Krka Settlement Agreement

5.5.3.3.1 An agreement between undertakings

(1705) In view of the case law mentioned in section 5.2.1.3.1, the Krka Settlement Agreement is an agreement, and Krka and Servier can be considered as undertakings

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C-429/08, EU:C:2011:631, paragraph 136; and Judgment in T-Mobile Netherlands and others, C-8/08, EU:C:2009:343, paragraph 27.

[2305] For factual background, see section 4.3.3.6.

within the meaning of Article 101 of the Treaty. The Krka Settlement Agreement is therefore an agreement between undertakings within the terms of Article 101(1) of the Treaty.

5.5.3.3.2 Restrictions on competition disabling or hampering Krka's ability to enter the market in a timely and viable way

(1706) Before the Settlement Agreement was concluded, Krka was free to pursue its commercial activities with the aim of entering new markets in a timely and viable manner, or to continue to viably market generic perindopril, including by pursuing the legal actions involving Servier.[2306] The Settlement Agreement contains two key restrictions of this ability to compete, namely (i) a non-challenge obligation, and (ii) a non-compete obligation, effectively meaning that Krka could no longer compete with its existing perindopril product, which was in the alpha crystalline form, in the respective markets.[2307] These restrictions were obtained in exchange for a significant inducement flowing from the Licence Agreement with which Servier granted an asymmetric licence to Krka. The licence is considered asymmetric as it was granted for seven Member States considered to belong to Krka's core markets, while Krka was, through the terms of the patent settlement, excluded from the remaining EU markets where it was preparing to launch perindopril and contesting Servier's position.

(1707) The subsequent analysis aims to establish whether the Krka Settlement Agreement, viewed as a whole, can be seen as a restriction of competition eliminating Krka as a potential competitor in the markets where Krka committed to withdraw from competition for the periods foreseen in the agreement itself.

(1708) As explained, Krka considered that the crucial patent protecting Servier's market exclusivity, the '947 patent, was anticipated in the prior art, and thus invalid.[2308] Krka, whose product at the time contained alpha crystalline form protected by the said patent, thus had an interest in having the patent annulled, and had initiated both EPO opposition proceedings and, after the Opposition Decision, annulment proceedings in the UK as a counterclaim to Servier's infringement/interim injunction action.

2306 Krka argues that this finding is misconceived, and based on facts unknown to Krka at the time of the settlement, when, after the Opposition Decision, Krka believed it clearly infringed the '947 patent, and did not feel free to continue with launch preparations (Krka's reply to the Statement of Objections, paragraphs 108 and 111, ID8742, p. 56-57). This is unfounded. The analysis is strictly based on *the ex ante* perspective and examines Krka's commercial and legal options that Krka could – and did – pursue prior to the agreement, notably its invalidity actions against the '947 patent, defence against the interim injunction in Poland, and continued marketing in the five markets where Krka had already launched. As established in section 5.5.2, Krka remained a competitor of Servier.

2307 Servier claims that, as reflected by a moderate 3% royalty rate, the protection offered by the '947 patent, was limited (Servier's reply to the Statement of Objections, paragraph 1003, ID10114, p. 345, Servier's reply to the Letter of Facts, ID10289, p. 149-151). While the very validity of the '947 patent was widely contested, the Commission does not concede that the scope of protection granted by that patent was narrow, given that the alpha form was considered by some as the most stable crystalline form (see, for example, ID1307, p. 59), and that some other forms appeared also to be converting to alpha (paragraph (347)), the patent (if valid) was perceived to have a very broad exclusionary scope (see, for example, paragraphs (2688) and (2689). While there were some projects to develop new, patent-free forms of perindopril, only one company, Sandoz, actually viably launched such perindopril before the '947 patent was invalidated by the EPO. Effective generic entry only happened once the '947 patent was annulled in national litigation or by the EPO.

2308 See, for example, paragraphs (830), (834) (844), (851), (873), (874) and (895).

(1709) According to Krka, the agreement was a legitimate way to end a genuine dispute as the parties found a mutually acceptable compromise,[2309] and the restrictions were essential to the settlement and did not go beyond the scope of the patents-in-suit.[2310] While the agreement between Krka and Servier is indeed assessed as a settlement based on a genuine dispute (and thus not a sham settlement), the fact that the parties reached a mutually acceptable compromise does not as such exonerate it from the purview of Article 101 of the Treaty, as this is common to the notion of an agreements. While settlements can generally be considered as legitimate means to avoid litigation, they are not exempt from Article 101 of the Treaty, in particular where the compromise was based on the restrictions of competition, and an economic inducement to accept the restrictions, as an arrangement to share the markets. In the present case, the assessment of restrictions cannot be done without taking into account the entire balance of considerations, in particular the inducement from Servier to Krka.

(1710) Thus, the assessment of restrictive provisions needs to take account of the combined effect of the two agreements forming part of the Krka Settlement Agreement, the Settlement Agreement and the Licence Agreement. The subsequent analysis aims to establish whether the two restrictive elements, the non-challenge and the non-compete obligation, brought about an immediate and absolute elimination in the 18/20 markets of Krka as a potential competitor, in return for a significant inducement to Krka.

5.5.3.3.2.1 The non-challenge obligation

(1711) The non-challenge obligation for Krka is contained in clause I(iv) of the Settlement Agreement, has a world-wide scope and relates to patent challenges of direct and indirect nature (i.e. through third parties).[2311] The non-challenge obligation thus requires withdrawal from all current invalidation actions, namely Krka's annulment actions in the UK aimed against both the '340 and the '947 patent and its opposition / appeal against the '947 patent before the EPO. Moreover, Krka was bound to refrain from any new challenges of these two patents in the EU or elsewhere.

(1712) The non-challenge obligation had two main consequences. First, it prevented Krka from establishing its technology as a *de iure* non-infringing technology for the production of perindopril for the entire EU, available both for own distribution of final perindopril products and for supplying customers for distribution in various markets.[2312] Second, the non-challenge obligation also prevented the objective legal

2309 Krka's reply to the Statement of Objections, paragraph 81, ID8742, p. 45-46.

2310 Krka's reply to the Statement of Objections, paragraphs 125-127, ID8742, p. 63-64.

2311 See paragraph (910).

2312 Krka argues that the Commission's assessment is incorrect, as Krka did attempt to establish its technology by launching EPO Opposition. After the Opposition Decision, situation however changed, and Krka decided to discontinue its disputes and settle (Krka's reply to the Statement of Objections, paragraph 121, ID8742, p. 61). Krka's argument deviates from the facts – the settlement did not coincide with Krka's initiation of opposition proceedings, but with Krka's litigation with Servier, including Krka's own counterclaim for revocation of the '947 patent, which was initiated after the Opposition Decision and before the settlement. This goes to show that Krka was not only free to continue its legal challenge to the '947 patent, but actually pursued this avenue. Krka also claims that the non-challenge obligation did not have any actual impact, as it could not enter the market with its existing perindopril before the EPO decision on appeal, but could enter with the new product (Krka's reply to the Letter of Facts, ID10202, p. 9-10). This position not only disregards Krka's actual challenges against the '947 patent before national courts, but also the potential to initiate (directly or through partners) further challenges.

review of patent validity (particularly for the '947 patent) based on Krka's challenge, disabling the possible benefit for Krka and other generic producers in case the patents were finally to be invalidated. For example, Ratiopharm and Krka had in the past discussed litigation strategies concerning the '947 patent in France, the Netherlands, Finland and Portugal.[2313] The Commission does not deny that the settlement did not preclude litigation by other companies.[2314] Yet, the object of the agreement was to remove the immediate competitive threat by Krka to Servier's position. In any event, Krka was one of very few companies involved in patent challenges before national courts (and not the first one to have settled litigation with Servier with an amicable arrangement with Servier), and also considered that it had a better case for the opposition procedure before the EPO.[2315] Given that the strength of arguments and/or evidence can vary significantly from one patent challenger to another, removing a strong challenger may impact the final outcome of the litigation/opposition.

(1713) To conclude, the non-challenge clause granted Servier a 100% certainty that Krka would not represent a competitive threat through its legal challenge to Servier's patent position, both concerning the validity and (non)infringement of the '947 and '340 patents.

5.5.3.3.2.2 The non-compete obligation

(1714) Clause V of the Settlement Agreement provides that *"[f]or the duration of the validity of the ['947] Patent, [Krka] shall not directly or indirectly launch and commercialize any generic form of the Specialty [i.e. pharmaceutical products containing perindopril API in the alpha crystalline form] and/or combination products containing the generic form of the Specialty which would infringe the ['947] Patent, in the countries in which the Patent is still valid, unless otherwise expressly authorised by SERVIER*". Likewise, Krka also warranted that it would not supply such perindopril to any third party.[2316]

(1715) Krka was at the time one of the only two generic companies (along Apotex) which managed to complete the independent development of generic perindopril and received marketing authorisations in a number of Member States. The non-compete obligation prevented Krka from launching its existing generic perindopril in a number of Member States (and elsewhere) in the following manner. Krka committed not to launch perindopril in the alpha crystalline form[2317] either directly or through third parties (Clause V(2) of the Settlement Agreement).

(1716) The Settlement Agreement implies a possibility for Servier to expressly authorise Krka to launch and commercialise generic products containing the "Specialty". This is the interface between the Settlement Agreement and the Licence Agreement, both constitutive parts of the Krka Settlement Agreement as established above. In turn, the Licence Agreement[2318] granted express authorisation for Krka to commercialise its

2313 See paragraph (869).

2314 See, in this respect, Servier's reply to the Statement of Objections, paragraphs 984-985, ID10114, p. 340, Servier to the Letter of Facts, ID10289, p. 161-162, Krka's reply to the Letter of Facts, ID10202, p. 37-38.

2315 See paragraphs (851), (867), (874).

2316 See paragraph (908).

2317 It is noteworthy that no reference to the '340 patent, also subject matter of the underlying litigation, is made.

2318 See paragraph (910).

generic perindopril in seven CEE Member States (i.e. Czech Republic, Hungary, Lithuania, Latvia, Poland, Slovakia and Slovenia). As a consequence, the limitation of the Licence Agreement to the seven CEE Member States signifies that the non-compete obligation applies to the remaining 18/20 Member States[2319] (also "the restricted Member States"). In many of the restricted Member States, Krka's perindopril was one of the first ones to receive marketing authorisations,[2320] and thus closest to the actual product launch. France, the Netherlands and the UK can be singled out as such countries.

(1717) The duration of the agreement was limited and would run until the expiry of the '947 patent, that is to say 2021, and/or termination of validity of the '947 patent and/or the '340 patent in the respective territory. Although Clause II provides that the Settlement Agreement does not apply to jurisdictions where no valid national counterparts of the '947 patent application and/or the '340 patent exist, the agreement effectively covered the whole of the EU.

(1718) To summarise, the non-compete obligation meant that Krka and/or its distribution partners in the EU were contractually prevented from commercialising its existing generic perindopril (in the alpha crystalline form) in the restricted Member States for which no licence was granted and where marketing authorisations were obtained, imminent or envisaged. The restriction applies both to situations where Krka would supply generic perindopril directly and to situations where it would supply the market through a local partner, as was planned for most of the restricted Member States.[2321] Thus, the Krka Settlement Agreement induced Krka to abandon its prerogatives under patent law (in addition to patent invalidity and non-infringement actions, to launch at risk or to be a source of future supplies to other companies willing to challenge Servier's patent position).

(1719) Krka claims that the agreement was not restrictive, as the company remained free to invent around the '947 patent, which it in fact did and received marketing authorisations in autumn 2009 and during 2010.[2322] The claim that the non-compete obligation concerns only the patents-in-suit (notably the '947 patent) is incontestable. Under the settlement agreement, Krka remained free to develop other forms / salts of perindopril, and indeed took on the development of an alternative, non-alpha form of perindopril. However, the fact that the agreement did not completely eliminate all avenues for Krka to develop generic perindopril does not mean that the agreement was not restrictive. The development of a novel form of perindopril also implied a significant delay of a possible entry into the market (according to Krka, two to

2319 Prior to the accession of Bulgaria and Romania, i.e. for the period 27 October 2006 – 31 December 2006, the assessment only covers 18 restricted Member States.

2320 See, for example, Table 9.

2321 Servier claims that the non-compete clause was inherent to the settlement, as it would have made no sense for Servier to settle if Krka remained free to launch at risk (Servier's reply to the Statement of Objections, paragraph 992, ID10114, p. 342-343). The Commission clarifies that it does not object to the non-compete obligation as such. As explained in paragraphs (1706) and (1707), the Commission's conclusions concern only the combination of the restrictions with the significant inducement to accept such restrictions, and thus catch the Krka Settlement Agreement as a whole. The Commission moreover agrees with Servier that non-challenge and non-compete obligations are complementary and mutually reinforcing. They provide more protection to Servier than if only a single type of these obligations were used.

2322 See paragraph (964).

three years[2323]), and, not least, the significant uncertainty whether the new development project would at all be successful.[2324]

(1720) Krka furthermore contends that since the non-compete obligation was limited to perindopril covered by the '947 patent, there was no restriction as Krka's perindopril would be excluded by that patent in any event. In other words, Servier in fact needed no such contractual clause to prevent the commercialisation of Krka's perindopril.[2325] The Commission holds that the fact that the obligation was limited to alpha form perindopril is not decisive for the legal assessment. It is true that Servier could (and in fact did) attempt to bar the marketing of alpha form perindopril without the need for a contractual non-compete obligation. Yet, the non-compete obligation provided an advantage in that it excluded the alleged infringer without the need to establish, by a court of law, that it was in fact infringing a valid patent. Krka was supplying at risk already, and actually avoided an interim injunction in Hungary, while other companies launched in the UK, and later in the Netherlands. A patent does not give patent holders the right to exclude competitors and their technology in return for an inducement. Yet, the non-compete obligation effectively prevented the generic company from launching at risk[2326] (and probably facing litigation), or agreeing to supply third parties which may have the incentive to initiate litigation or launch at risk in the markets covered by the settlement[2327]. Such effects will be even stronger when the generic company is also prevented from launching a patent challenge.

5.5.3.3.2.3 Servier's interest in Krka's commitments as a part of the Krka Settlement Agreement

(1721) The restricted markets included Servier's globally biggest national markets for its perindopril (such as France and the UK) for which Krka had obtained or was about to obtain marketing authorisations and entered or was about to enter into a number of supply arrangements with generic companies active in these markets. Servier reported an EBIT profit of EUR [nine digit figure] from the sales of perindopril in 2006 in the main national markets for which Krka agreed to abstain from entry.[2328] At least a significant part of that profit would have been lost for Servier if Krka had managed to enter the market with its generic perindopril and/or had prevailed in patent litigation (which Krka strategy documents considered to be amongst the company's most important strengths vis-à-vis Servier).

(1722) Contemporary evidence on planned API production suggests that in terms of quantity, Krka expected to sell much more in Western European markets than in CEE Member States.[2329] Krka moreover concluded a number of licence and supply

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2323 See paragraph (913).

2324 "*Any generic medicinal product must be bioequivalent and a new polymorphic form requires substantial development work on formulation to be bioequivalent with reference product (originator), with no warranty of success (it should be stressed that complexity of the development of generic product is usually underestimated as simple copying, while it is less known that all major generic companies are regularly facing unsuccessful development)*", "*[…] one of the main reasons [for Krka's challenge to the '947 patent] was also the inability to develop around the '947 patent…*" See Krka's reply to the Statement of Objections, paragraphs 8, 10, ID8742, p. 10, 11.

2325 Krka's reply to the Statement of Objections, paragraphs 132-134, ID8742, p. 65-67.

2326 See paragraphs (1176) and (1693).

2327 See paragraphs (1693) to (1698).

2328 Member States included for the purpose of this calculation are: Belgium, Greece, the Netherlands, the UK, France, Ireland, Portugal, Germany, Italy and Romania.

2329 See paragraph (839).

agreements with large generic companies, such as Stada and Ratiopharm, with which it had discussed launch and litigation strategies for a number of markets, including France and the Netherlands.[2330]

(1723) The restrictions of the Krka Settlement Agreement remove the threat emanating from Krka and/or its distribution partners both to Servier's patents and market position in the restricted markets for a multi-year period, potentially even until the '947 patent's expiry in 2021.

(1724) Although the grant of a licence for the '947 patent did entail certain opportunity costs for Servier (as it could no longer assert the '947 patent against Krka in the future in an attempt to outright exclude Krka), the sole licence to Krka also ensured an arrangement whereby both Servier and Krka committed not to introduce a third competitor on the market. Provided that there were no other independent entrants in view of the remaining uncertainty for the generic (unable to get a licence), the licence secured market stability to the only two players on the market.

(1725) Servier claims that it had "**interest instead in establishing a commercial partnership with Krka for countries where the latter was well established*", whereby "**[t]he licence granted by Servier to Krka falls within Servier's policy of developing its revenues linked to perindopril"*. Servier in particular argues that such commercial partnership would allow it to benefit from Krka's promotional efforts for its perindopril[2331] and explains that co-marketing agreements are frequent in the pharmaceutical sector.[2332] The Commission notes that the licence agreement provided for no commercial partnership with Krka beyond the payment of royalties. There was no co-marketing agreement. On the contrary, Servier devised and implemented a number of actions to confront generic penetration by Krka, for example, in Poland, which included the "**Aikido*" strategy accompanying Servier's switch to perindopril arginine (which was not substitutable with Krka's perindopril erbumine),[2333] pharmacy stock saturation,[2334] and the complaint to Polish authorities that Krka's promotional materials for Prenessa amounted to unfair competition.[2335] This shows that Servier's attitude towards Krka in the seven licensed markets could hardly be described as one of cooperation.[2336] Moreover, Servier's perindopril arginine was not substitutable for Krka's perindopril erbumine product in Poland, and

2330 See paragraph (881).

2331 Servier's reply to the Statement of Objections, paragraphs 943, 955, 956, ID10114, p. 330, 333. This claim is also assessed under Article 101(3) of the Treaty in section 5.7.3.2. The Commission notes that this argument seems to be in contradiction with Servier's statement that the only advantage from the settlement agreement for Servier was to avoid litigation and to avoid the exposure to damages claims to Krka and Ratiopharm in case of defeat (Servier's reply to the Letter of Facts, ID10289, p. 175. In this respect, the Commission notes that Servier's arguments fail to explain why Krka's entry was restricted in the 18/20 markets, if Servier's interest was only to avoid litigation costs and potential claims for undue exclusion from the market.

2332 Servier's reply to the Letter of Facts, ID10289, p. 156-157.

2333 ID9971, p.157-163, ID9973, p.55-60.

2334 See paragraph (2350).

2335 See paragraph (876).

2336 Servier argues that the Commission's reference to Krka's entry as a threat to Servier is at odds with the description of the market conditions post-settlement as a de facto duopoly (reply to the Letter of Facts, ID10324, p. 155). The Commission notes that the two concepts are not irreconcilable. Even if Servier initially reacted defensively to Krka's entry in order to prevent or limit the diversion of perindopril sales to Krka, this does not imply that the market could not stabilise around two suppliers, in particular after the settlement agreement secured that there could be no other supplier with a status comparable to Krka's.

thus Servier could not benefit from a potentially broader penetration of perindopril erbumine resulting from Krka's promotional activities.

(1726) The CEE markets are typically branded generic markets, where there is in principle no automatic generic substitution and prescriptions refer to the brand. Therefore also generic companies need to promote own brands. Levels and speed of generic penetration may thus be inferior to those in markets with automatic generic substitution (prescription by the non-proprietary name (INN) rather than the brand).

(1727) Based on the sales and price data for Poland, it can be observed that the market equilibrium (notably concerning prices and market shares) was very stable throughout the period where only Servier and Krka were present. This is further exemplified by Servier's decision not to launch an own generic in Slovakia two years later, in November 2008: *"*no interest in it [Egis, part of Servier group] launching as long as there is no proven risk of a generic other than Krka capable of launching;"*[2337] It appears that the same strategy was followed concerning other licensed CEE markets.

(1728) Thus, even in the CEE markets where Servier has licensed Krka, this has not led to a situation where Servier's earnings would be significantly eroded by effective competition, but to a *de facto* duopoly with Krka which Servier itself sought to maintain to preserve its revenue stream. The Commission clarifies that this duopoly did not exclude a certain degree of competition between the parties.[2338] However, the number of competitors can influence the intensity of price competition, and Servier and Krka committed that they would not allow the entry of a third (licensed) competitor (for example, a licensed distributor, or authorised generic). Unlike in the UK, where the prices were driven down due to the presence of three generics from July 2007, Krka and Servier faced no other generic competition. While the Krka Settlement Agreement did not offer full protection against independent generic entry by third parties,[2339] there were no impending patent litigation procedures, no attempts to launch at risk or with a form of perindopril not covered by the '947 patent. Thus, even if there was still a degree of remaining potential competition, there was uncertainty whether these projects could lead to a successful entry in view of the high barriers to entry, and in any case, there would be a delay. This is why the situation is, for the purpose of this assessment, referred to as a *de facto*, and not *de iure*, duopoly.

(1729) Servier could thus draw significant benefits from the Krka Settlement Agreement. On the one hand, Servier shielded 18/20 EU markets, including two of its biggest markets, from competition from Krka's patent challenge and the existing perindopril product.[2340] The preceding analysis has shown that, in markets such as France, the Netherlands and the UK, the price reductions from generic entry were very

2337 See paragraph (965).

2338 See, for example, Servier's reply to the Statement of Objections, paragraphs 972 and 973, ID10114, p. 337.

2339 Servier's reply to the Statement of Objections, paragraph 976, ID10114, p. 338.

2340 Servier contests this on several grounds: first, the settlement only recognised Servier's valid rights which would exclude all infringing perindopril; second, only procedures with Krka were stopped, without prejudice to litigation with other companies before national courts or the EPO; and third, there was no risk of competition from Krka, as the latter had decided to develop a new form of perindopril and abandon the existing product (Servier's reply to the Statement of Objections, paragraphs 963-965, ID10114, p. 334-335). Concerning the first and the third point, reference is made to sections 5.1.3 and 5.5.2, and for the second point, to paragraph (1712).

significant, and the consumers could benefit from price cuts ranging from 27% to as much as 90%.[2341] On the other hand, Servier provided legal certainty for Krka's commercial presence in the remaining seven branded generic markets, where generic competition resulted in more limited, while still significant, price reductions (for example 17% in Poland).[2342]

(1730) This finding is corroborated by a contemporaneous assessment of the Krka settlement by Lupin, an outside observer:[2343]

"It would seem the rationale for this settlement from Servier's view is that it protects the key markets where high level substitution and/or INN perscribing is prevelant [sic] *(UK / France) …*

By allowing Krka to enter branded generic markets of CEE it creates 'brand' competition amd [sic] *more controlled erosion, but does not lead to a 'land-slide' switch to generics".*[2344]

5.5.3.3.3 Inducement for the restriction - Krka's interest in Servier's commitments as part of the Krka Settlement Agreement

(1731) Unlike the other settlements assessed in this decision, the Krka Settlement Agreement contained no cash payment from Servier to Krka. This assessment will establish that the licence Servier granted to Krka for the seven EU markets induced Krka to accept the restrictive provisions of the agreement, and was actually an instrument for the undertakings to divide and allocate markets between themselves.

(1732) This section is divided into three sub-sections. First, the Commission will assess the licence itself, its importance for Krka and its precise purpose. Second, this section will examine the benefits of the licence to both Servier and Krka. Third, it will establish that the Licence Agreement provided a significant inducement for Krka to accept the overall terms of the Krka Settlement Agreement.

5.5.3.3.3.1 Specific assessment of the licence and its precise purpose

(1733) The Krka Settlement Agreement contains an advantageous sole licence which constituted an economic inducement for Krka to refrain from competing in the 18/20 restricted markets. The inducement made the amicable solution a more attractive proposition than the competitive scenario where Krka would continue challenging Servier's position across the EU. The inducement did not consist in a

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2341 See paragraph (2529).

2342 Servier states that it would have been difficult to prevent competition from Krka in the markets where it had already entered (either because no patent was yet granted, or because litigation outcome was uncertain, and an injunctions was unlikely to be granted to Servier) (reply to the Letter of Facts, ID10289, p. 157-158). First, the Commission observes that this contradicts Krka's claims that, absent the settlement, Krka would be forced to exit these markets (for example, Krka's reply to the Letter of Facts, ID10202, p. 23). Second, the claim is consistent with the Commission's view that the licence was not a precondition for Krka's entry (notably, Krka had already launched on 5 out of seven licensed markets), but endowed Krka with legal and commercial certainty.

2343 See paragraph (915).

2344 Servier contests that this observation is irrelevant as it results from a third party and reflects a profound misunderstanding of the circumstances, in particular by ignoring the fact that the '947 patent was preventing Krka's entry (Servier's reply to the Statement of Objections, paragraph 969, ID10114, p. 336). The Commission clarifies that this evidence is not considered as direct proof of Krka's and Servier's objectives, and notes the following: (i) Lupin's views broadly correspond to Krka's stated objectives for the deal, (ii) Lupin's document does take into account the existence of the '947 patent, as it elaborates various scenaria dependent on the then on-going UK litiation on the '947 patent.

cash payment, but in allocating markets where Krka would be allowed to market perindopril alongside Servier, while the 18/20 other markets would be allocated to Servier and Krka would have to withdraw from competing.

(1734) In the framework of the Krka Settlement Agreement, Krka received a sole licence[2345] on the '947 patent for seven Member States (Czech Republic, Hungary, Lithuania, Latvia, Poland, Slovakia and Slovenia). The licence stipulated royalty payments amounting to [0–5]* % of Krka's sales of products containing the alpha polymorph of the perindopril erbumine.[2346] As will be further explained below, the licence had advantageous terms and ensured a *de facto* duopoly with Servier in view of the companies' position in these seven markets and is thus analysed as an inducement to Krka as part of the market sharing arrangement.[2347]

(1735) The Krka Settlement Agreement does not mention any other specific cost or performance on the side of Krka to the benefit of Servier which would be capable of explaining why Servier granted Krka a licence. It explicitly provides that the parties shall bear their own costs of litigation (Clause I(iii)).

(1736) Servier's competitive relationship with Krka was thus contractually structured in an asymmetric way, while providing economic incentives for both parties. On the one hand, the non-compete and non-challenge obligations of the Settlement Agreement covered all 27 Member States. On the other hand, the Licence Agreement which overrode the aforementioned non-compete obligation only covered seven CEE Member State markets. Servier thus gave up the possibility to assert patent infringement in these markets to Krka's benefit. In the remaining 18/20 markets (the restricted markets), Krka was contractually prevented from competing based on its patent challenge and the existing perindopril product.

(1737) The subsequent assessment will examine the benefits the arrangement secured for Krka and show that they served as an inducement for Krka to withdraw from competing fully with Servier.

5.5.3.3.3.2 Allocation of seven markets shared with Servier was an inducement for Krka's to refrain from competing with Servier elsewhere in the EU

(1738) Krka enjoyed strong commercial presence in the 7 Member States for which it received a licence. According to Krka, the opportunity cost of not concluding the Krka Settlement Agreement would amount to "*in 3 years well above €10 mio*" of lost profits.[2348] In other words, this is a rough estimation of the commercial value of the

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2345 The term "sole licence" is used within the meaning of paragraph 162 of the Technology Transfer Guidelines. Krka's claims that the Commission objects to the licence being a sole licence (Krka's reply to the Statement of Objections, paragraphs 143 and 146, ID8742, p. 72-75) are unfounded. The licence is assessed in the context of identifying benefits to Krka flowing from the Krka Settlement Agreement. This decision finds no infringement in the seven Member States for which the licence was granted.

2346 See paragraph (910).

2347 Krka claims that interpreting the Licence Agreement as an inducement would be misconceived and unsupported by evidence, and would amount to a claim that licensing is *per se* suspicious and problematic in competition law (Krka's reply to the Statement of Objections, paragraph 137-138, ID8742, p. 68-69). The Commission does not consider licensing as a restrictive practice in itself, but assesses whether the licence was for accepting to withdraw from competing in the remaining 18/20 markets, and is as such tantamount to market allocation.

2348 ID9927, p. 3. Servier makes the following criticism in this respect (reply to Letter of Facts, ID10289, p. 151-152). First, the figure provided by Krka is a "rough estimation" and therefore has limited probative value. The Commission recalls that this estimate is consistent with Krka's more detailed profit expectations provided in its reply to the Commission's RFI ([EUR 3-8 million] per year for the Czech

licence for the seven markets as reported by Krka. The following elements explain why the prospect of acquiring a licence from Servier was commercially attractive for Krka.[2349]

(1739) Firstly, the Commission finds that the level of royalties at 3% of Krka's sales value was sufficiently low to still represent an inducement to Krka[2350], in particular in view of the following: (i) Servier did not contest, but even implicitly acknowledged that the royalty rate was limited[2351]; (ii) the licence agreement granted Krka the status of a second seller in a situation where no other supplier was on the market, or was close to entering.[2352] and that (iii) if the agreement had been negotiated without any additional considerations related to the non-licensed markets, the rational licensor holding a position of market incumbent should have at least asked for a royalty close to its own foregone profit margins over the sales captured by the licensee. In this context, the Commission notes that Servier's EBIT margin was approximately [two digit figures]% in Poland, the Czech Republic and Hungary, as reported for the financial year 2007.[2353] In addition, the royalties were to be calculated on the basis of Krka's prices that were lower from Servier's prices. Finally, royalties for the amount

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Republic, Hungary and Poland combined, see paragraph (877)). Second, Servier claims that the Commission failed to show that Krka's expected earnings from 18/20 markets were inferior to EUR 10 million (the estimated value of the licence for seven markets). This is incorrect. First of all, the Commission took into account the fact that the 7 markets were Krka's most profitable core markets, and the fact that Krka obtained a sole licence. In addition, a comparison of Krka's profit expectations (see paragraphs (877) and (878)) shows that expected earnings from Western European markets roughly matched those from the three largest Central and Eastern European markets. These profit expectations are comparable, provide insight into their relative size/ratio, and thus generally represent the way Krka valued its earning prospects with perindopril sales in the EU prior to the Krka Settlement Agreement. Furthermore, the Commission notes that the expected earnings from the seven markets and the 18/20 markets differed in terms of the related risks, in particular the immediate risks for Krka in the seven markets were more limited in the wake of the licence agreement, as also recognised by Servier (reply to the Letter of Facts, ID10289, p. 157). This observation further supports the above findings as to the relative size/ratio of Krka's profit expectations with respect to the two groups of the markets.

2349 Krka argues that the Commission's assessment disregards the fact that the licence was a royalty bearing licence, and fails to refute that the royalties were not a fair price for the licence (Krka's reply to the Statement of Objections, paragraph 147, ID8742, p. 75). The Commission considers that even a commercial arrangements at arms' length can constitute an significant inducement to accept settlement restrictions (see paragraph (1190)). Section 5.5.3.3.3 examines if the royalty bearing Licence Agreement could constitute such an inducement.

2350 Krka argues that the Commission's assessment does not substantiate why it considers the level of royalties to be moderate, while overall, over EUR 1.1 million have already been paid to Servier (Krka's reply to the Statement of Objections, paragraph 147, ID8742, p. 75). Servier claims that the Commission's claim that the 3% royalty rate is moderate in view of Servier's foregone profit margins is disconnected from reality (Servier's reply to the Statement of Objections, paragraph 976, ID10114, p. 338). These arguments are addressed below.

2351 "**Servier obtained a 3% royalty on Krka's sales (Article 3.1), which is an indication that the protection offered by the '947 patent was quite narrow. If the protection had been broader, Servier would have demanded a higher royalty*," Servier's reply to the Statement of Objections, paragraph 1003, ID10114, p. 345.

2352 Servier observes that, in view of Krka's presence on the five markets: "**The "duopoly" was therefore already a market reality*" (Servier's reply to the Statement of Objections, paragraph 972, ID10114, p. 337). However, the Licence Agreement excluded the possibility of a third licensed supplier.

2353 ID1158.

of EUR 1.1million were paid over a period of four years for a perindopril turnover of around EUR 30m and represented only a small fraction of Krka's margins.[2354]

(1740) Secondly, the licensed markets were Krka's core EU markets, where Krka had traditionally been present, had strongest distribution network and had highest earnings. The restricted markets were traditionally less important for Krka, and its commercial presence was limited.[2355]

(1741) Thirdly, in these licensed markets, the sole licence either enabled Krka to enter the market with generic perindopril, or to continue marketing it with certainty that it would not be exposed to Servier's patent infringement actions.

(1742) Fourthly, the licence granted to Krka was a sole licence for the seven licensed markets. While Servier's patent position could be challenged by other generics, the barriers to entry nonetheless remained high, and this guaranteed Krka and Servier a *de facto* duopoly in the supply of perindopril for a period of time. No other independent generic company had this certainty, nor could it acquire such certainty in view of the fact that the terms of the Krka Settlement Agreement prevented any other company from obtaining such a licence from Servier and/or a sub-licence from Krka. Therefore, this granted Krka significant competitive advantage over other generic companies. This is fully in keeping with Krka's endeavours to reach an "*agreement on joint activity to control the market*" with Servier.[2356]

(1743) In line with the above, Krka's profits from sales in the Czech Republic, Hungary and Poland can serve as an illustration that the benefits of the licence from Servier were significant. In 2007, the first full year of the licence agreement, Krka expected to achieve a gross margin of EUR [3-8 million] in those three Member States.[2357] The licence could potentially run until the expiry of the '947 patent, that is to say 2021, hence the first year profits should be multiplied accordingly.[2358] Thanks to the licence, Krka was no longer running the risk that Servier would successfully exclude Krka in one or more of these markets, and claim damages. Krka's profits were safe from Servier's potential enforcement of the '947 patent and its national equivalents in the concerned Member States. Otherwise, Krka's expected profits should have been discounted for the risks related to selling a potentially infringing product.[2359]

(1744) The sole licence did not provide Krka (and Servier) with a *de iure* monopoly, which would secure a legal title to exclude all other generic companies. However, it secured Krka a unique market position where only two operators supplied perindopril, and were not under the mutual threat of patent infringement litigation, while the barriers

2354 At any rate, it is not the low level of royalties but the fact that the sole licence was granted against a commitment not to enter or challenge Servier's patents in a number of other, restricted markets, that is central to this analysis.

2355 See paragraph (913).

2356 See section 4.3.3.2.

2357 See paragraph (877).

2358 Assuming continuous profits at the first-year level and a 10-15% annual discount rate applicable from year two, the profit cumulated until 2021 would amount to EUR [23.1-28.8 million].

2359 It cannot be excluded that after discounting for all associated risks and taking into account potentially foregone profits from entry on the non-licensed markets, Krka remained neutral in deciding between the options of (i) pursuing the path of litigation and entries at risk and (ii) settling with Servier. However, even in such a scenario, the settlement had negative consequences for consumer welfare on the non-licensed markets, where by an economic inducement in the form of the said licence, Servier managed to neutralise its competitor's incentives to enter the non-licensed markets and so potentially deprived the consumers from savings that would have materialised in the case of Krka's generic entry.

to entry for other generics remained high, albeit not insurmountable. Such situation could persist over a period of time, and in fact did so for well over two years. In this setting, Krka gained market shares steadily, and did not engage in aggressive price competition to win larger portions of the market from Servier. For example, when due to obtaining reimbursement status in Poland, Krka had the opportunity to effectively offer perindopril to consumers at discounted prices without impacting its profit margins, it instead chose to maintain the price effectively paid by the consumers and thus increase its margins.[2360] Krka reduced its prices only shortly before further generic entry ensued in 2009.[2361]

5.5.3.3.3.3 Interdependency between Servier's licence and Krka's commitment to withdraw from competing in the restricted markets

(1745) On a preliminary note, the Commission clarifies that a self-standing sole licence agreement as described in the previous section cannot be as such, and in particular regardless of the licence fee agreed, considered to constitute a value transfer rendering any patent settlement agreement encompassing it inevitably contrary to Article 101 of the Treaty. Licenses are actually the means to grant other market players access to the know-how protected by a patent. It is also the patent holder's right to choose whether he wants to exploit his patent himself, or leave this to other companies and only participate in their success via license fees, which are typically lower than the potential profits form exploiting the patent himself. The license agreement is problematic only to the extent that, as in the present case, it is advantageous to the licensee and served as an inducement to secure restrictions on competition in 18/20 markets not covered by the licence as a part of the market sharing arrangement. The above analysis demonstrated that the Krka Settlement Agreement provided significant benefits to both Servier and Krka.[2362] In the next step, it will be assessed whether the benefits provided a significant economic inducement for Krka to accept the settlement terms and agree to dividing and allocating the markets.

(1746) Krka specifically admitted that Servier's sole licence was linked to Krka's withdrawal from competition in all other markets "*f) [Employee name of Krka]* and [employee name of Servier]* agreed on main points: defined territories, defined commercial terms (royalty), Krka agreed to withdraw opposition against '947 matter and not enter any market as long as '947 patent was valid*".[2363] Moreover, Krka admitted that

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2360 See paragraph (2351). Servier claims (reply to the Statement of Objections, paragraph 977, ID10114, p. 338) that this example is irrelevant as the Krka Settlement Agreement did not restrict Krka's pricing policy. The Commission does not affirm that the settlement contained such restrictions. This example merely illustrates that the degree of duopolistic competition allowed Krka to raise the prices and that the arrangement constituting the inducement to enter the Krka Settlement Agreement appears to have indeed been commercially very attractive.

2361 See paragraph (2351). Servier claims that generic entry in Poland in 2009 did not seem to have an impact on Krka's pricing (Servier's reply to the Statement of Objections, paragraph 977, ID10114, p. 338)). Yet, it is plausible to assume that Krka adapted its prices in the anticipation of generic entry, which occurred at even lower prices and undercut Krka's reduced prices.

2362 Krka claims that the Commission "*considers that profits derived from legitimate license deals … are an unlawful inducement*" (reply to the Letter of Facts, ID10202, p. 23). The Commission clarifies that it is the restriction of competition in the 20 markets, and not the licence itself that brings the settlement within the purview of Article 101(1) of the Treaty.

2363 See paragraphs (898), and (930). Krka's statements are internally consistent, see for example also paragraph (901): "*Servier agreed to grant license to Krka to sell the product in alpha form in seven CEE countries; Krka agreed not [sic] challenge validity of alpha patent*".

the licence agreement was a pre-condition for Krka to accept the restrictions: "*Krka has proposed that it would have been prepared not to challenge the validity of EP patent and withdraw UK proceeding, if Servier had been prepared to grant license for markets in Central&Eastern Europe*".[2364] This suggests that, on a stand-alone basis, neither the Licence Agreement not the Settlement Agreement would have been concluded on identical terms.

(1747) The geographic scope of the licence cannot be explained by patent differences in these territories. Krka itself never claimed that the decision to accept a licence for the core markets and withdraw from competing in the restricted markets would be based on differences in its assessment of the patent situation concerning the '947 and its national equivalents. Although the patent situation was not identical in the licensed markets and the restricted markets, there was a broad convergence concerning the status of the '947 patent and its equivalents. On the one hand, the decision of EPO Opposition Division upheld the '947 patent mainly in the Western European Member States, and grants of national equivalents of the '947 patent by patent offices in the CEE Member States were in progress. On the other hand, there remained significant patent challenges to the '947 patent in Western Europe, including by Krka, and there were signals questioning Servier's ability to enforce its patents in CEE markets (for example, Servier's interim injunction request against Krka was rejected in Hungary in October 2006).[2365]

(1748) In addition, Krka recognised that with the Krka Settlement Agreement, it had "*sacrificed*" the markets in Western Europe in favour of the CEE markets as its core EU markets. Krka explained that its decision on the settlement terms was based on the presence of marketing teams in its traditional markets.[2366] This is also how, based on publicly available information, other market players could perceive the arrangement. Reference is again made to Lupin which considered that the settlement allowed Krka "*to launch in CEE countries and withdraw from W. Europe*".[2367]

(1749) Based on the above, it can be concluded that the grant of the licence for the '947 patent by Servier served as a significant inducement for Krka to accept the

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2364 ID1307, p. 84. Servier argues that this statement, suggesting that Krka proposed the deal, contradicts the Commission's conclusions that Servier induced Krka to withdraw from competition (reply to the Letter of Facts, ID10289, p. 152-153). In the Commission's view, what matters is not who initiated the discussions, but whether the licence from Servier affected Krka's incentives to continue to compete in the 20 markets. Servier also claims that Krka's declaration does not exclude that Krka would in any event abandon litigation. The Commission notes that the overall body of evidence relating to Krka confirms that obtaining a licence was a pre-condition for Krka to withdraw from litigation and, more generally, competition with Servier (see, for example, paragraphs (853), (912), (913), (915) and (930)). Therefore, the settlement restrictions for 18/20 markets were not based on the merits of the patent case, but were dependent on whether Servier would offer an attractive enough proposition to Krka.

2365 See Table 5.

2366 See paragraph (913): "*Markets in Western Europe were less significant for Krka […], thus we were prepared to sacrify them for getting immediate access to markets in CEE*". This disproves Krka's statement that the settlement was not based on the inducement in the form of a licence for 7 EU markets (Krka's reply to the Statement of Objections, paragraph 136, ID8742, p. 68). Likewise, this also directly and literally negates Servier's contention that Krka did not sacrifice "**its entry into Western European countries in exchange for a licence for the CEEC*" (Servier's reply to the Statement of Objections, paragraph 966, ID10114, p. 335).

2367 See paragraph (915).

restrictive terms of the Krka Settlement Agreement and agree to divide and allocate the EU markets.[2368]

5.5.3.3.4 Object of the Krka Settlement Agreement

(1750) The Krka Settlement Agreement contained restrictive clauses preventing Krka from competing effectively with Servier in 18/20 Member States, including Servier's most important markets, by imposing a non-challenge and a non-compete obligation.

(1751) Krka argues that these restrictions, and more generally the settlement, were based on the "*corresponding strength of each party's litigation case*".[2369] According to Krka, the restrictions reflect the patent situation in the aftermath of the "*shocking*" and "*dreadful*" Opposition Decision.[2370] Yet, the above analysis in section 5.5.3.3.3 has disproven Krka's assertions. In addition to evidence showing that Krka persisted in its course of challenging Servier's patents after the Opposition Decision, it openly admitted that the licence agreement was a condition for Krka to accept the restrictions.[2371] This shows that the restrictions were not a necessary or typical outcome of the given patent situation, contrary to Krka's reply to the Statement of Objections. On the contrary, these restrictions were only accepted in exchange for a significant economic inducement in the form of Servier's licence to Krka, granting the latter the legal certainty to continue to market, or launch, generic perindopril in the remaining seven Member States. The restrictions in the 18/20 markets therefore did not reflect the merits of the patent case.

(1752) In the *BAT Cigaretten-Fabriken* case, the ECJ examined whether Article 101 of the Treaty would apply to so-called delimitation agreements, which generally serve to amicably determine the scope of the parties' trade mark rights. It should be noted that such agreements bear significant resemblance to patent settlement agreements, as they both serve to resolve possible disputes by agreement instead of litigation, and improve legal certainty. The ECJ held that "*such agreements are [not] excluded from the application of Article [101] of the Treaty if they also have the aim of dividing up the market or restricting competition in other ways*".[2372]

2368 The reference to dividing, sharing and/or allocating markets in the context of the Krka Settlement Agreement should be understood as follows. Through the Krka Settlement Agreement (combining the Settlement Agreement and the Licence Agreement), the parties exchanged the elimination of the competitive risk from Krka in the Western markets (through Krka's invalidity claims or potential launch at risk) to the benefit of Servier in return for the sole licence to Krka in the seven Eastern markets where Krka gained certainty that Krka will not be sued for infringement of Servier's patents. As a result, this agreement amounts to (i) a guarantee for Servier that its monopoly in the Western countries will not be threatened by its most direct potential competitor through its existing product (Krka had already the MA in several countries) and (ii) a guarantee for Krka that its position in the Eastern countries which was not safe from a patent perspective will not be challenged by Servier, its only competitor there. As a consequence, competition was restricted in the 18/20 Western markets, whilst no such finding is made for the seven licensed CEE markets.

2369 Krka's reply to the Statement of Objections, paragraph 103, ID8742, p. 54, and reply to the Letter of Facts, ID10202, p. 21-25.

2370 Krka's reply to the Statement of Objections, paragraphs 99 and 101, ID8742, p. 54-55.

2371 See paragraph (1746).

2372 Judgment in *BAT v Commission*, C- 35/83, EU:C:1985:32, paragraph 33. Concerning this judgment, Servier does not contest the possibility that settlement agreements can infirnge Article 101of the Treaty, but emphasised that the circumstances of the case were different, as it concerned a clause preventing the challenge of trade mark rights even after legal protection expired (Servier's reply to the Statement of Objections, paragraph 113-114, ID10114, p. 97-98). The Commission does not dispute Servier's

(1753) Yet, the terms of the Krka Settlement Agreement do exactly that: they divide the EU markets between Krka and Servier. Servier grants a sole licence and thus accompanying legal and economic certainty to Krka for seven Member States which comprise most important markets for Krka, and where Krka had already been present prior to the agreement, with Servier as the only competitor. In exchange, Krka withdraws from competition on the 18/20 remaining markets which comprise most important markets world-wide for Servier, which had, on the other hand, been traditionally less important for Krka.[2373]

(1754) Krka argues that the Krka Settlement Agreement was based on the merits of the patent situation and was prompted by the risks of marketing a product which could be found as infringing Servier's '947 patent. [2374] While a difference in the merits of the patent situation between markets and different patent-related risks would be relevant for the assessment of the object of this agreement, the situation is different if one looks at the facts of the case. If the Krka Settlement Agreement were based on patent-related risks, as Krka argues, one could expect the settlement to differentiate between two types of patent situation. The first group consists in markets where Krka was already marketing perindopril at risk of patent infringement and was thus confronted with a threat that its product would be found infringing Servier's patents, entailing also its liability for damages. The second group consists in markets where Krka had not yet launched the product and was therefore not at all exposed to damages for patent infringement. However, Krka not only received a licence for the markets where it was already present but also for markets where it had not yet launched its perindopril (Latvia and Slovakia). The settlement was thus not based on the difference in patent–related risks for Krka, but on the economic zones of interest, as Latvia and Slovakia belonged to Krka's "core markets", for which Krka "sacrificed" the 18/20 markets. This further confirms that the object of the settlement was not to find a solution only or mainly based on patent-related considerations, but to divide and allocate markets between Servier and Krka based on business considerations such as "core markets".

(1755) The parties argue that the agreement was not restrictive but pro-competitive as it allowed Krka to start or continue marketing in seven Member States, where it would otherwise infringe Servier's patent. This is best characterised by Servier's statement that the Krka Settlement Agreement served to: "**terminate an uncertain litigation and establish a mutually beneficial commercial cooperation in a context that excluded in any event competition between Servier and Krka (deadlock)"*.[2375] The Commission emphasises that the agreement reduced competition in 18/20 markets where consumers had absolutely no possibility to draw any potential advantage that

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presentation of the underlying specific facts of the judgment. However, nothing in this judgment suggests that the above-quoted principle is limited to the circumstances of the case.

2373 According to Krka, it was not "*Krka's primary intention to withdraw from EU 18/20 markets and leave them to Servier*", as these markets were not Krka's core markets (Krka's reply to the Statement of Objections, paragraph 162, ID8742, p. 83). First, the above assessment in section 5.5.2 has shown that Krka had dedicated significant efforts to prepare for launches in the Western European markets. Second, Krka's insistence on these markets not being its core markets (as compared with the seven markets where Krka was traditionally present) only corroborates the Commission's assessment and confirms the economic rationale for the market sharing arrangement.

2374 Krka's reply to the Statement of Objections, paragraphs 50, 77, 83 and subsequent , ID8742, p. 30, 44, 47.

2375 For example, Krka's reply to the Statement of Objections, paragraph 141, ID8742, p. 71-72. Servier's reply to the Statement of Objections, paragraphs 945, 953, ID10114, p. 330, 332.

may flow from the licence. This is based on the following elements. First, no Court ever found Krka to infringe a valid patent with its perindopril and there was therefore no "*blocking position*" within the meaning of the Technology Transfer Guidelines. Krka had already taken a decision to launch and actually commercialised perindopril in five out of the seven CEE markets, including the most important ones such as Poland and Hungary. As the '947 patent equivalents were, for the most part, not yet granted in these five markets, the licence did not enable Krka to launch (as Krka was already on the market), but afforded a higher degree of future legal and commercial certainty.[2376] Thus, even without the licence, there was real potential for competition both in the Western European and the CEE markets. Second, as Servier's basic tenet that there was no competition between Servier and Krka is unsupported by facts, the question is whether the "**mutually beneficial commercial cooperation"* was indeed pro-competitive in nature. Servier stated that: "**Both parties had an interest in restoring legal certainty in their commercial environment"*.[2377] However, the increased certainty for Krka in the seven Member States came at the expense of Krka's competitive potential for the 20 restricted markets, where no licence was granted and where Servier gained certainty that Krka's challenge would be discontinued. The object of the agreement was thus in barring all uncertainty and competitive risks stemming from Krka's patent dispute/litigation with Servier for a considerable period of time in the 18/20 restricted Member States. Servier and Krka replaced the competitive risks from litigation with a "**mutually beneficial commercial cooperation"* in the form of a *de facto* duopoly in the seven markets.[2378] The object of the deal was so plain that it could be observed by a competitor without an insight into the details of the agreement.[2379] It is recalled that, in Irish Beef, the Court of Justice condemned arrangements which "*substitute [] practical cooperation between undertakings for the risks of competition*".[2380]

(1756) To conclude, the Krka Settlement Agreement had the object to divide and allocate markets between Servier and Krka, by allowing Krka to continue marketing or launch generic perindopril in seven Member States which constituted Krka's core markets in a *de facto* duopoly with Servier, as a reward for the restrictions on entry in the form of Krka's commitment to desist from competing with Servier in the remaining 20 Member States, including by not challenging Servier's patents across the EU.

5.5.3.3.5 The parties' intentions

(1757) The intention of the parties can be an additional indication of the object of a given agreement. A description of respectively Krka's and Servier's intentions will be provided in the following paragraphs.

5.5.3.3.5.1 Krka's intentions

(1758) At the time of the settlement, Krka had launched perindopril in a number of CEE markets, and was involved in litigation against Servier to ensure viable entry in the

2376 Servier's reply to the Statement of Objections, paragraph 962, ID10114, p. 334.

2377 Servier's reply to the Statement of Objections, paragraph 962, ID10114, p. 334.

2378 Servier argues that the use of the notion of "duopoly" is incongruent, as the relevant market, according to Servier, comprised at least all other ACE inhibitors (reply to the Statement of Objections, paragraph 974, ID10114, p. 338). This claim is flawed and directly contradicts Servier's position from paragraph 970 of its reply for the reasons set out in footnote 3285 below.

2379 See Lupin's statement quoted at paragraph (915).

2380 Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 34.

UK, as one of the first, if not the first company, to have received marketing authorisation for generic perindopril. It had also prevailed in Hungarian proceedings where Servier's application for an interim injunction against Krka was rejected.

(1759) In light of Krka's challenges to the '947 patent as assessed in section 5.5.2, it should be borne in mind that Krka top management saw a settlement with Servier as the preferred alternative ("*an agreement with Servier concerning alpha would be ideal*"[2381]), as it avoided competition from other generics ("*a successful opposition namely opens doors to everybody*"[2382]). Krka was aware of the advantages of a settlement agreement, and the termination of its patent challenge, over continued litigation, even if successful. In case Krka's arguments prevailed and Krka were to win its annulment case against Servier (either in opposition or a revocation action), this would "*unfortunately [open] the market for everybody*".[2383]

(1760) In view of the inducement in the form of the advantageous licence for seven CEE Member States, the Krka Settlement Agreement is essentially consistent with Krka's strategy for "*joint activity to control the market*" with Servier.[2384] In brief, such an agreement should, according to Krka, have encompassed (i) the possibility for Krka to manufacture API in Slovenia, (ii) the transfer of Krka's technologies to Servier against compensation, and (iii) the withdrawal of Krka's EPO opposition. These elements eventually became the essential cornerstones of the market sharing arrangement as brought about by the Krka Settlement Agreement (and the subsequent Assignment and License Agreement between the same parties concluded two months later). Servier removed Krka as a direct challenger for 18/20 restricted Member States in return for Krka's comfortable duopolistic market position in the remaining seven Member States.[2385] This evidence further distinguishes this case

2381 See paragraph (873).

2382 See paragraph (874).

2383 See paragraph (844).

2384 See paragraph (853).

2385 Krka and Servier continue to contest the importance of this document, which Krka claims the Commission has "*utterly misconstrued and misinterpreted*". According to Krka, the document was a summary of most important Krka's advantages in relation to Servier, and a summary of Krka's thoughts on potential opportunities after 2008. Hence, the document would not set out Krka's perindopril strategy. Moreover, the acquisition of a licence from Servier which was discussed never came to fruition as talks in October 2005 had no follow up (Krka's reply to the Statement of Objections, paragraph 61-62, ID8742, p. 34-35). Krka's explanations are not credible and are not supported by the evidence. The email was not only intended to summarise opportunities after 2008 – this was but one out of the three scenario discussed – but to set out strategic advantages and options concerning perindopril. Most importantly, the email contains a section elaborating an "*agreement on joint activity to control the market*" which explicitly outlines the quid pro quo of a possible agreement between Servier and Krka. Such an agreement would extend beyond 2008. In view of the forward looking nature of the document, specific analysis regarding Krka's deal making options with Servier, commercial implications, and the fact that it was prepared by the Board Member in charge of R&D for the attention of Krka's CEO, the document is beyond doubt of strategic nature, and relevant for the purpose of the present assessment.
Servier in addition claims that the document has no probative value for the following reasons: (1) it only inculpates Krka and not Servier, (2) Krka could not control the patent situation as there were in total ten opponents, (3) the email predated by more than a year the Settlement Agreement, the Licence Agreement, and the Assignment and Licence Agreement, which were concluded in a different context, influenced by the Opposition Decision, upholding the '947 patent (Servier's reply to the Statement of Objections, paragraph 1022, ID10114, p. 350). On a preliminary note, Servier itself acknowledges that Krka was following the course set in this strategy document - in paragraph 1088 of its reply, Servier does not contest that, "**[a]ccording to Krka, the negotiations failed owing to Servier's refusal to grant Krka a licence for the patent covering the alpha form of perindopril tert-butylamine*". Concerning the first point, the Commission recognises that the document represents Krka's, and not necessarily also

from a situation where the generic company's acceptance of restrictions is only or mainly driven by the perceived merits of the patent situation.

5.5.3.3.5.2 Servier's intentions

(1761) Servier's internal document "*Coversyl: defense against generics*" (by [employee name of Servier]*, who also negotiated and signed the agreement for Servier) confirms beyond doubt that Servier considered patent settlements to form a part of that (successful) strategy. All the settlement agreements concluded prior to this document (June 2006) are mentioned within in this document, either under the heading "*Did it work?*", where an explicit reference to the Niche and Matrix settlements is made, or referred to as a partnership (with Teva) to launch perindopril if/when mandatory. The document mentioned Krka amongst the (remaining) sources of generic competition.[2386]

(1762) Moreover, when Servier lost the UK litigation with Apotex on first instance, and the UK part of the '947 patent was annulled, its immediate comment was "**4 years gained = great success*".[2387] This was in spite of the fact that the '947 patent could have provided up to 14 more years of patent protection to Servier. Servier's statement confirms the existence of a direct link between losing patent litigation and the length of the "**years gained*" after the expiry of the SPC. The "**4 years gained*" were thus at least partly due to Servier's reliance on the '947 patent, demonstrating a nexus to the actual delay of generic entry.[2388] As avoidance of litigation obviously strengthens

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Servier's, strategic consideration concerning the Krka-Servier relationship on perindopril. Even if so, the document nonetheless shows that the objective of the "*joint activity to control the market*" was amongst the plausible results of such an arrangement between Servier and Krka. Second, arguments and types of available evidence may differ from one opponent to another and may no longer be available, or effectively pursued, if the opposition is withdrawn. In addition, Krka's plans could be *a fortiori* logically extrapolated to litigation where Krka was, at the time of the agreement, one of the very few (remaining) challengers before national courts (UK, Hungary). Third, Servier fails to explain why a document, which does not concern day-to-day operations, but lays out a strategy for the period from 2005 to 2008 and beyond for a key new product, would be obsolete by the time of the settlement negotiations which started less than a year after the strategy was produced. Moreover, its relevance is only buttressed by the fact that the solutions of the Krka agreements with Servier closely follow the parameters of the outlined agreement on "*joint activity to control the market*".

2386 See paragraph (886). Servier argues that the document is irrelevant for the purpose of proving its intentions concerning the Krka Settlement Agreement. First, the agreement was concluded four months after the presentation. Second, the document does not elaborate a strategy concerning Krka. Third, the Commission bases its conclusion on a simple reference to the Niche/Matrix settlement (Servier's reply to the Statement of Objections, paragraph 1028, ID10114, p. 351). In the Commission's view, Servier fails to explain why a strategy document concerning Servier's defence against generics would lose its relevance only four months after its creation. Concerning the second point, the nature and structure of the document, as well as the context in which reference is made to Krka, make it clear that Krka was amongst the generics against which "defense" was considered. The absence of a more specific strategy towards Krka or other generics is not surprising as it predates the Opposition Decision and the subsequent legal actions involving Krka (and others). Third, Servier has implicitly confirmed that patent settlements were a successful tool to defend its market exclusivity for perindopril. It is therefore reasonable to infer that if a patent settlement were used to settle litigation with Krka, this would follow the same or similar objectives as the preceding settlements with Niche, Matrix and Teva (all directly or indirectly referred to in the document).

2387 See paragraph (184).

2388 Servier argues that it was the Opposition Decision that delayed the entry of generics, as well as the generic companies' strategy to rely on invalidation of the '947 patent instead of inventing around the patent (Servier's reply to the Letter of Facts, ID10202, p. 176). The Commission does not contest that the Opposition Decision entailed delays of generic entry. The actual delays depended on whether the generics had the ability and the incentives to compete by initiating patent litigation or launching at risk.

and/or prolongs the protection offered by the patent, patent settlements can be logically seen as contributing to Servier's success, which could be even higher in those markets where the generics could only enter as late as six years after the expiry of the SPC

5.5.3.3.6 Intermediate conclusion - Krka Settlement Agreement as a market sharing arrangement

(1763) In summary, the Krka Settlement Agreement is an agreement between undertakings akin to market sharing whereby Krka essentially renounced on its ability to compete through the non-challenge and non-compete obligations in 18/20 Member States, including Servier's two biggest worldwide markets, the UK and France. As an economic inducement to accept these commitments, Krka received a sole licence for the '947 patent in seven CEE Member States, considered to belong to Krka's core markets where its commercial presence and margins were the highest. This included two markets in which Krka had not yet entered at the time of the patent settlement and was not exposed to patent infringement risks, thus confirming that the choice of licensed markets was based on criteria other than patent-related risks. The licensing arrangement preserved Servier's market exclusivity for perindopril in 18/20 Member State markets, while it allowed for a *de facto* duopoly by Servier and Krka in the remaining seven Member States without "*unfortunately [opening] the market for everybody"*. This market sharing arrangement moreover appears to be fully aligned with Krka's strategy on "*joint activity to control the market*" with Servier.

5.5.3.4 Additional distortion of competition from the Assignment and Licence Agreement between Servier and Krka

(1764) Only two months later, Krka and Servier concluded an Assignment and Licence Agreement for the acquisition, by Servier, of Krka's competing technology to produce perindopril. In a first step, this section will examine the content of the agreement and its object in its legal and economic context, in particular. In particular, the purpose of the technology acquisitions will be examined taking into account the price paid by Servier, and the value of acquisition for Servier. Subjective intentions shall also be considered. Lastly, the agreement will be examined as a part of a single and continuous infringement, in combination with the Krka Settlement Agreement.

5.5.3.4.1 Context of the conclusion of the Assignment and Licence Agreement

(1765) According to Krka, Servier initiated discussions on the acquisition of Krka's two patent applications, WO 2005/113500 (synthesis process for perindopril) and WO 2005/094793 (preparation of perindopril formulations) approximately a month after the conclusion of the Krka Settlement Agreement. In view of the Krka Settlement Agreement, in particular the licence for the '947 patent for Krka's core markets and the potential development of non-alpha perindopril, Krka "*found the offer to assign patent applications to Servier attractive (thus not having control over them as patent holder), provided however that a price would be satisfactory* [sic] *high"*.[2389]

(1766) It has been demonstrated that the object of the Krka Settlement Agreement was to share EU markets for perindopril between Servier and Krka. In addition to being a

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Patent settlements affected the incentives and the ability of the respective generics to compete both before the Opposition Decision (Niche/Unichem, Matrix, Teva) and after it (Krka and Lupin).

2389 See paragraph (945).

challenger to Servier's patent and market position in the 20 Member States, Krka was at the time of the Settlement Agreement one of the very scarce and thus important sources of alternative technologies to produce perindopril API and formulations meeting regulatory standards, including the European Pharmacopoeia requirements. Yet, the Krka Settlement Agreement contained no restriction on Krka's possibility to transfer this technology to other generic companies for these markets. And, according to Krka, "*[a] company which held title of these patents (in particular the process patent) or have a license, would have a commercial product*".[2390] At the same time, Servier claimed that it had "**always sought to improve the quality and the synthesis process of perindopril and to this end talks were initiated with KRKA as from 2005*".[2391]

(1767) According to both Krka and Servier, Servier had not carried out a due diligence concerning the patent applications' potential for industrial use, and no confidentiality agreement was entered into for that purpose. Moreover, Servier was not able to produce any contemporaneous documents, such as investment/business plans, explaining how the EUR 30 million investment into alternative technology would be amortised, or feasibility studies, analysing how the acquired technologies could be technically integrated to improve Servier's production processes.

5.5.3.4.2 Terms of the Assignment and Licence Agreement

(1768) The Assignment and Licence Agreement ("ALA"), was signed on 5 January 2007 by the same representatives of Krka and Servier who had also signed the Settlement Agreement and the Licence Agreement.

5.5.3.4.2.1 An agreement between undertakings

(1769) With respect to the ALA, the same reasoning as explained in section 5.5.3.3.1. applies. Hence, the ALA is an agreement between undertakings within the terms of Article 101(1) of the Treaty.

5.5.3.4.2.2 Assignment of patent applications as a restriction of competition disabling generic competitors to have access to Krka's perindopril technology

(1770) The ALA[2392] essentially consists in a transfer of two Krka's patent applications concerning a process for the synthesis of perindopril (WO 2005 113500) and for preparing perindopril formulations (WO 2005 094793). The technology protected in these patent applications was actually used for the production of Krka's perindopril which was, according to Krka, meeting the regulatory standards (notably the requirements of the European Pharmacopoeia monograph) while also reportedly respecting Servier's process patents.[2393]

(1771) Krka remained free to undertake the development of new perindopril technology and the resulting products, and has indeed done so by initiating the development of the so-called perindopril CET, a non-alpha form of perindopril. This development was not restricted by the Krka Settlement Agreement or the ALA, yet the restrictions contained in these two agreements signified that no technology could be available from Krka earlier than two to three years from the period when the agreements were

2390 See paragraph (957).
2391 See paragraph (937).
2392 See paragraph (927).
2393 See paragraph (957). For Servier's arguments on infringement of process patents, reference is made to paragraph (1692).

signed, if at all, given the inherent development risks. In fact, the first marketing authorisations for perindopril CET were granted to Krka only in the autumn of 2009.[2394]

(1772) The acquisition occurred under specific market circumstances in which there were only very scarce alternative sources of potentially viable API technology independent of Servier at the time of the acquisition.[2395] The transfer of Krka's technology to the incumbent, Servier, at the time still holding a monopoly for perindopril sales in restricted markets and sharing the seven licensed CEE markets with Krka, entailed an immediate one-off distortion of competition within the meaning of Article 101(1) of the Treaty. By removing Krka's ability to freely license out or assign its technology to third parties, i.e. other generics, Servier effectively foreclosed the potential avenue of competition based on the use of Krka's technology by third parties. Such technology could, for example, serve as a platform for new patent challenges. In combination with the Krka Settlement Agreement, ALA thus provided Servier with absolute protection from any remaining potential competition stemming from Krka's technology.[2396]

(1773) Krka claims that the ALA imposed no limits on the scope of use of the back licence granted to Krka. Thus, Krka would be free to use the technology to produce for a third party buyer and through this channel the generic competitors still had access to this technology.[2397] This is incorrect and in direct contradiction to the obligations on

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2394 See paragraph (968).

2395 See for example, Table 49, and section 7.3.3.1. Servier contends that the Commission fails to show that Krka technology was enabling, indispensable, or unique, and that its assignment to Servier would thus deprive potential entrants of their ability to enter. Servier lists a number of entrants following the annulment of the '947 patent. Moreover, as the technology led to alpha crystalline form, it would not allow generic entry in the EU markets (Servier's reply to the Statement of Objections, paragraphs 1095-1098, 1125, ID10114, p. 366-367, 373-374). First, The Commission acknowledges that Krka's technology was not unique in the market, but was, on balance, nonetheless a very important source of competition. (i) Krka technology was one of very few technologies incorporating a process proven to lead to products meeting regulatory requirement (only 3 at the time), (ii) Krka's processes were also cost-efficient and known to yield good quality product. This is, for example, confirmed by a large number of generic companies sourcing Krka's product upon the lapse of the Krka Settlement Agreement. (iii) Servier's list of entrants does not reflect the sources of competitive constraint at the time of the ALA. Moreover, it is not informative concerning the real number of alternative sources of competition. Many of the companies sourced perindopril from the same technology/ producer (eg Teva UK, Generics UK = Servier, Consilient, Ratiopharm, Teva = Krka, Actavis, Ranbaxy, Tillomed = Glenmark). For an assessment of the remaining competition after the Krka Settlement Agreement/ALA, see assessment of effects (section 5.5.3.5.4).Second, at a time where Servier had already removed 4 challengers to its market exclusivity, ALA foreclosed access to an accomplished technology as a potential source of competition by third parties (paragraph (1612)). Even though the processes had been confirmed to lead to a marketable product, this assessment qualifies the technology not as an actual, but only as a "a potential avenue for competition". This means that the technology could serve as a basis for entry of new generic products, including by means of a patent challenge, where needed.

2396 Servier points that none of the terms of the ALA has been considered as restrictive as such in the Statement of Objections, and instead the Commission sought to find a concealed anti-competitive object behind the obvious object of transferring technology (Servier's reply to the Statement of Objections, paragraphs 1102, 1103, ID10114, p. 368). The Commission clarifies that, in the specific context of this case, it is inadequate to consider the restrictions flowing from the ALA in isolation from other limitations on Krka's ability and incentives to compete, considering the comprehensive legal relationship between Servier and Krka. As explained in paragraphs (1805) and (1806), the restrictions on competition from the ALA were analysed in conjunction with the restrictions from the Krka Settlement Agreement, which together removed all scope for immediate competition from Krka.

2397 Krka's reply to the Statement of Objections, paragraph 161, ID8742, p. 82.

Krka stemming from the Krka Settlement Agreement. The Settlement Agreement prohibited Krka from supplying to any third party perindopril products covered by the '947 patent (which Krka was producing based on the assigned technology).[2398] Krka could thus only commercialise its perindopril in the seven markets covered by the Licence Agreement, where Krka would in any event not supply other generics.[2399]

5.5.3.4.2.3 Significant financial consideration

(1774) As a consideration for the two patent applications, Servier paid an amount of EUR 30 million in two instalments of EUR 15 million each in January 2007 and January 2008. Servier declared that the price was an adequate and fair price for the acquisition of the patent applications (Article 1, paragraph 4 of the ALA).

(1775) However, to properly assess the ALA, including the purpose of the considerable payment to Krka, the inherent value of the transferred technology from the parties' perspective needs to be considered.

Value for Servier

(1776) At the outset, the Commission recalls that the Court of Justice held in *Aalborg Portland* that "*[i]n most cases, the existence of an anti-competitive practice or agreement must be inferred from a number of coincidences and indicia which, taken together, may, in the absence of another plausible explanation, constitute evidence of an infringement of the competition rules*".[2400]

(1777) Servier's product manager for perindopril confirmed that Servier's normal policy in acquiring IPRs would be to prepare a feasibility study concerning the benefits of use of such IPRs prior to the acquisition itself.[2401] However, no such feasibility studies have been submitted by Servier. Servier only claimed that it had entrusted a team to assess such patent acquisitions,[2402] but failed to provide any documents showing how this team assessed the commercial benefits of any of Servier's acquisitions. Neither Servier nor Krka provided an elaborate description of factors determining the final sum of EUR 30 million, and instead claim that the sum was simply the outcome of the negotiating, or bargaining, process.[2403]

2398 See paragraph (908).

2399 See paragraph (910).

2400 Joined Judgments in *Aalborg Portland and Others v Commission*, C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P, EU:C:2004:6, paragraph 57.

2401 See paragraph (1030).

2402 See paragraph (1029).

2403 See, for example, paragraph (956). Servier contends that the purchase price of EUR 30 million was determined in negotiations, and represents only a modest sum compared to its profits. If the purchase price is not covered by benefits, this may at worst mean that Servier made a bad investment, but it is still too early to draw such a conclusion (Servier's reply to the Statement of Objections, paragraphs 1112-1114, ID10114, p. 370). The Commission observes that this fails to explain why Servier, as a reasonable economic operator, did not make an adequate analysis of the scope for potential commercial benefits of the technology prior to the acquisition. Given the inherent risks of the acquisition, the expected benefits would need to significantly exceed EUR 30 million if the deal were to make commercial sense for Servier. What matters is not that Servier finally does not use the technology, but that there is an absence of demonstrable genuine commercial interest in the protected process improvements.
Servier further argues that this acquisition sought to preserve Servier's freedom to operate (Servier's reply to the Statement of Objections, paragraphs 1115, ID10114, p. 372). Servier does not explain in which way its freedom to operate was under threat. It needs to be underlined that the acquired

(1778) According to Servier, the purchase aimed at improving its manufacturing processes for perindopril, and the payment reflected negotiations with the assignor.[2404]

(1779) Yet, the content of the agreement, in particular the conditions under which the technology was transferred to Servier (in particular no transfer of know-how or due diligence, no study of possible commercial benefits, weak warranties by Krka and a deferred transfer) suggests that Servier was not following this acquisition with a view to commercially exploiting the acquired technology.[2405]

(1780) The transfer of patent applications was staggered to reflect the two EUR 15 million instalments to be paid by Servier. Patent application WO 2005 113500 (perindopril synthesis process) was to be transferred on 10 January 2007, while the transfer of the second patent application, WO 2005 094793 (perindopril formulations) was deferred by a full year, to 10 January 2008 (Article 2). Upon transfer of title for each of the patent applications, Krka received a non-exclusive, irrevocable, non-assignable, royalty free licence with no right to sub-license (other than to Krka's affiliates) on the applications / ensuing patents (Article 4).

(1781) Krka's warranties were of a limited nature: it was bound to make available the documentation directly relating to the patent procedure for the two patent applications (Article 1, paragraph 3), but not to allow a full due diligence of the patent applications prior to the acquisition, nor to transfer any know-how on the actual exploitation of the transferred technologies. Not only did Servier not examine the potential commercial benefits from the acquired technology before the purchase,

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technologies were substitutes to several alternative substitute technologies that Servier had already controlled. Servier had been viably producing perindopril for almost two decades, while Krka's technology was the only remaining means for Krka to represent an immediate competitive threat to Servier. In any event, Servier could have secured its freedom to operate by less restrictive means, e.g. by obtaining a non-exclusive licence. At any rate, the Commission notes Servier's claims that it was its own technology ('947 patent) that was blocking Krka's, and not vice versa.

2404 See paragraph (938).

2405 Servier claims that the Commission is wrong to consider these conditions as indicating that Servier lacked the intention to exploit the technology. Servier had extensive experience and did not need to also transfer Krka's know-how. Moreover, Servier carried out conclusive tests of Krka's technology. Finally, Servier's corporate culture was not such as to systematically elaborate analytical documents for the purpose of acquiring technology, but to trust the competent employees (Servier's reply to the Statement of Objections, paragraphs 1104-1106, ID10114, p. 368-369). In the Commission's view, while it should in principle be always possible to reconstruct the production process following the patent teachings, detailed information on exact production parameters may significantly enhance the added value of the acquired process. For example, annex 10 to Servier's reply to the Statement of Objections, is an internal chemistry analysis by the head of the Oril plant concerning the WO 2005/113500 application, which according to Servier, established an interesting yield from the use of one reagent (Servier's reply to the Statement of Objections, paragraph 1110, ID10114, p. 370). The Commission's reading of the document however reveals that Servier's experiment based on the patented technology had a lower yield than explained in the application for one component, and problems were identified concerning "**carbanine caking*". The ensuing comment was: *"*PRODUCTION???"*. The document is therefore far from conclusive. Moreover, Servier did request the transfer of know-how in certain other cases (for example, Azad). In any event, experiments by the head of the Oril plant do not contain an economic assessment of the benefits that could be derived from these technologies, in line with the explanations by [employee name of Servier]* (paragraph (1777)). If Servier's claims were to be taken at face value (quod non), in total EUR [80–95]* million would be spent on technology acquisitions without a single document explaining the benefits for the company (and establishing internal corporate responsibility for the exonomic use of significant company funds). At any rate, Servier has consistently failed to identify the "**people with the necessary competences*" and on the basis of which business factors they took the decisions to acquire technology.

but Krka also gave no warranties for the technical utility or completeness of the applications and the embodied inventions and for the final award of the patents (Article 1, paragraph 4). The possibility that the acquired patent applications would not be granted was not merely hypothetical, as Servier in fact experienced difficulties in proving that the invention in one of Krka's applications was not anticipated in one of Lupin's patents (acquired by Servier only weeks later).[2406] Against this background, the absence of due diligence or stronger warranties appears even more striking.

(1782) Moreover, ALA contains no obligation for Krka to undertake activities necessary to support the patent application WO 2005/094793 during the one year period between the entry into force of the agreement and the date of the effective assignment of the said patent application.[2407] This is in stark contrast with Krka's commitment to "*use all reasonable care and skill […] to pursue the filing, prosecution and maintenance of the patents*" as stipulated in three technology transfer agreements (including an assignment agreement) concluded between Servier and Krka in September 2008.[2408]

(1783) Servier reported to have indeed used the teachings of WO 2005/113500 in order to improve its manufacturing process, while no such practical implementation of WO 2005/094793 has been reported. The analysis will, by consequence, differentiate between the inherent commercial values of the two patents.

(i) WO 2005 113500 (perindopril synthesis process)

(1784) Servier claims to have used the teachings of the perindopril synthesis patent application and also to have achieved aggregate savings of EUR 2 million over a period of six years, starting in the period 2005/2006.[2409]

(1785) Servier has not supported its claim by any contemporaneous documents. Moreover, Servier contends that the savings were made already in the 2005/2006 period, which actually predates Servier's actual acquisition of Krka's technology. Therefore, it appears questionable whether the alleged savings were at all achieved, and if so,

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2406 See paragraph (953). Servier observes that the risk of confronting prior art objections is inherent to patent applications. What mattered though, so Servier claims, is that it continued pursuing the applications (Servier's reply to the Statement of Objections, paragraph 1107, ID10114, p. 369). The Commission observes that, even if acquired for strategic purposes, it is only normal that Servier continues to prosecute its patent applications. Yet, Servier lacks a specific and facts-based explanation why the acquisition of such an overlapping substitute technology was commercially justified.

2407 The parties argue that, since Krka transferred patent applications to Servier, it was normal that it was no longer responsible for the further prosecution of the applications (Krka's reply to the Statement of Objections, paragraphs 166-167, ID8742, p. 85, Servier's reply to the Statement of Objections, paragraph 1108, ID10114, p. 370). In the Commission's view, Krka's explanation would be plausible in case the patent applications were immediately transferred to Servier. This was however not the case – the first patent application was assigned to Servier only seven months later and the second one a full year after the conclusion of the agreement (see paragraph (927)) – and during these periods Servier had no contractual guarantee that Krka would duly prosecute the applications.

2408 See paragraph (928) and related footnote.

2409 See paragraph (952). According to Servier reply to the Statement of Objections (paragraph 1111, ID10114, p. 370-371), the technology was interesting as it provided an alternative to perindopril arginine as a way to have a more stable product. As Servier took the strategic decision to move to perindopril arginine, exploiting the technology no longer made sense. The Commission observes that, at the time of the ALA, Servier had already launched perindopril arginine salt in some Member States and was in intense preparations to launch it elsewhere in order to confront impending generic entry (paragraphs (220), (233) - (238)). This admission by Servier thus indirectly confirms that, at the time of the ALA, Krka's technology was already obsolete for Servier's production purposes.

whether there was a causal link between these cost savings and the acquisition of Krka's technology.

(1786) Given Servier's failure to provide evidence on the expected (*ex ante*) evaluation of savings achieved with Krka's process improvement,[2410] one can examine whether the actually achieved savings of only EUR 2 million over six years (before discounting, around EUR 6 million if projected over the entire patent term since Servier's acquisition) could be representative of what Servier expected to achieve. There are no indications that Servier attempted in the past to use this patent application for any other cost-efficient process modification. Servier merely stated that a further modification could be foreseen, which however would still require "**a lot of development work*"[2411]. This suggests that, unlike for the abovementioned improvement which, according to Servier, had been implemented prior to the acquisition of Krka's patents, Servier had not undertaken any advanced development work.

(1787) Against this background, the benefits which appear likely to be achieved are limited to the alleged savings from the process improvement which have amounted to EUR 2 million so far, and could reach EUR 6 million over the remaining patent term (before discounting). This is EUR 9 million inferior to the upfront payment of EUR 15 million, and in view of the interest rates/discounted future value, the actual gap may be even wider. Moreover, the claimed savings do not take into account additional costs incurred by Servier with the further development needed for industrial exploitation.

(1788) It appears that, neither at the time when ALA was concluded, nor later, did Servier thoroughly analyse the commercial potential flowing from the potential industrial application of the WO 2005 113500. Moreover, the savings that Servier actually alleges to have been realised using this technology remain highly questionable and in any event significantly inferior to Servier's payment for the technology. Thus, there are feeble indications that Servier, as a reasonable economic operator, acquired the patent application WO 2005/113500 with a view to achieve a return of investment from the commercial exploitation of the technology. In any event, the payment of EUR 15 million was well in excess of the commercially attributable value of the patent application.

(ii) WO 2005/094793 (preparation of perindopril formulations)

(1789) Unlike for the synthesis process, Servier has advanced no claims that Servier achieved, attempted to achieve, or had specific plans to achieve cost-efficiencies by developing modifications to the existing methods. Moreover, the transfer of this patent application was deferred by a year further intimating Servier's lack of interest in commercially exploiting this technology.[2412]

2410 Servier objects to the *ex post* assessment of the value of the acquired technology, as this disregards that only the potential, but not the actual, benefits were known at the time of the acquisition (Servier's reply to the Statement of Objections, paragraphs 1109, 1110, ID10114, p. 370). The Commission agrees that an *ex ante* assessment should be the principal point of departure of such an analysis. The Commission clarifies again that the actual savings were only examined in view of Servier's consistent failure to provide evidence on the expected (*ex ante*) evaluation of savings.

2411 See paragraph (953).

2412 Servier claims that the Commission ignored the fact that Servier and Krka had already discussed a possible acquisition of Krka's patent application WO 2005/094793 in 2005. Servier was thus not only familiar with the subject matter of the patent application, but, in the absence of any dispute with Krka in

(1790) On this basis, it can be concluded that the evidence at hand suggests that the inherent commercial value of the patent application for Servier was negligible, or none.

Value for Krka

(1791) It is recalled that Krka was granted a back-license for its own technology and retained the right to use the technology to produce for the markets licensed under the Krka Settlement Agreement. Krka did not forego the use of its technology. Therefore any additional value from this technology presented a windfall for Krka (the only opportunity cost being that of possibly forfeited licensing income).

(1792) Krka explained that, absent the licence granted by the Krka Settlement Agreement, the two patent applications represented no market value for Krka as their use at the time would be limited to marketing at the risk of patent infringement. In addition, Krka argued that no generic company expressed interest in acquiring or licensing in these patent applications, as their focus is rather on acquiring the regulatory dossiers and supplies of the final product.[2413] However, although companies had not expressed interest in acquiring Krka technology (by either a licence or assignment), this does not mean that such a possibility was only hypothetical. Firstly, while not so frequent, it was not out of the ordinary that generic companies would seek to licence-in, or purchase, API technology, including that for perindopril (Sandoz, Sochinaz).[2414] Second, one needs to consider that, prior to the agreement, Krka was considered primarily as a supply/licensing partner for perindopril formulations, which is the more common type of cooperation between generics. Yet, by virtue of the Krka Settlement Agreement, Krka was eliminated as a source of regulatory dossier/supplies shortly, i.e. only two months before the ALA was signed. From an *ex ante* perspective, this is a very short period as compared to 14 years, the maximum possible duration of the restrictions from the Krka Settlement Agreement, during which such demand could emerge. It is therefore much less likely that, within the very narrow time window of only two months, generics would manifest their interest to acquire the technology from Krka. As Krka was in negotiations with Servier for a

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2005, also made an offer of EUR 10 million, a price similar to the one paid in the context of the ALA, which would show that this was the market price (Servier's reply to the Statement of Objections, paragraphs 1089, 1112, ID10114, p. 364, 371). As acknowledged by Servier, acquisition discussions only related to one Krka patent, WO 2005/094793. Servier has not advanced any claims that it intended to use, or actually used, this technology (paragraphs (952)-(955). The Commission observes that the 2005 negotiations between Krka and Servier covered a range of agreements (ID0119, p. 181-225 as quoted by Servier). The set of draft agreements also included a draft Assignment and Licence Agreement for the acquisition of Krka's patent (presumably prepared by Krka - ID0119, p. 185-188), and a commitment by Servier to licence all its perindopril patents to Krka as of 1 October 2008. Krka was thus considering to postpone market entry against the payment for the acquisition (EUR 35 +5 million asked). Servier seems to have only counter-offered EUR 10 million and no licence for its patents as of October 2008 ((ID0119, p.191-198). Therefore, the sums in these draft agreements cannot be seen as representing an accurate reflection of the perceived value, as the negotiations equally comprised Krka's request for a licence as of October 2008. It is however noteworthy that the draft agreement resembles the ALA (and the settlement agreement) in two important aspects (1) EUR 30 million in the ALA closely corresponds to EUR 35 million sought by Krka in the draft agreement, (2) both the draft agreement, and the Krka Agreements implied a licence and belated entry of Krka onto some or all EU markets.

2413 See paragraph (947). Likewise, in view of the fact that no companies expressed interest for Krka's technology, Servier claims that the finding that Krka's technology could serve as a basis for new generic entry is unfounded (Servier's reply to the Statement of Objections, paragraph 1093, ID10114, p. 365-366).

2414 See Table 49.

large part of this two months period, it is also normal that it did not actively market its technology to other operators. Importantly, Krka itself mentioned that having a licence to Krka's patents would be a plausible avenue to having a commercial product.[2415] This being said, it is unlikely that Krka could extract the same or comparable total payment amount for its technology from third generic parties. Most importantly, the overall development budgets (including regulatory costs) for generic perindopril were in the magnitude of up to EUR [1-4] million, approximately ten times lower than the price of the patent applications.[2416]

(1793) Moreover, Krka recognised explicitly the value of its patent application for new (i.e. generic) entry: *"[e]ven if alpha patent had been revoked, [Krka] patents could have been "a key" for entering markets with a product having required purity – set of the assigned patents enabled any company to have a product/API of a purity required by Phar.Eu. […] Phar.Eu. has set very high purity standards for perindopril. Krka's patents were solving very concrete technological problems and this was the value of the assigned patents.* ***A company which held title of these patents (in particular the process patent) or have a license, would have a commercial product***" (original emphasis).[2417]

(1794) This shows that Krka considered that the value of the assigned technology was foremost that of a "key" for new (generic) market entry. Previous transfers or tentative transfers of perindopril technology confirm that a technology transfer between generic operators was not merely a hypothetical possibility. In addition, Krka had a higher incentive to license-out its technology once it was restricted from competing in the 18/20 Member States with its existing perindopril product by virtue of the Krka Settlement Agreement.

5.5.3.4.2.4 Intermediary conclusion on financial consideration.

(1795) The circumstances of the negotiation and the conclusion of the ALA, the content of the ALA, as well as the way the acquired technology was subsequently used (or not) by Servier suggest a wide gap between the high sum Servier paid for the two patent applications, and the actual, or expected, benefits from the acquired technology, which were, at best, moderate, if any at all.

(1796) This gap is better explained by Krka's statement, considering the value of the transferred technology primarily in its being a key for new, generic entry onto the market.

2415 Paragraph (1766).

2416 Krka also argues that the Commission failed to explain why Krka would have waited to sell its technology, in particular as the two patents were obsolete (as Krka abandoned perindopril in alpha form), and Servier was the only interested buyer (Krka's reply to the Statement of Objections, paragraphs 157, 163, ID8742, p. 81, 83-84, See also Servier's reply to the Statement of Objections, paragraph 1127, ID10114, p. 374). In the Commission's view, such timing of sales (by Krka, a reportedly captive seller to a buyer, Servier, alleging to block the technology with its '947 patent) can be explained by an on-going relationship between the parties consisting of inducing Krka to renounce/transfer its technology to the benefit of Servier (see paragraph (1811)). This is moreover also fully consistent with Krka's strategy document (paragraph (853)). Concerning Krka's claim that its technology was obsolete, and could only be sold to Servier, the Commission observes, in addition to the above arguments, that Servier was willing to offer a selling price comparable or higher to other consummated or attempted technology acquisitions ([company name]*, Azad, Lupin, Sandoz) which casts strong doubts on the captive nature of Krka's technology.

2417 See paragraph (957).

5.5.3.4.3 Parties' objectives

(1797) To better understand the context in which the ALA was concluded, one needs to recall the above finding that the object of the Krka Settlement Agreement was to share EU markets between Servier and Krka.

(1798) The Commission's file contains no explicit contemporaneous indications as to Servier's intentions behind the conclusion of the ALA.[2418] During the investigation, Servier claimed that the ALA was unrelated to the Krka Settlement Agreement and that its purpose was solely to acquire technology to improve its manufacturing processes and achieve savings.[2419] Yet, in *tempore non suspecto*, Servier had admitted that the EUR 30 million payment was linked to the settlement.[2420] This is corroborated by how the patent acquisition was carried out, and by an absence of any significant attempts to recoup the investment into the technology by exploiting it.

(1799) Moreover, this acquisition has been preceded by a number of acquisitions, or attempted acquisitions of generic perindopril technology, including from [company name]*, Azad, and Generics UK. It is recalled that in the Azad agreement, Servier explicitly acknowledged that it purchased Azad technology in view of its interest "***to strengthen the defense mechanism*** *for its own alpha, betha and gamma forms of perindopril*"[2421] (emphasis added).

2418 Servier claims that the Commission does not bring any convincing evidence to support its claim that the ALA served to reinforce the market sharing between Servier and Krka. First, there is no contemporaneous evidence that would allow for such a conclusion; second, Krka's statements are speculative and not borne out by the evidence (Servier's reply to the Statement of Objections, paragraph 1092, ID10114, p. 365). The Commission recalls that it is not necessary that the parties have the intention of restricting competition for the agreement to constitute a restriction by object: "*even supposing it to be established that the parties to an agreement acted without any subjective intention of restricting competition, such considerations are irrelevant for the purposes of applying [Article 101(1)]*" (Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 21; see also Judgment in *General Motors*, C-551/03 P, EU:C:2006:229, paragraph 64). Second, while Servier focuses on Krka's statements during the investigation, there are both direct and circumstantial indications concerning the parties' objectives, as presented below.

2419 Servier contests that there was a link between the payment for patent applications and the settlement agreement. (Servier's reply to the Statement of Objections, paragraph 1084, ID10114, p. 363). As it evidently flows from section 5.5.3.3.3, the assessment of the Krka Settlement Agreement does not consider the payment of EUR 30 million as an inducement for Krka to accept the restrictive settlement terms, and leaves open as undecided the question whether there was a link between the settlement and the ALA. Nonetheless, such statements may still reveal a unity of purpose of the two sets of agreements.

2420 See paragraphs (933) - (935). Servier contends that the Commission's assertion is solely based on the fact that Servier submitted the entirety of agreements between Servier and Krka in reply to the Commission's question on patent settlements in the context of the Pharmaceutical Sector Inquiry (Servier's reply to the Statement of Objections, paragraph 1084, ID10114, p. 363). The Commission takes the view that Servier's reply obscures the fact that the company not only submitted the ALA in reply to a request for settlement agreements and related agreements, but also characterised, in the period which predated the present investigation, the payment as a settlement sum transferred to Krka. Servier even revised the sum of value transfer from EUR 15 million to EUR 30 million in a further reply to the Commission's clarification question (see paragraph (935)) Therefore, Servier did not, as it now claims, simply provide more information than needed in the context of the Sector Inquiry by mistake – it consistently presented the ALA as being related to the settlement agreement. This only changed during the Commission's investigation in the present case.

2421 See paragraph (369). Servier claims that the reference to other acquisitions is irrelevant for the acquisition of Krka technology. At most, this would show that Servier was effectively interested to acquire third party technology (Servier's reply to the Statement of Objections, paragraph 1117, ID10114, p. 372). The objective of "strengthening the defense mechanism" for Servier perindopril

(1800) Krka argues that the assessment fails to explain why Krka was prohibited from selling the rights to its technology, especially as it incurred significant cost and started development of a new form of perindopril.[2422] The Commission considers that Krka's general entitlement to dispose of its IPRs is not at stake here. The Commission only takes issue with Krka's exclusive transfer of IPRs to Servier. In the circumstances at hand, Krka was aware that acquisitions of perindopril technology by Servier could lead to foreclosure of generic competitors.

(1801) Even prior to the ALA, other generic companies, such as Teva, considered that there was an "*industry consensus […] that Servier will attempt to take out API sources"*. Based on its commercial contacts with Krka prior to the ALA, Teva internally reported that "*KRKA feel there is a strong likelihood that Servier will attempt to buyout all API manufacturers"*.[2423] Krka admitted, also *ex post facto*, that in view of the Krka Settlement Agreement, it "*found the offer to assign patent applications to Servier attractive*". On the same token, Krka also admitted that it "*assumed that Servier feared that patents could have been assigned or licensed to any third competitor who could have developed a product with required Phar.Eu. purity, even if alpha form had been revoked – Krka's patents solved "purity problem*". The head of Krka's patent department stated even more explicitly that for Servier, the object of the acquisition was in "*blocking to competitors very economic processes.* […] *We think we were able to block two economic and viable options"*. He added that "[t]*here could be other [viable options] but I am not aware of any other*".[2424]

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patent position is fully consistent with other actions by Servier as well as with perceptions by Krka and other parties (Teva) – see below. The terms of the attempted acquisition of Sandoz technology, a year after the ALA, […]*. Servier made the purchase conditional on fulfilling regulatory requirements, industrial use, and, importantly, non-infringement of Servier patents. Servier was thus not interested in the technology in the case it would presumably infringe one of its patents, and this regardless of the potential benefits it could yield to Servier from process improvement. Sandoz technology would only be purchased if it had verifiably allowed for a viable independent entry (which actually was the case, but Sandoz eventually quit the negotiations and launched the product) (paragraphs (406) - (409)). In its reply to the Letter of Facts (ID10289, p. 177), Servier claims that such inferences are speculative, and in contradiction with the Commission's assessment of the Lupin Settlement Agreement, where the Commission would have, according to Servier, considered the absence of such purchase conditions as indicative of anti-competitive nature of the agreement. This is incorrect. In both cases, the terms of the (proposed) agreements betray a lack of genuine interest in the commercial exploitation of the generic company's substitute technologies. It would otherwise be hard to explain why Servier, if genuinely expecting to achieve significant efficiencies from process improvements from a USD [40–55]* million acquisition, would only be interested to buy Sandoz technology if it were not (partly) covered by Servier's patent claims, which would however have no impact whatsoever on Servier's exploitation of the acquired technology. […]*.

2422 Krka's reply to the Statement of Objections, paragraphs 159 and 163, ID8742, p. 82-84. In paragraph 163, Krka also argues that the Commission's assessment was performed purely from an ex post perspective and was thus flawed. In the Commission's view, Krka fails to explain in which respect and in which specific instance the ex post analysis was allegedly followed in the Statement of Objections. As developed in this and the preceding sections, the Commission's assessment is fully based on the circumstances at the time of the transactions, as well as parties' ex post explanations concerning these circumstances. The Commission's findings do not contend that Krka was in a situation devoid of commercial risks, although the Krka Settlement Agreement did already secure to Krka legal and commercial certainty in its profitable core markets. The assessment also does not question that the ALA may have been the most lucrative avenue (a financial windfall of 30 million) for Krka to follow. This does however not imply, as was found in the present case, that such an avenue is lawful.

2423 See section 4.2.3.

2424 See paragraph (957).

(1802) It needs to be underlined that the transfer of Krka's technology formed part of the "*joint activity to control the market*", as outlined in a document from 2005 by a member of Krka's Board of Directors setting out a strategy from 2005-2008, and beyond 2008.[2425] During the investigation Krka explained the notion of the "control of the market" as follows: "*Servier would have retained valid patent for alpha form, while Krka would get immediate access to the CEE markets – in such way the '947 patent would protect Servier and its market, while [Krka] would get access to sell immediately on its traditional markets. Such solution would also enable minor number of competitors"*.[2426]

(1803) All of the above evidence points into the direction that the ALA had been concluded with the object to reinforce market allocation between Servier and Krka and lessen competition from third parties. It appears that Krka's technology concerning perindopril API and formulations, considered as "key" to enter the market, was therefore transferred to Servier to disable any third parties, i.e. other generic companies, from accessing it (by licensing or acquisition) in order to enter the market. Krka itself considered that Servier was buying this technology to prevent viable generic entry.

5.5.3.4.4 Conclusion on the object of the ALA

(1804) The ALA, concluded two months after the Krka Settlement Agreement, should be analysed in the context of the arrangement between Krka and Servier to share markets, whereby Krka withdrew from competing in 18/20 Member States, while both companies entered into a de facto duopoly in seven CEE Member States.

(1805) While the Krka Settlement Agreement prevented Krka from contesting the validity or enforceability of Servier's patents and from supplying perindopril in the restricted markets, Servier was not fully protected against Krka, at least for the 18/20 markets where Krka withdrew from competition with its existing perindopril formulations. The threat, as confirmed by Krka, came from the possibility that generics would get access to Krka's technology to produce perindopril API and formulations in particular for the restricted markets in the 18/20 Member States.

(1806) In this respect, the ALA closed the gap and preserved the *status quo* achieved with the market sharing arrangement endorsed in the Krka Settlement Agreement. By the acquisition of Krka's technology, Servier ensured that Krka no longer had the competitive ability to license out or assign its technology to other generic companies. At the same time, Krka was granted a licence back for its own technology allowing it to continue producing generic perindopril for the seven licensed territories under the Krka Settlement Agreement.

(1807) The significant payment of EUR 30 million for Krka's technology is disconnected from Servier's expected or actual earnings from the commercial exploitation of the

[2425] See section 4.3.3.2. For Servier's comments concerning the relevance of this document, see footnote 2385.

[2426] According to Servier, this quotation by Krka only concerns the licence for the '947, and not the acquisition of technology (Servier's reply to the Statement of Objections, paragraph 1119, ID10114, p. 372-373). The Commission notes that Krka's explanations primarily relate to the question of settling and a licence from Servier, and do not explicitly tackle acquisition which the strategy itself considered as a part of this "joint strategy". Krka nonetheless acknowledged that this strategy was a mix of patent and regulatory measures (patent assignment fits this general description) which, amongst other, aimed at a minor number of competitors (paragraph (854)).

patent, which remain marginal, if any. Instead, the magnitude of the payment, too, suggests that it forms part of the market sharing arrangement between Servier and Krka. The payment is significantly inferior to the loss of earnings that Servier could suffer following an effective generic entry in the 20 restricted markets (the EBIT profits in selected 13 EU markets alone amounted to EUR [150-350] million in 2007).[2427] At the same time, the payment is superior compared to what Krka could have likely earned by transferring this technology to other generics.[2428] Assuming that Krka would charge a [0–5]* % royalty rate (by analogy with the licence for the '947 patent), the total turnover of generic companies using Krka technology would need to exceed EUR 1 billion (after discounting), which is unrealistic.

(1808) Although Servier contends, *ex post facto*, that the aim of the ALA was to acquire technology to improve its perindopril production processes, there is no evidence to support that Servier had expected any efficiencies, actually achieved them, or at the very least genuinely attempted to achieve them. The content and the context of the ALA (weak warranties, deferred transfer, no due diligence) equally suggest that the agreement may an object other than the commercial exploitation of the acquired technology.

(1809) This is further supported by the evidence indicative of the parties' subjective intentions. The ALA follows a pattern of earlier acquisitions or attempted acquisitions of generic perindopril technology by Servier, some of which were explicitly aimed at strengthening Servier's "*defense mechanism*". A number of generic companies, including Krka, considered that Servier was pursuing a strategy of buying out already scarce sources of perindopril API. The ALA, together with the Krka Settlement Agreement, fell squarely within Krka's strategy to jointly control the market with Servier, with a "*minor number of competitors*".

(1810) Based on the above, it can be concluded that the ALA is an agreement which has as its object to impose further restrictions on Krka's ability to remain a source of competition to Servier, and thus strengthen the market sharing arrangement put in place by the Krka Settlement Agreement. In this context, the EUR 30 million payment served as a form of rent sharing between the parties.

5.5.3.4.5 Krka Settlement Agreement and the Assignment and Licence Agreement form a single and continuous activity consisting in a set of agreements restricting competition under Article 101(1) of the Treaty

(1811) The following factors[2429] suggest that the conclusion, by Servier and Krka, of both the Krka Settlement Agreement and the Assignment and Licence Agreement formed part of a single and continuous activity to restrict competition by sharing markets for perindopril in the EU:

- consistent and short sequence of time between the signing of the two agreements (October 2006 until January 2007). During this period, just over two months, Servier reportedly expressed interest in the acquisition only a month after the settlement, and the negotiations started

2427 Calculated based on the data underlying section 6.4.5.3.

2428 The payment to Krka was at least ten times higher than the total expenditure in development of generic perindopril by most of the companies observed.

2429 See, for example, Commission Decision COMP/C-3 /37.990 – Intel, Official Journal C 227, 22.9.2009, p. 13–17, p. 495-499; and of Article 101 in Joined Judgments of 12 December 2007, *BASF AG and UCB SA v Commission*, T-101/05 and T-111/05, ECR, EU:T:2007:380, paragraph 209.

immediately. There were no important developments affecting the main markets targeted by the agreements;

- high degree of centralisation: the agreements were signed by the same representatives of Servier and Krka, i.e. [employee name of Servier]*, Servier proxy and Director General for international operations, including Northern, Central and Eastern Europe, and [employee name and function with Krka]*;[2430]

- restrictions in the agreements follow the same objective: market sharing between Servier and Krka: the agreements contain a series of restrictions which aim at putting in place a market sharing arrangement between Servier and Krka (18/20 MS reserved to Servier andseven MS shared between Servier and Krka). This arrangement, as described above, relies on a combination of non-compete and non-challenge obligations, selective licensing from Servier to Krka, and a transfer of all completed Krka perindopril technology (accompanied by a license-back to Krka to enable Krka to supply the seven licensed markets);

- similar method of restricting competition: both the Krka Settlement Agreement and the ALA are based on offering an inducement to accept restrictions, which is tantamount to sharing of markets or rents. The Krka Settlement Agreement granted Krka legal certainty against patent infringement through a licence for seven of its core, CEE markets, as an inducement for Krka to withdraw from competing with Servier on the remaining 18/20 EU markets, including Servier's biggest markets. The ALA stipulated a very significant payment of EUR 30 million for Krka's transfer of its perindopril technology to Servier as an additional measure to prevent competition from Krka. Given the circumstances of the acquisition and (non)use of this technology by Servier, this can be best explained as a form of rent sharing.

(1812) The above shows that Krka Settlement Agreement and the Assignment and Licence Agreement constituted an overall plan for a common course of action. It can be concluded that the Krka Settlement Agreement and the ALA followed Servier's and Krka's objective to share markets by preventing or limiting generic competition between, or to, Krka and Servier. These agreements between Servier and Krka follow the same objective, use similar methods, and were signed in a short sequence of time by the same representatives of both Servier and Krka. The Krka Settlement Agreement and the ALA (together also referred as the "Krka Agreements") therefore amount to a single and continuous restriction of competition under Article 101(1) of the Treaty.

[2430] Concerning Servier's rhetoric question whether all agreements signed by [employee name of Servier]* form part of a single and continuous activity (Servier's reply to the Statement of Objections, paragraph 1128, ID10114, p. 374), the Commission explains that [employee name of Servier]* was not only a signatory and negotiator for all the investigated agreements between Servier and Krka, but also of other settlement agreements, and also the author of Servier's strategy document: "Coversyl: defense against generics". This suggests that [employee name of Servier]* was closely involved in, and centralised the design and the execution of Servier's strategy concerning perindopril, in this case concerning generic competition from Krka.

5.5.3.5 Krka Settlement Agreement and the ALA restrict competition by effect pursuant to Article 101(1) of the Treaty

(1813) The previous section concluded that the Krka Agreements amounted to a single and continuous restriction of competition by object, the Commission will, nonetheless, for the sake of completeness, show in the present section that the Krka Agreements were likely to cause restrictive effects on competition between Servier and Krka. For the general framework for assessment of restrictive effects, reference is made to section 5.1.7 above.

(1814) To determine if the Krka Agreements were likely to entail restrictive effects on competition, the following elements need to be considered: (i) Servier's competitive position, (ii) whether Krka was an actual or potential competitor of the originator company; (iii) content of the agreement (the inducement changes the incentives of the generic party to accept the exclusive clauses of the agreement), and (iv) competition that would have existed in the absence of the agreement. The latter point will focus on the competitive behaviour that Krka would have been likely to engage in, absent the agreement, and on the other relevant sources of competition to Servier thereby demonstrating the importance of Krka as a competitive threat.

(1815) For points (i) to (iii), the analysis in this section will rely on the preceding conclusions in this Decision, which will be shortly summarised for ease of reference. Thus, the present section will focus in more detail on point (iv).

(1816) This decision is geographically limited to the markets in France, the Netherlands, and the UK. These three markets have been selected as they fulfilled the following two cumulative conditions: (i) they belong to the markets for which Servier's market position has been assessed in the preceding analysis (see sections 6 and 7) and (ii) they belong to the markets where Krka needed to withdraw from competition pursuant to the Krka Settlement Agreement (the 18/20 restricted markets).[2431]

5.5.3.5.1 Servier's competitive position

(1817) In the framework of the dominance assessment under the standards of the Article 102 of the Treaty analysis, it was established that Servier held a dominant position on the perindopril final product market and the upstream perindopril API technology market (see sections 6.5 and 7.3). According to the Horizontal Guidelines, these findings are directly transposable to the assessment of market power under Article 101(1) of the Treaty.[2432]

(1818) In the context of the Krka Agreements, Servier thus had an interest in protecting its market exclusivity in the 18/20 markets (including most important markets for Servier), as there had been virtually no launch of generic perindopril and therefore its supra-competitive rents were intact and thus not competed away. In addition, even after granting a licence to Krka for the remaining seven CEE markets, Servier enjoyed a *de facto* duopoly with Krka for a number of years. Accordingly, Servier's perindopril sales generated an EBIT profit of EUR 244 million in 2005 and EUR [150-350] million in 2007.[2433]

2431 This does not imply that such or similar effects would not be likely for other territories covered by the assessment of the Krka Agreements as a restriction by object.

2432 *Guidelines of the applicability of Article 101 of the Treaty of the Functioning of the European Union to horizontal co-operation agreements*, OJ 2011/C 11/01, point 42.

2433 Calculated based on the data underlying section 6.4.5.3.

(1819) This also afforded the means to protect its market power: continued inflow of rents in the absence of price competition from generics provided the "deep pocket" to Servier from which it was able to finance rent sharing with generics in return for their withdrawal from competition. To illustrate the significant financial incentive from the originator company, one can compare the transfer of EUR 30 million pursuant to the ALA[2434] to the EUR [2.5-7] million gross margins Krka was expecting in the first year of launch in Western Europe [2435] in the case of annulment of the '947 patent. As generic companies' margins generally tend to dynamically diminish as time passes,[2436] this comparison shows that the overall payment amount in the ALA likely exceeded expected profits in the most lucrative period of launch with an early mover advantage.

5.5.3.5.2 Krka and Servier as actual or potential competitors

(1820) Based on the facts in section 4.3.3 and according to the assessment in section 5.5.2, it was possible to conclude that Krka was a potential competitor to Servier in the production and supply of perindopril for the EU markets at the time the settlement with Servier was concluded, including the market covered by the assessment of restrictive effects, that is France, the Netherlands, and the UK. Krka was an actual supplier of perindopril in five geographic markets and was preparing to enter a number of other markets, which shows the intentions of the company in this respect. More importantly, Krka was able to enter the markets where it was not yet an actual supplier within a short period of time as it had completed the development of its product. Krka was also actively clearing the way for its product through litigation in the UK and was convinced of the invalidity of the '947 patent.[2437]

5.5.3.5.3 Content of the Krka Agreements

(1821) As indicated in detail in the previous sections relating to the Krka Settlement Agreement, Krka committed not to enter with the perindopril product it had actually developed in 18/20 Member States.[2438] Krka also committed no longer to challenge the '340 and '947 patents of Servier. In return, Krka was granted a royalty-bearing licence for the '947 patent for seven CEE markets, a significant economic inducement to sacrifice the restricted markets. As established above in section 5.5.3.3.7., this arrangement amounted to market sharing between Servier and Krka.[2439]

(1822) In addition, Servier also acquired two patent applications protecting Krka's technology, and in turn Krka received EUR 30 million and an exclusive licence-back, allowing it to continue to produce and market perindopril pursuant to the Krka Settlement Agreement. As established above in section 5.5.3.4, this acquisition

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2434 Not counting Krka's actual earnings under the licence in seven CEE markets (approximately EUR [3-8] million gross margin in three largest markets, Czech Republic, Hungary and Poland in 2007).

2435 See paragraph (878).

2436 See, for example, the developments in the UK and the Netherlands following generic entry, section 6.5.1.2.6.

2437 Servier's arguments in this regard (Servier's reply to the Statement of Objections, paragraphs 1044-1054, ID10114, p. 355-357) are essentially the same as the ones which were addressed in section 5.5.2.

2438 It is recalled that the accession of Bulgaria and Romania to the EU took place on 1 January 2007.

2439 Concerning Servier's statement that the Krka Settlement Agreement was pro-competitive, as the licence allowed Krka to launch or continue to commercialise perindopril in seven markets (Servier's reply to the Statement of Objections, paragraphs 1069-1070, ID10114, p. 360), the Commission refers to the above analysis of essentially the same arguments in paragraph (1755).

amounted to an additional restriction with the same objective of strengthening the market sharing arrangement by foreclosing access to Krka's technology to other generic companies.

(1823) Servier claims that the combination of Krka Agreements can have no anti-competitive effects, as none of the individual effects was capable of restricting, or actually restricted, competition.[2440] This is unfounded. The subsequent section will explain the restrictive effects from the Krka Settlement Agreement, as reinforced by the Assignment and Licence Agreement.

5.5.3.5.4 Competition that would have existed in the absence of the Krka Agreements and the Importance of Krka in view of the remaining sources of competition

(1824) This section will examine the competition that would have existed in the absence of the restrictive provisions of the Krka Settlement Agreement and the ALA. The section will focus on the competitive behaviour that Krka would have been likely to engage in, absent the agreements, and on the other relevant sources of competition to Servier thereby demonstrating the importance of Krka as a competitive threat to Servier.

Likely behaviour absent the Krka Agreements

(1825) In the absence of the restrictive provisions of the Krka Settlement Agreement, Krka would have remained a competitive threat as a potential generic entrant with perindopril in the UK, France and the Netherlands. Krka would have retained significantly more incentives and ability to compete and challenge Servier's market position if it had not settled or had settled on less restrictive terms in the absence of the licence agreement as the economic inducement to accept restrictions in 18/20 Member States, including in particularly France, the Netherlands, and the UK, notably allowing for earlier generic entry in the markets.

(1826) In its reply to the Statement of Objections, Krka argues that it only had three options following the Opposition Decision. First, it could abandon launch and wait for the final decision of the EPO Board of Appeal. Second, it could launch at risk but this was commercially unacceptable. Third, it could settle the dispute and negotiate a licence. In addition, it could also try to develop a new formulation not covered by the '947 patent.[2441] The Commission considers that Krka fails objectively to present the available options before the settlement. First, and foremost, Krka's explanation contradicts its own course of action, and remarkably omits to take note of the on-going litigation before national courts, in the context of which it launched counterclaims for annulment of Servier's patents in the UK and successfully averted an interim injunction in Hungary.[2442] Thus, Krka did not appear to have abandoned perindopril erbumine products, but continued with marketing such products at risk in the 5 markets where it had already launched and challenged patents asserted by

2440 Reply to the Statement of Objections, paragraph 1133, ID10114, p. 375.

2441 ID8742, paragraphs 205 and 175, p. 100 and 88.

2442 On the contrary, Servier pointed out that continued litigation was one of the two options available to Krka. If Krka took the first option and continued litigation it could, under the best possible scenario, obtain revocation within one year (two years if appealed) in the UK, and within two to three years for the EU, without any guarantee of success, Under the second scenario, it could attempt to settle and negotiate a licence from Servier. In any event, Krka could not have penetrated the EU18/20 markets absent the settlement agreement (Servier's reply to the Statement of Objections, paragraphs 968- 969, ID10114, p. 336). These points are addressed in the present section.

Servier in the UK (in addition to EPO opposition), which affirms their continued endeavours to enter Western European markets.[2443] Second, the development of a novel form of perindopril is not mutually exclusive with other alternatives, and can represent a complementary second limb of any alternative Krka would opt for. In case Krka continued with litigation absent the settlement, the alternative product development could provide a fall-back position.

(1827) Hence, it appears plausible that, absent the non-challenge obligation, Krka would have remained a challenger to the validity of the '947 before the UK courts and the EPO. Through a number of its generic partners, for example Ratiopharm, which undertook to Servier to suspend perindopril activities pending the Krka litigation, Krka was interested to directly or indirectly market its perindopril in other Western European markets.[2444] Krka previously considered that its patent case was amongst the best ones, and that it was a particular threat to the '947 patent which was pivotal for Servier's continued product exclusivity.[2445] Although the High Court judge did not invalidate the '947 by a summary decision, as requested by Krka, and instead ordered a full trial, he acknowledged that Krka had "a powerful base" to challenge the validity of the '947 patent in the UK.[2446]

(1828) Secondly, in the absence of the non-compete obligation, Krka would have remained a threat due to its completed development of perindopril (with granted marketing authorisations) as supplier to local distribution partners (such as Ratiopharm, Teva and Stada) which could challenge Servier's patents (as Teva did in the Netherlands and Czech Republic) or enter at risk. Absent the Krka Settlement Agreement, Krka would have retained the ability and incentives to compete and pursue commercial strategies independently of Servier, taking into account the patent situation. Even if Krka restarted the development of a potentially non-infringing form of perindopril, it admitted that it expected that the development would take –two to three years.

(1829) Thirdly, Krka would have retained the freedom to sell or license out the rights to its perindopril technology to third parties, representing an additional source of competitive pressure to Servier.[2447]

2443 While the Commission cannot rule out that Servier would ultimately prevail in the litigation, the evidence in section 5.5.2 demonstrates that Krka had a real concrete possibility to overcome the patent barrier.

2444 For example in France and the Netherlands, where it received marketing authorisations in October 2006. See section 4.3.3.8.

2445 Servier repeated its claims that the non-challenge obligation was without effect, as there were several other opponents before the EPO, and parallel (or possibly new) litigation procedures before the UK courts (Servier's reply to the Statement of Objections, paragraphs 1058-1059, ID10114, p. 358). The Commission refers to its assessment in paragraph (1712). In addition, concerning the UK litigation, the Commission notes the following. There were two more actions for annulment of the '947 in the UK at the time of the PSA, by Apotex and Lupin as the only remaining "hostile players" (paragraph (1842)). Krka was aware of the pattern of previous settlements, and thus of Servier's strategy to conclude consequent settlement agreements with all parties it had hitherto been involved in litigation with, including Krka itself. In view of a limited number of generics in advanced perindopril development comparable to Krka, it was plausible that Servier would consider reaching settlements with these companies, too. This was confirmed by actual course of events, as presented in section 5.1.7.3.

2446 See paragraph (904).

2447 Basing itself on the developments following the revocation of the '947 patent, giving rise to a multitude and diversity of generic entrants, Servier claims that the Assignment and Licence Agreement had no restrictive effects (reply to the Statement of Objections, paragraph 1132, ID10114, p. 374-375). This argument is misconceived as it does not consider the competitive structure and the likely anti-competitive effects at the time of the conclusion of the agreement. For example, when the '947 patent

(1830) In the absence of the above obligations (except for the non-challenge obligation), the competitive threat from Krka would normally be maintained irrespective of whether the parties would not have settled or would have settled on less restrictive terms, notably allowing earlier generic entry.[2448] Even if entry at risk or patent challenge by Krka or its distribution partners absent the agreement could potentially fail, there was nonetheless a significant enough likelihood that Krka's course of actions would be successful so that prospects for actual competition would have been better in the absence of the agreement. Moreover, even if Krka and its partners abandoned immediate plans to launch perindopril at risk, and the on-going litigation only concerned the UK, and not France and the Netherlands, it is not excluded that if generics prevailed in litigation in one Member State, spill over effects could reinforce their confidence and lead to new patent challenges[2449] and/or launches at risk in other markets (as was actually the case in the Netherlands and Czech Republic following the annulment in the UK of the '947 patent).

(1831) In summarising the options available to them, the parties omit that of a less restrictive settlement. To avoid market sharing, Krka and Servier could have negotiated a less restrictive settlement for the Member States most immediately affected by litigation (notably the UK and the Netherlands) where the restrictions would only be based on the merits of the litigation and not leveraged by an inducement unrelated to the actual litigation. Alternatively, the settlement could grant Krka earlier entry or a licence for the entire EU territory, or limit the restrictions from the settlement agreement to the Member States covered by the licence agreement.

(1832) During the investigation, Krka claimed that the Krka Settlement Agreement actually accelerated generic entry, and not delayed it, as it received a licence for the '947 patent in seven Member States.

(1833) First of all, this statement only concerns the licensed territories, and does not consider the impact of the agreement on Krka's ability and incentives to compete in

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was revoked, Krka's technology was again a source of perindopril supplies either by direct sales or by supplying other generic companies, as the non-compete restrictions of the Settlement Agreement were no longer in force.

2448 Servier claims that the fact that Krka did not launch in the UK following the annulment of the '947 patent in July 2007 seriously weakens the Commission's position that Krka could potentially launch at risk (Servier's reply to the Statement of Objections, paragraph 1055, ID10114, p. 358, reply to the Letter of Facts, ID10289, p. 163). Krka explained that given the remaining risks, it opted to wait for the decision on the appeal, but provided no contemporaneous evidence to support its claim. The Commission notes that this explanation closely corresponds to the objective of prolonging the uncertainty, which Servier's patent director identified amongst the main motives for appealing the first instance decision even if the appeal had "**almost no chance*" (paragraph (185)). Clause II of the Settlement Agreement could be read as implying that the settlement is only terminated once both the '947 patent and the '340 patent cease to be in force. In the UK, this occurred in September 2008. Moreover, a number of factors suggest that Krka lacked a competitive edge, which made it less attractive to take the risk and launch before a final court decision, or the risk of violating the settlement agreement. Firstly, Krka could no longer control the course of the invalidity action in the UK (and elsewhere) as the Krka Settlement Agreement prevented it from contesting the validity of either the '947 or the '340 patent. Second, in addition to Apotex, two authorised generics also entered the market (described by Servier as the "nuclear weapon" scenario (paragraphs (203) - (205))). Consequently, Given that price levels were significantly depressed by the presence of three generics, it is questionable if Krka had a sufficient economic incentive to launch at risk.

2449 It is recalled that, in the context of their cooperation, Ratiopharm and Krka were discussing patent litigation strategies for both France and the Netherlands (see paragraph (869)).

the remaining 18/20 Member States,[2450] where the combination of non-challenge and non-compete obligation, and the assignment of Krka's technology to Servier eliminated Krka as a source of competition to Servier for a number of years. Secondly, it is unclear to which extent the Krka Settlement Agreement actually enhanced competition in the licensed Member States, as Krka had already launched its perindopril in five of these Member States prior to settling with Servier.[2451]

(1834) Therefore, in the absence of the restrictions in the Krka Agreements, Krka would have remained a prominent potential competitor to Servier through its challenge to patent validity, its advanced product development, and its API technology for which patent protection was sought.

Remaining competition

(1835) Given the removal of a potential source of competition to Servier, the subsisting market structure at the time of the conclusion of the agreement will be examined, in particular by identifying other relevant sources of competition and whether they could be perceived as capable of sufficiently constraining Servier to offset the effects of the Krka Agreements.

(1836) The analysis will focus on generic competition which was by far the most important source of constraint on Servier's prices and volumes for perindopril.[2452]

(1837) There was no generic perindopril on the market at the time the agreement was concluded, and there was no effective generic entry afterwards until May 2009, with only few exceptions, such as the UK (annulment in July 2007), and the Netherlands (entry at risk in December 2007 followed by patent annulment in June 2008).

(1838) It is recalled that, at the time of the Krka Agreements, the '947 patent was still in force in all countries where it was granted. There were few companies whose perindopril was meeting the requirements of the European Pharmacopoeia. Patent and regulatory barriers to entry were thus still high. Accordingly, the sources of competition to Servier, as identified in the Commission's market investigation, were thus limited to those perindopril developers which were actively taking patent-related measures to launch a viable perindopril product. These operators were either contesting the validity of the '947 patent, or seeking to launch a non-infringing form of perindopril. In the course of the investigation, Krka identified Niche as the most likely entrant in 2004 and 2005, and Apotex, Ivax/Teva, Cipla, Lupin, Lek/Sandoz and Glenmark[2453] as the most likely entrants in 2006 and 2007.[2454]

2450 Including France, the Netherlands and the UK, the only markets covered by the present assessment.

2451 Servier argues that there is a contradiction between Commission's finding that to remove a possibility to win a patent challenge constitutes a restriction by competition, and the position that removing patent risks for Krka by granting it a licence would not be an improvement to the competitive situation (Servier's reply to the Statement of Objections, paragraph 1071, ID10114, p. 361). The Commission accepts that the licence increased Krka's legal certainty in the seven markets and served as an economic inducement for Krka. This said, Krka could also have achieved legal certainty by pursuing existing or new legal challenges in these markets absent the settlement. In any event, the Commission did not reach any conclusion concerning the restriction of competition in the 7 licensed markets. What matters is that, to the extent the licence may have possibly improved competition in the seven markets, it not only did not improve, but actually worsened the competitive situation in France, the Netherlands, and the UK (and more generally 18/20 Member States where licence was not granted but restrictions applied).

2452 See section 6.5.1.2.6.

2453 Including other companies sourcing Glenmark's perindopril, Specifar, Vulm and Polpharma. ID0043, p. 159-162.

(1839) As elaborated in section 5.1.7.3, the first group of operators were thus generic companies with an advanced perindopril development which initiated invalidity actions against the '947 patent. As mentioned above, after reverse payment patent settlements with Niche, Matrix and Teva, the only remaining patent challengers in the UK (where all litigations/disputes directly leading to the investigated settlements took place) were Krka, Lupin and Apotex (Teva was only a potential challenger outside the UK).

(1840) The second group consisted of few generic operators developing non-infringing form of perindopril. At the time of the Krka Agreements, only Sandoz and Cipla had an advanced project for perindopril possibly avoiding any of Servier's patents, including the '947.[2455]

(1841) It is recalled that the aforementioned Servier anti-generic strategy document identified the main sources of competition Servier was facing in June 2006. Apart from Niche, Matrix and Teva, which were in the interim removed as a threat through the settlements,[2456] Servier only mentioned Krka, Glenmark,[2457] Apotex and [name of Lupin business partner]* (which was in fact sourcing its API from Lupin).

(1842) This assessment of competitive landscape largely coincides with Krka's aforementioned perception of likely entrants in or before the period 2006-2007 as mentioned in paragraph (1838) above.[2458] Servier's internal correspondence in December 2006, just after Krka settled, demonstrates that Servier expected only two "hostile players" in the market upon the eventual launch of its authorised generics by Teva and another generic company. These two players were Apotex and Lupin.[2459]

(1843) Thus, Krka was one of the closest threats to Servier: as a potential supplier to Teva, it had underpinned Teva's launch threat to Servier which led to the Teva Settlement Agreement, it was the first company to launch generic perindopril in the EU (CEE markets), and to have a UK marketing authorisation. It was also in the process of obtaining marketing authorisations elsewhere (amongst others, France and the Netherlands in October 2006). Krka was also confident that its arguments for the invalidity of the '947 were amongst the best ones. Apart from Krka, there were only three other comparable generic threats to Servier with advanced perindopril development, either actively contesting the validity of the '947 patent (Apotex, Lupin), or with non-infringing forms of perindopril (Sandoz). Apotex had completed perindopril development, but was vulnerable to potential infringement claims by Servier in the country of manufacture, Canada. Unlike Krka, Lupin and Sandoz had not yet received marketing authorisations, and therefore a certain delay compared to Krka could be expected.

2454 ID1307, p. 35.

2455 See paragraphs (2694) and subsequent. Cipla's project, while advanced, appeared to possibly infringe Servier's patents, and as no legal action was started by the company, Cipla needs not to be regarded as a direct threat to Servier to the same extent as Krka.

2456 Another generic company, also mentioned in the report, did not have an own perindopril product and also concluded a distribution agreement with Servier. See section 4.1.2.5.1.

2457 At that time, Glenmark's development was less advanced at the time, and was fraught by possible infringement of Servier's process patents. Accordingly, although Glenmark had perindopril in the alpha form, it was not challenging any of the relevant patents, adopting a passive attitude. Therefore, Glenmark needs not to be regarded as a direct threat to Servier to the same extent as Krka.

2458 Krka's competitive overview is also corroborated by similar overviews relating to the same period by Lupin (ID0054, p. 144 - 148) and Teva (ID0085, p. 11 - 13).

2459 See paragraph (1024).

(1844) Hence, where there has been no actual generic entry, and there is already only a very limited number of potential competitors with prospects of a viable launch in view of the persisting barriers to entry (in particular patent and regulatory compliance), the removal of a single competitor significantly reduces the likelihood of a timely and effective generic entry (and therefore increases the probability generic entry will be delayed to the detriment of consumers).

(1845) In addition, one needs to recall Servier's expected/prospective actions to confront generic entry, which posed an additional source of uncertainty as regards the likely behaviour of the remaining potential competitors.

(1846) Thus, as shown in section 5.1.7.3, even for the already very limited competition from the three remaining sources identified above, there was, at the time of the Krka Agreements, a strong possibility that they would be removed from competition by an agreement or otherwise.

5.5.3.5.5 Conclusion – the Krka Agreements were likely to entail restrictive effects for competition

(1847) The above analysis recalled that Servier held significant market power in the market for perindopril formulations and the upstream market for perindopril API technology, in which also Krka was active as at least a potential competitor. Servier induced Krka into a market sharing arrangement by offering a licence for the disputed '947 patent which secured legal certainty in Krka's seven core Member States, while Krka withdrew from competition with Servier in the remaining 18/20 EU markets, including some of Servier's biggest markets. Krka Settlement Agreement and the Assignment and Licence Agreement constituted an overall plan for a common course of action. Accordingly, the market sharing arrangement was strengthened by Servier's purchase, for EUR 30 million, of Krka's technology, thus barring the latter as a possible input to other generic companies, and closing all advanced ways for Krka to remain a source of competition to Servier.

(1848) The Krka Agreements thus reduced competition between the parties to the agreement, Servier and Krka. In 18/20 Member States not covered by the licence, Krka could no longer compete with Servier the way it would have in the absence of the agreement based on the completed perindopril product development, and/or as a source of independent perindopril technology. As Krka was also a potential supplier of perindopril products to other generic companies, the agreement also affected competition between Servier and these additional potential competitors to Servier.

(1849) For the three markets concerned by the analysis of restrictive effects, France, the Netherlands and the UK, the Commission found that in the period of the conclusion of the Krka Agreements, Krka was an important source of competition to Servier. It had completed the development of perindopril and either launched it in a number of CEE markets, or was in advanced launch preparations in others (e.g. the UK, Netherlands). Krka was also challenging the validity of the '947 patent (for which it was convinced to have a strong case). While there were only three other potential competitors posing a comparable competitive threat, Krka, together with Apotex, posed a more immediate threat, as it had already received the marketing authorisations. Thus, also its technology to produce perindopril API meeting the regulatory standards was potentially attractive to other generic companies. With Krka's withdrawal from 18/20 markets, including specifically France, the Netherlands, and the UK, the likelihood of generic delay increased appreciably. To complement this, there was considerable uncertainty as to whether the remaining

sources would subsequently also reach an agreement with, or be otherwise blocked by Servier. The removal of Krka thus likely affected the overall competitive structure concerning perindopril.

(1850) On the basis of the foregoing considerations, the Commission finds that, concerning the markets in France, the Netherlands, and the UK, the Krka Agreements were such as appreciably to restrict potential competition among Servier and the generic companies and barred *"real concrete possibilities"* for Servier and Krka to compete among them or *"for a new competitor to penetrate the relevant market and compete with the undertakings already established"*.[2460] By discontinuing Krka's patent challenge, removing the possibility of launch at risk with Krka's product or transfer of Krka's technology to other generic companies, the Krka Agreements appreciably increased the likelihood that Servier's market exclusivity would remain uncontested for a longer period of time and that consumers would forego a significant reduction of prices that would ensue from timely and effective generic entry.

5.5.3.6 Effects on trade within the meaning of Article 101(1) of the Treaty

(1851) Article 101(1) of the Treaty only applies to agreements and practices "*which may affect trade between Member States* ". This criterion has three basic elements.[2461]

(1852) First, "trade between Member States" must be affected. The concept of trade covers all forms of economic activity including establishment. According to settled case law[2462] an agreement that has an impact on the competitive structure in more than one Member State is by its very nature capable of affecting trade between Member States. Trade between Member States may be affected also in cases where the relevant market is national.[2463]

(1853) Second, it is sufficient that the practice "may" affect trade, i.e. that it is sufficiently probable that the practices are capable, based on an objective assessment (as well as subjective elements, if any), of having an effect on the patterns of trade, or on the competitive structure. Trade must not necessarily be reduced; the pattern of trade must simply be capable of being affected by the restrictive agreement.

(1854) Third, the effect on trade of the agreement must be appreciable. This element requires that the effect on trade between Member States must not be insignificant and it is assessed primarily with reference to the position of the undertaking(s) on the market for the products concerned.

(1855) By discontinuing Krka's efforts to viably enter the market, including through its commercial partners in several Member States, the economic activities in which such undertakings were engaging were affected. Since Krka had, at the time of settlement, concluded a number of supply/licence agreements for its generic perindopril in the EU (some of them covering several restricted Member States), which had to be suspended or terminated following the conclusion of the settlement agreement, the

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2460 Joined Judgments of 15 September 1998, *European Night Services and Others v Commission*, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198, paragraph 137.

2461 *Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81–96, point 18.

2462 Joined Judgment of 8 October 1996, *Compagnie maritime belge transports and Others v Commission*, T-24/93, T-25/93, T-26/93 and T-28/93, ECR, EU:T:1996:139, paragraph 203; Joined Judgment in *Commercial Solvents v Commission*, C-7/73 and C-6/73, EU:C:1974:18, paragraph 32.

2463 *Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81–96, points 19-22.

practice had both an effect on trade and on the competitive structure. The significant price decrease following the annulment of the '947 patent in the UK exemplifies the effects of generic entry on the competitive structure in the restricted Member States.[2464]

(1856) By removing Krka as a potential competitor to Servier in the restricted Member States, the Krka Settlement Agreement, actually or at least potentially, affected trade between Member States. In view of the magnitude of perindopril sales in the Member States concerned (see paragraph (2129)) the actual or potential impact on trade can be said to be appreciable.

5.5.4 Conclusion – the Krka Agreements restrict competition within the meaning of Article 101(1) of the Treaty

(1857) The above analysis has demonstrated that the Krka Agreements consisted of a market sharing agreement based on a combination of the patent settlement restrictions and an advantageous licence as an inducement to Krka, and an assignment of Krka's patent applications to Servier. The Krka Settlement Agreement (the Settlement Agreement and the related Licence Agreement) was found to have had as its object to restrict competition by removing Krka as one of the close potential competitors to Servier in 18/20 Member States. Krka discontinued all activities needed for a viable and timely generic entry, which would challenge Servier's market position in 18/20 markets, including core markets for Servier, and in return received a sole licence for seven Member States, including core markets for Krka. This effectively amounts to market sharing. The Krka Agreements also comprised an assignment to Servier of Krka's patent applications which the latter considered as "key" to have a commercial generic product. This assignment was found to further strengthen the market sharing arrangement from the settlement. The combination of the agreements (Krka Agreements) was found to constitute a single and continuous restriction of competition by object under Article 101(1). The Commission refers to sections 5.1 (and in particular to paragraph (1112)) and 5.5.3 (and in particular 5.5.3.4) for its considerations on the appreciable degree to which the agreements in question restricted competition and to section 5.5.3.6 for its analysis of effect on trade between Member States. The analysis in those sections shows that for a restriction by object that may affect trade between Member States, the Commission does not have to prove an appreciable restriction of competition, but that in any case the Krka Agreements did restrict competition to an appreciable degree.

(1858) In addition, it has also been shown that, given the prevailing market conditions at the time of the settlement, and considering its content, the Krka Agreements were also capable or likely to entail restrictive effects on competition pursuant to Article 101(1) of the Treaty in the three markets concerned by the analysis of restrictive effects, France, the Netherlands and the UK.

(1859) The parties' claims under Article 101(3) of the Treaty are analysed in section 5.7.

5.6 Assessment of the Lupin Settlement

(1860) This section sets out the assessment of the Lupin Settlement Agreement concluded between Servier and Lupin on 30 January 2007 ("Lupin Settlement Agreement") pursuant to Article 101 of the Treaty.

[2464] See section 6.5.1.2.6.

(1861) In the context of the Lupin Settlement Agreement, Lupin refrained from selling generic perindopril (effectively until generic entry from third parties occurred) and from challenging a number of Servier's patents, in return for a payment by Servier of EUR 40 million for, allegedly, a staggered purchase of Lupin's three patent applications for perindopril and an option for a future distribution arrangement.

(1862) The Lupin Settlement Agreement will be first assessed as a restriction by object under Article 101(1) of the Treaty. Secondly, and even though it is not necessary to examine the effects of an agreement when it is established that its object is to restrict competition, an analysis of the Lupin Settlement Agreement as a restriction by effect was undertaken.[2465]

5.6.1 The Lupin Settlement Agreement is a reverse payment settlement which restricts competition by object under Article 101(1) of the Treaty

(1863) This assessment is divided into five subsections. First, a brief introduction will present the elements relevant for the assessment whether there is a restriction by object, and the specific context of the Lupin Settlement Agreement. Second, the Commission will establish that Lupin and Servier were potential competitors at the time of the settlement. Third, the restrictive terms of the settlement agreement will be assessed followed by, fourth, a description of the parties' intentions. Fifth, a concluding sub-section will summarise the assessment of the Lupin Settlement Agreement as a restriction by object under Article 101(1) of the Treaty.

5.6.1.1 Introduction

(1864) The general economic and legal context for the assessment of reverse payment patent settlements has been set out in section 5.1. In addition, the general factual background to the Lupin Settlement Agreement has been set out in section 4.3.4.

(1865) The specific legal and economic context of the Lupin Settlement Agreement can be summarised as follows.

(1866) After a series of agreements entered into by Servier, at the time the Lupin Settlement Agreement was concluded in January 2007, there was still no generic perindopril on the market. Servier held the monopoly of sales of perindopril since 1989. Perindopril was Servier's most important product at the time. Servier's sales of perindopril continued to progress, and generated an EBIT profit of EUR [150-350] million 2007.[2466] During that period, every month without generic entry represented around EUR [eight digit figure] of profits for Servier.

(1867) Lupin initiated the in-house development of generic perindopril (both API and formulations) in around 2002. In 2003-2005, it filed patent applications for three alternative processes for the manufacture of perindopril. Based on its alpha form perindopril API, it was amongst the forerunners when it applied for marketing authorisation in January 2006. In November 2006, Lupin was in intensive preparations for regulatory approval and was expecting to enter the market by

[2465] Judgment in *T-Mobile Netherlandsand and others*, C-8/08, EU:C:2009:343, paragraphs 28 – 30; and Joined Judgments in *GlaxoSmithKline Services and Others v Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, EU:C:2009:610, paragraph 55.

[2466] Member States included for the purpose of this calculation are: Belgium, Greece, the Netherlands, the UK, the Czech Republic, Hungary, Poland, France, Ireland, Portugal, Germany, Italy and Romania. Calculation based on the underlying data of section 6.4.5.3.

April 2007 alongside only a handful of other generic competitors (including Teva and Krka).

(1868) Lupin had been advised by its patent attorney that the declarations submitted in the EPO opposition proceedings regarding the '947 patent "*seem to present a strong case for the invalidity of the ['947] patent*".[2467] As its perindopril API was in the alpha form, Lupin was one of the eight remaining opponents to the '947 patent before the EPO. In October 2006, it also initiated an invalidity action against the '947 patent before the High Court.

(1869) Lupin followed the developments of other generic operators in the UK market closely and in particular the settlements concluded by Servier. Lupin was well informed of Servier's previous settlements with generic companies (which were all signed before Lupin's agreement), as well as the pending marketing authorisation of its generic competitors.[2468]

(1870) After Servier and Lupin entered into the settlement, there was only one other pending litigation against Servier's '947 patent (namely Apotex). Therefore, after the settlements with Niche/Unichem, Matrix, Teva and Krka, Lupin presented a major generic threat to Servier.[2469]

(1871) As will be shown below, Servier and Lupin agreed that Lupin would not enter the market, and would discontinue its patent challenge in return for a very significant financial inducement of EUR 40 million, allegedly in consideration for three patent applications Lupin transferred to Servier. This specific arrangement will be assessed as a restriction of competition by object.

5.6.1.2 Lupin and Servier as actual or potential competitors

(1872) In order to examine whether Article 101 of the Treaty can apply to the Lupin Settlement Agreement, it needs to be assessed whether Lupin and Servier were actual or potential competitors.

(1873) At the time of conclusion of the Lupin Settlement Agreement, Servier and Lupin were not yet actual competitors in the production and supply of perindopril on the EU markets. Lupin had not yet received a marketing authorisation and had not launched a generic version of perindopril.

(1874) During the investigation, both Servier and Lupin argued that they did not consider Lupin as a potential competitor to Servier. They mainly alleged that Lupin did not have a viable product at the time of conclusion of the settlement as it had encountered a number of technical and regulatory difficulties.[2470] More specifically, the main arguments brought forward by Servier and Lupin to argue that they were not potential competitors can be summarized as follows:[2471]

- Regulatory position: Lupin did not have a marketing authorisation for its product, and was confronted with difficulties and delays in obtaining one. Especially, Lupin needed to conduct again a bioequivalence study in order to obtain MHRA approval in the UK.

2467 See paragraph (1011).

2468 See, for example, paragraph (1023).

2469 See paragraph (1024).

2470 See, for example, paragraph (1050).

2471 Lupin's reply to the Statement of Objections, paragraphs 35 - 54, ID8752, p. 16 – 18; Servier's reply to the Statement of Objections, paragraphs 1156 - 1195, ID10114, p. 380 - 389.

- Commercial strategy: Lupin did not have a partner to commercialize its product. Most prominently, [name of Lupin business partner]* communicated its intention to terminate its relation with Lupin in early January 2007.
- Patent situation: The '947 patent was a blocking patent and there was no certainty that Lupin would prevail in the litigation. Moreover it was not attractive anymore for Lupin to continue litigating since it would not get the necessary regulatory approval on time to be a first-mover and the litigation was costly. Lupin would also not launch at risk.
- Production difficulties: Lupin experienced capacity problems in 2007-2009.

(1875) However, the Commission considers that Lupin was a potential competitor to Servier for the reasons explained in this section.

(1876) It is recalled that a potential competitor does not have to have a readily marketable product, as long as the company has the ability to enter within a "*short period of time*".[2472] The parties' claims can be further rebutted by reference to the contemporaneous evidence included in this section.

Product development and regulatory position

(1877) Perindopril was seen as one of Lupin's best product development opportunities. For example, in a presentation by [employee name and function with Lupin]* in a Strategy Meeting held on 25 July 2006 on the *"Business plans for 08/09"*, forecasts show perindopril as the most important product with expected sales amounting to over 30% of total sales of Lupin in 2006/07 and 2007/08.[2473]

(1878) Lupin had engaged in the development of a generic version of perindopril as of 2002 and had filed patent applications for three new processes concerning the production of perindopril/intermediates. This development was well advanced at the time of the settlement. From internal documents it can be deduced that, at the time of the settlement, Lupin was preparing to be on the market in April 2007.[2474]

(1879) Furthermore, Lupin was already active in commercializing API and seeking to out-license its dossier to partners.[2475]

(1880) Lupin was actively pursuing the regulatory approval procedures. It – either directly or through an agent - had applied for a marketing authorisation in a number of Member States, including the UK and France.[2476] While Lupin faced difficulties in obtaining regulatory approval, those difficulties were not insurmountable and Lupin continued actively to resolve them (see section 4.3.4.3).[2477] It is not denied by the parties that the difficulties intensified only after the settlement.[2478]

2472 See section 5.1.3.

2473 See paragraph (993) and ID0055, p. 21.

2474 See paragraph (1021).

2475 See section 4.3.4.2.

2476 See paragraph (1000).

2477 In its reply to the Statement of Objections, Lupin indicated that "*Lupin senior management were **committed to salvaging this product***" (emphasis added), even though they "*were also concerned that this problem would, at the very least, delay the approval of the product for a significant period of time*" (paragraph 161, ID8752, p. 43). In their replies to the Letter of Facts, Servier (paragraphs 666 – 671 and 720 – 729, ID10324, p. 193 - 194) and Lupin (paragraphs 35 - 39, ID10247, p. 9 - 10) questioned

(1881) Regarding the UK, both Servier and Lupin alleged that Lupin considered it probable that it would not get regulatory approval.[2479] However, this claim has not been substantiated by any contemporaneous evidence. In their replies to the Statement of Objection and in the course of the Oral Hearing, Servier and Lupin put emphasis on the deficiency letter that was received by Lupin on 13 November 2006 and contained a question on the bioequivalence study.[2480]

(1882) Furthermore, Lupin initially argued in a reply to an RFI that "*Anapharm admitted to Lupin by letter dated 14 November 2006 that it had found evidence of back-conversion in its retesting of Lupin's product. As a result, Anapharm advised that the Perindoprilat results previously submitted to the MHRA should not be considered valid and the current method would need to be modified and revalidated*".[2481] Servier relied on this element for its defence.[2482] However, in its reply to the Statement of Objection,[2483] Lupin later omitted the reference to any letter from Anapharm dated 14 November 2006 ("the Anapharm letter"), and instead referred in a footnote to an email from August 2007 (thus postdating the Lupin Settlement Agreement). In reply to a Commission's RFI regarding the Anapharm letter, Lupin later explained this deletion was due to a change in the external counsel team, the inability of the new team to locate the Anapharm letter and the fact that it "*did not consider the document concerned to be particularly material to the submission in question*".[2484] In the course of the investigation, it eventually emerged that the Anapharm letter[2485] had been incorrectly dated,[2486] and was an annex from the 28 March 2007 submission of

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whether on 14 November 2006, Lupin knew the extent of the MHRA query and the time and cost ramifications for the perindopril project. Contemporaneous documents suggest that the subject was discussed internally and, on 14 November 2006, [employee name of Lupin]* was able to assess the situation and prepare a note explaining different scenarios (see paragraphs (1020) to (1022)), and an email in which [employee name of Lupin]* made a direct reference to the deficiencies by saying "*[…]we file deficiencies by December [a]nd has to be tightened if we are to be ready for market*" (see ID0054, p. 144). Servier contests the conclusions reached by [employee name of Lupin]* in its note and states that considering the issues encountered by Anapharm "**it is highly improbable that the optimistic scenario formulated in November 2006 […] and which was subject to a response to the MHRA 'by December', had been maintained*". However, despite the MHRA deficiency letter, Lupin did not request Anapharm to stop working on the project. Moreover, on 11 January 2007 Lupin requested Anapharm to focus only on the perindopril project (instead of the perindopril + indapamide project) to be able to reply to the MHRA (ID0524, p. 28). If Lupin would have estimated that it did not have the ability to enter the market (as alleged by Lupin in its reply to the Letter of Facts, paragraph 40, ID10247, p. 10), or if Lupin would have lost its trust in Anapharm (as claimed by Servier in its reply to the Letter of Facts, paragraph 728, ID10324, p. 194), then Lupin's requests to Anapharm to continue its analysis would not make economic sense, particularly as of 18 December 2006, when the first contact between Lupin and Servier took place.

2478 Lupin's reply to the Statement of Objections, paragraph 162, ID8752 p. 43; Servier's reply to the Statement of Objections, paragraph 1403, ID10114, p. 411.

2479 Lupin's reply to the Statement of Objections, paragraph 161, ID8752 p. 43; Servier's reply to the Statement of Objections, paragraph 1268, ID10114, p. 403.

2480 See paragraphs (1001) - (1003).

2481 Lupin's reply to the RFI of 5 August 2009, ID1039, request 15, p. 27.

2482 Servier's reply to the Statement of Objections, paragraph 1162, ID10114, p. 381.

2483 Lupin's reply to the Statement of Objections, paragraph 161, ID8752, p. 43.

2484 Lupin's reply to the RFI of 7 June 2013, ID9746, p. 3 - 4.

2485 ID9558.

2486 The document dated 2006 contains results from experiments conducted in January 2007. Lupin acknowledged that "*it may not be accurate to say that the content of the Anapharm Letter was communicated to Lupin on 14 November 2006*" (Lupin's reply to the RFI of 12 April 2013, ID9699, paragraph 9, p. 4).

Lupin to the MHRA.[2487] Therefore, the regulatory delay that could be inferred from the Anapharm letter was not a fact that shaped Lupin's perindopril strategy at the time of the settlement.

(1883) At any rate, exchanges between Lupin and its contractor Anapharm took place in the month leading to the Lupin Settlement Agreement and continued after its conclusion. Regarding the MHRA deficiency letter of 13 November 2006,[2488] a problem had been identified with the analytical method used by Lupin's contractor Anapharm.[2489] Further tests were being conducted in January 2007, and Lupin was seeking a swift reply to the MHRA.[2490] This reply was sent to the MHRA on 28 March 2007. Hence no contemporaneous evidence suggests insurmountable difficulties in Lupin's regulatory process.[2491]

(1884) Lupin continued with the development even after the conclusion of the Lupin Settlement Agreement until marketing authorisation was finally received in July 2008 (even if it apparently decided not to use it).[2492] It appears that the delay was not so much due to product deficiencies of Lupin's perindopril as such, but could be, for the most part, ascribed to the fact that Lupin's service provider used a wrong method in its analysis submitted for the regulatory approval. Finally, taking into account that Lupin is a rational commercial operator aiming at maximising its profits, Lupin's continued investments into the regulatory approval would not make sense if Lupin (as it is now claimed) had considered the project as non-viable at the time of the settlement. Lupin in its reply to the Letter of Facts[2493] acknowledged that, despite significant delays, it actively sought regulatory approval.[2494] Lupin also differentiated between the viability of the perindopril project and a viable (*i.e.*, ready to market) product. Lupin stated that at the time of the conclusion of the Lupin Settlement Agreement it did not have a regulatory approval and, consequently, it did not have a viable product. However, the legal test for potential competition is whether, in light of the structure of the market, Lupin had "*real concrete possibilities*" to enter the market and compete with Servier in the absence of the Lupin Settlement Agreement.[2495] Contrary to what Lupin argued, it is not necessary to have a "ready to

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2487 The letter was Annex 3 to Lupin's reply of 28 March 2007 to the MHRA (ID9751).

2488 Annex 2 to Lupin's reply to the RFI of 12 April 2013, ID9745.

2489 "*Despite diligence on Lupin's part in actioning the requests sent through by the MHRA, the approval process was significantly delayed due to deficiencies in the bioequivalence study conducted at an outside CRO, Anapharm*" (ID1039, p. 26).

2490 Annex 2 to Lupin's reply to the RFI of 12 April 2013, ID9745, p. 41.

2491 Servier in its reply to the Letter of Facts (paragraphs 713 - 719, ID10324, p. 192 - 193) referred to the correspondence between Anapharm and Lupin from 14 November 2006 to 4 January 2007. According to Servier, that correspondence showed that "**before the conclusion of the agreement with Servier, it was certain that Lupin would not obtain an MA in the UK before the end of litigation […]".* However, there are no contemporaneous documents that suggest that Lupin intended to abandon its plans to launch perindopril after receiving the MHRA deficiency letter. On 14 November 2006, Lupin still expected to be in the market in April 2007 (see paragraph (1003)); and the additional issues encountered by Anapharm on 21 November 2006 and 4 January 2007 did not impede sending a reply to the deficiency letter on 28 March 2007. Even Servier pointed out in its reply to the Letter of Facts the multiple instances in which Lupin contacted Anapharm to request an "**[…] update of the situation*" (paragraph 717, ID10324, p. 192), which suggests that Lupin had not given up at the time and continue to believe in its perindopril project.

2492 See section 4.3.4.9.3.1.

2493 Paragraphs 30 - 34, ID10247, p. 8 - 9.

2494 Lupin's reply to the Letter of Facts, paragraph 36, ID10241, p. 8.

2495 Judgment of 14 April 2011, *Visa Europe Ltd and Visa International Service v European Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 68; Joined Judgments of 15 September 1998, *European*

market" product. The "*ability to enter*" within the meaning of the case-law must be interpreted on the basis of the possibilities and opportunities which would have made Lupin able to enter the market within a sufficiently short period, absent the agreement with Servier.[2496] Contemporaneous evidence indicates that even after 13 November 2006 Lupin internally estimated that it could be on the market in April 2007 and that Lupin kept pursuing a regulatory approval.[2497] Regarding France, the process of seeking regulatory approval was under way, and was eventually successful (see paragraphs (1000) and (1090)). Despite claims by Servier that Lupin's file was facing various issues, contemporaneous evidence does not indicate that Lupin was confronted with insurmountable difficulties.[2498]

(1885) Regarding the Netherlands, Servier pointed out that a third party gave up on potential supply of perindopril API from Lupin after receiving two deficiency letters.[2499] As disclosed in the Letter of Fact, the third party in question was Teva.[2500] Teva had filed its dossier for perindopril with the Netherlands regulatory agency in 2005. It stopped "*its own development of perindopril*" in the Netherlands in July 2006. However, this was in all likelihood because Teva gave preference to other supply sources. As Servier points out in its reply to the Letter of Facts, at the time of the second deficiency letter, Teva was still negotiating with Krka a supply agreement covering the Netherlands.[2501] In fact, in July 2006, Teva was "*very close to signing a 5 year deal with Krka for the Netherlands […]*".[2502] Furthermore, Teva had acquired Ivax only months ago and had taken over Ivax' advanced program for the development of perindopril,[2503] which allowed Teva to launch perindopril in the Netherlands in 2008.

Commercial strategy

(1886) Lupin was actively looking for commercial partners to market perindopril in Europe. It had signed two distribution agreements with [name of Lupin business partner]* and was seeking further partners.[2504]

Night Services and Others v Commission, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198, paragraph 137.

2496 See Judgment in *Visa Europe Ltd and Visa International Service v European Commission*, footnote 2495 above, EU:T:2011:181, paragraphs 82 - 83 and 168, referring to Judgment in *Delimitis v Henninger Bräu*, C-234/89, EU:C:1991:91, paragraphs 20 - 21.

2497 See paragraphs (1003) and (1880).

2498 Servier in its reply to the Statement of Objections (paragraph 1165, ID10114, p. 382) stated that "**emails exchanged in September 2006 between Lupin and Venipharm (Lupin's agent in France) suggest that the Perindopril file was having various problems*". The supporting email is from 10 January 2007 (ID6755 p 57 – 58). However, Servier omits to quote the two paragraphs that suggest that, while a discussion on impurity level was on-going, suggestions on ways forward are made. Furthermore, the document quoted by Servier in its paragraph 1166 (ID8899, p. 1 – 8) dates from September and October 2008, i.e. postdating the Lupin Settlement Agreement.

2499 Servier's reply to the Statement of Objections, paragraph 1168, ID10114 p. 382.

2500 ID10276, p. 9, consisting on an *ex post* explanation provided by Lupin in a letter prepared on 25 June 2009.

2501 See paragraph (816), ID10324, p. 183.

2502 ID0350, p. 648.

2503 See for instance paragraphs (655) and (663).

2504 See section 4.3.4.2. Regarding the geographic scope of those distribution agreements (see paragraphs (993), and (995) to (997)), Lupin in its reply to the Letter of Facts qualified [employee name of Lupin]'s* presentation of January 2006 as "visionary" and not reflective of Lupin's strategies later that year (paragraphs 20 - 21, ID10247, p. 5 - 6). However, the agreement signed with [name of Lupin business partner]* in July 2006, the discussions and emails exchanged with [name of Lupin business

(1887) In their reply to the Statement of Objections, both Lupin and Servier pointed out that Lupin could not be a potential competitor insofar as it did not have commercial partnerships in place at the time of the agreement.[2505]

(1888) Servier notably pointed out that "**the only trading partner of Lupin, [name of Lupin business partner]*, even decided to terminate their distribution agreement shortly before the agreement between Lupin and Servier*".[2506] An email to Lupin indeed announced in January 2007 [name of Lupin business partner]'s* intention to end their partnership.[2507] But the announcement came only at the time when negotiations between Lupin and Servier had already been initiated, while the actual agreements with [name of Lupin business partner]* were only terminated after the Lupin Settlement Agreement.[2508] Moreover, a contemporaneous document shows that [name of Lupin business partner]* wondered whether Lupin's passive behaviour in interacting with [name of Lupin business partner]* might have been influenced by the parallel settlement negotiations with Servier.[2509] While Lupin was later able to

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partner]* in the second half of 2006, and the fact that Lupin was actively looking for other commercial partners do not seem to indicate a significant change in Lupin's strategy regarding the geographic scope.

2505 Lupin's reply to the Statement of Objections, paragraphs 181 – 185, ID8752, p. 49 – 50; Lupin's reply to the Letter of Facts, paragraph 60, ID10247, p. 14; Servier's reply to the Statement of Objections, paragraphs 1170 - 1176, ID10114, p. 382 - 384.

2506 Servier's reply to the Statement of Objections, paragraph 1144, ID10114, p 377; see also, Servier's reply to the Letter of Facts, paragraph 673, ID10324, p. 182.

2507 See paragraph (999). Servier, in its reply to the Letter of Facts, considered that the truth was that [name of Lupin business partner]* terminated its agreement with Lupin because "**[…][it was concerned with the litigation risks and the regulatory problems[…]*" (paragraph 741, ID10324, p. 197); however, [name of Lupin business partner]* signed two supply agreements with Lupin despite the concerns raised and discussed during the negotiation of those agreements (see paragraphs (994) to (996)). Servier also states that *"*[…] it would have been irrational for Lupin to take the risk of losing its only client before entering into an agreement with Servier*" (paragraph 741, ID10324, p. 197). However, Lupin's behaviour could be explained if it wanted to keep its relationship with [name of Lupin business partner]*, until it received a positive feedback from Servier following their initial contact in December 2006.

2508 Lupin in its reply to the Letter of Facts stated regarding the relationship between [name of Lupin business partner]* and Lupin that "*[t]he course of dealing between [name of Lupin business partner]* and Lupin […] shows a somewhat strained relationship in respect of the perindopril project from as early as August 2006*" (paragraph 51, ID10247, p. 11). In the replies to the Letter of Facts, both Servier (paragraphs 734 - 742, ID10324, p. 195 - 197) and Lupin (paragraphs 48 - 51, ID10247, p. 11 - 12) pointed out that [name of Lupin business partner]* communicated its concerns to Lupin on several occasions, *e.g.*, on 7 August 2006 (ID6994, p. 28), on 5 October 2006 (ID6821, p. 27), on 9 October 2006 (ID6757, p. 46), and again on 25 October 2006 (ID6821, p. 32); however, despite [name of Lupin business partner]'s* concerns in October 2006, Lupin still tried to obtain financial support from [name of Lupin business partner]* for the patent litigation in the UK (see paragraph (1897)), and it was not until 18 January 2007 (as Lupin points out) that the parties seemed to agree that "*the 'win-win' situation perceived on this project at the outset has receded* […]" (ID6760, p. 29), i.e., well after the discussions with Servier started. In any event, the agreement was only terminated in March 2007 (see paragraph (999)).

2509 ID0050, p. 81. In its reply to the Letter of Facts, Lupin considered [name of Lupin business partner]'s* view, sent to [employee name of Lupin]* by error, as "**speculative*" (paragraph 54, ID10247, p. 12). Servier also questioned [name of Lupin business partner]'s* opinion and claimed that "**[a]lthough the doubts expressed by [name of individual]* on Lupin's attitude are understandable at that time […], the Commission has […] evidence showing that Lupin's passive behaviour was not explained by the negotiations with Servier*" (paragraph 734, ID10324, p. 195 - 196). The Commission agrees with Servier that [name of Lupin business partner]'s* doubts regarding Lupin's passive behaviour were understandable at the time of the facts. As indicated by Lupin, [name of Lupin business partner]'s* email was an internal email only meant for [name of Lupin business partner]'s* employees, and not for Lupin. Hence, it is reasonable to assume that [name of Lupin business partner]'s* representative felt free

claim reimbursement from [name of Lupin business partner]*, it would otherwise probably have been for Lupin to compensate [name of Lupin business partner]* as it would not have been able to respect its supply/licensing obligations, irreconcilable with the Lupin Settlement Agreement. Besides, the parties' claims are further refuted by the fact that Lupin was in commercial dealings for the supply of its perindopril API/formulations with a number of other generic operators.[2510]

(1889) The intense commercial activity of Lupin is acknowledged in its reply to the Statement of Objections: "*Lupin marketed perindopril directly to numerous customers/partners*".[2511] While Lupin points out that potential partners raised concerns about "*the commercial viability of Lupin's perindopril products*", the supporting example postdates the Lupin Settlement Agreement.[2512] Nevertheless, if looking at further developments following the agreement Lupin eventually found two commercial partners.[2513] Finally, it is noted that Lupin also envisaged a direct to market strategy in the UK.[2514]

(1890) If, as claimed, Lupin had considered at the time that it was confronted with insurmountable difficulties to bring its generic perindopril to market, it would have stopped such activities. Actually, although Lupin does not sell its own perindopril, as noted above Lupin concluded two further agreements on product dossier licensing and the supply of finished Lupin formulations for perindopril in the period 2008-2010. Lupin also maintained commercial collaboration with several generic companies for the supply of its perindopril API such as [name of Lupin business partner]*, [third party] or Ratiopharm.[2515]

Patent situation

(1891) Lupin was confident that Servier's patent barriers could be overcome.[2516] At the various meetings reported, Lupin explained to potential customers that it was one of the companies with a non-infringing product.[2517] Lupin's internal documents show that the company believed it had a non-infringing product.[2518] Firstly, Lupin believed that its perindopril product did not infringe Servier's process patents. For example, Servier's synthesis process was considered to be *"entirely different from the*

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to express his views and doubts in an open way. The email shows the reaction of [name of Lupin business partner]'s* representative to the announcement of Lupin's sale of its patent applications to Servier (see paragraph (1079)). [Name of Lupin business partner]'s* representative expressed his hope that that agreement with Servier had not influenced Lupin's behaviour, specifically Lupin's "*previous reticence over IP disclosure*". In the following paragraph of the same email, [name of Lupin business partner]'s* representative pointed out that they had not *yet* signed the termination agreement with Lupin (the email was sent on 27 February 2007), and proposed to go ahead with the termination unless "*we see anything unethical here*".

2510 See section 4.3.4.2.

2511 Lupin's reply to the Statement of Objections, paragraph 181, ID8752, p. 49.

2512 Lupin's reply to the Statement of Objections, paragraphs 183 – 185, ID8752, p. 50. The example given by Lupin is that "*[Name of Lupin business partner]* cancelled its supply arrangement with Lupin in 2009 following production problems at Lupin's plant*" (see paragraph (1101)) occurring after the Lupin Settlement Agreement.

2513 See section 4.3.4.9.3.2., in particular, paragraph (1097).

2514 See paragraph (986).

2515 See section 4.3.4.9.3.2. and section 4.3.4.2.

2516 See, for instance, paragraph (1016).

2517 See, for example, paragraph (983).

2518 See section 4.3.4.1.2.

chemistry practiced by Lupin".[2519] Secondly, Lupin also commenced patent litigation in the UK and before the EPO against Servier with the aim to invalidate the '947 patent, considering it to be the major obstacle to entry on the European markets.[2520]

(1892) Lupin argued that the '947 constituted a blocking patent and that "*there can be no competition from generics until expiry of that patent*".[2521] However, there was no final judicial finding of a blocking position in any of the jurisdiction covered by the Lupin Settlement Agreement. On the contrary, there were two UK invalidity actions settled shortly before the agreement, and two more, Lupin's and Apotex', pending. Hence, there was no evidence concerning the issue of validity which would authoritatively confirm the alleged existence of a blocking position.[2522]

(1893) In its reply to the Statement of Objections, Servier argued that there was no certainty that the generics would prevail in the litigation and that "**Lupin was not reassured about its chances of winning*".[2523] The uncertainty of the outcome of litigation is not denied. There nevertheless existed a genuine patent dispute. Lupin had consistently challenged the validity of the '947 patent since 2004.[2524] Lupin had received advice on 18 November 2004 that the declarations submitted in the EPO opposition proceedings regarding the '947 patent *"seem to present a strong case for invalidity*".[2525] With respect to possible launch in France, Lupin considered that Servier's "*chance of winning [a patent challenge] may be better than in the UK*".[2526]

(1894) Both Servier and Lupin mentioned prominently that the EPO Opposition Division decision in July 2006,[2527] as well as the grant of the interim injunctions against Krka and Apotex, influenced Lupin's assessment of its patent case and its decision to settle.[2528] However, it is noted that Lupin filed its own invalidity action before the High Court in October 2006, i.e. after the EPO Opposition Division decision.[2529] Lupin had also appealed the EPO Opposition Division decision in November 2006.[2530] Moreover, Lupin's strategy note from 14 November 2006[2531] presents eight scenarios based on non-infringement or on revocation, no other outcome being mentioned.[2532] Finally, providing ex post clarification on its perception of the litigation in the course of the Oral Hearing, Lupin stated the following: "*To your question on what our view of the case was, it is correct that we*

2519 See paragraph (981).

2520 See section 4.3.4.5.

2521 Lupin's reply to the Statement of Objections, paragraphs 71 – 76 and 308, ID8752 p. 23 – 24 and 76.

2522 See point 32 of the Technology Transfer Guidelines, and footnote (1586) on their applicability.

2523 Servier's reply to the Statement of Objections, paragraphs 1144 and 1181, ID10114, p. 377. Similar arguments were made by Lupin, see ID6989, p. 2.

2524 See section 4.3.4.5.

2525 See paragraph (1011).

2526 See paragraph (990).

2527 See paragraph (163).

2528 Lupin's reply to the Statement of Objections, paragraphs 132 - 133, ID8752, p. 36; Servier's reply to the Statement of Objections, paragraph 1184, ID10114, p. 386.

2529 See paragraph (1015).

2530 See paragraph (1011).

2531 See paragraphs (1020) -(1022).

2532 In its reply to the Statement of Objection (paragraph 1192, ID10114, p. 368), Servier argued that the interpretation of this document was incorrect. It is nonetheless noted that the strategy note by [employee name of Lupin]* intended to inform Lupin's top management of the strategy to follow with perindopril; it does not at all mention the possibility that the '947 patent would be upheld (and, consequently, that the launch would need to be postponed possibly until 2021).

actually started litigating after Apotex was injuncted and after Apotex started litigating and I think we joined the case some time around October. And we did believe that there was a chance that we would succeed despite the EPO decision and that's why one starts litigating and we probably would have continued litigating had we been sure that we would get MHRA approval and would be able to actually make a commercial profit out of that litigation".[2533] Lupin confirmed in its reply to the Letter of Facts that this statement was "*consistent with Lupin's view at the time it joined the litigation in October 2006".*[2534]

(1895) Both parties further alleged that it was not attractive anymore for Lupin to continue litigating since it would not get the necessary regulatory approval on time to be a first-mover.[2535] Lupin hence risked "*free-riding*" from Apotex.[2536] However, Lupin's claim that it may not have continued litigation in any event does not appear supported by evidence on the file: [2537] (i) at the time of the settlement, it was not known to Lupin that the market authorisation procedure would be delayed to that extent (i.e., July 2008, see paragraphs (1089) - (1090)); (ii) as acknowledged by the parties Lupin's difficulties intensified after the Lupin Settlement Agreement; and (iii) there was also no certainty that Apotex would remain as a competitor (see section 5.6.2.4., for instance, paragraphs (2021) - (2023)). In any event, Lupin attempts to limit the conclusions only to the UK; however, it desisted from potential competition with Servier across the entire EU.

(1896) Furthermore, as for Servier, there is evidence demonstrating that the invalidation of the '947 patent was perceived as a non-marginal risk, a real concrete possibility, by Servier. Notably, it appeared that Servier was carrying out in January/February 2007 the necessary experiments aimed at rebutting the claim that the '947 patent was anticipated in the prior art. However, in the wake of these experiments, Servier stated in March 2007 that "**we [Servier] anticipate an unfavourable decision for us*".[2538]

(1897) Both parties also pointed out that litigation was costly.[2539] They have however failed to explain how this consideration would significantly change for Lupin in the few

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2533 Oral Hearing, recording of 18 April 2013, Lupin's intervention, at 01:28:00 (ID9654).

2534 Lupin's reply to the Letter of Facts, paragraph 16, ID10247, p. 4.

2535 Lupin's reply to the Statement of Objections, paragraph 26, ID8752 p. 13. In the reply to the Letter of Facts, Servier claimed that it was not interesting for Lupin to continue litigating since "**[…] it was joined with that of Apotex (same judge and same schedule), and Lupin could therefore benefit from any invalidation of the '947 patent by Apotex even if it ended its own action (and thus save significant litigation costs)*" (paragraph 656, ID10324, p. 178). Yet, neither contemporaneous documents nor Lupin's ex post explanations indicate that this was Lupin's reasoning at the time.

2536 Lupin's reply to the Statement of Objections, for instance, paragraph 358, ID8752 p. 88; and Lupin's economic annex by Oxera (a report entitled "*Economic assessment of Lupin's agreement with Servier in relation to* the *supply of perindopril*" was submitted as an annex to Lupin's reply to the Statement of Objections), for instance, paragraph 2.36, ID8753, p. 19.

2537 Servier in its reply to the Letter of Facts (paragraphs 688 - 690, ID10324, p. 186 - 187) emphasised Lupin's concerns regarding the profitability of entering in the UK market, where the "*brand price of perindopril is quite low*" (ID0494, p.57), as one of the reasons Lupin was no longer interested in pursuing litigation. However, the agreement signed between Lupin and Servier was not limited to the United Kingdom; it covered the 27 Member States in which Lupin may not have encountered the same issues. Servier also refers to additional Lupin's concerns regarding its ability to enter the British market. However, the document Servier relies on (ID0796) is an ex post explanation prepared by Lupin in June 2009.

2538 See paragraph (179).

2539 Servier's reply to the Statement of Objections, paragraph 1144, ID10114, p. 357; Lupin's reply to the Statement of Objections, paragraph 126, ID8752 p. 34. In its economic annex to the Statement of

months after Lupin's launch of its legal challenge in the UK. By consistently challenging Servier's '947 patent, Lupin appeared to have accepted "*the risks of expensive, lengthy and fundamentally uncertain litigation*" and there was a real concrete possibility for Lupin to also overcome the patent barrier. Servier pointed out in its reply to the Letter of Facts[2540] that in the course of the Oral Hearing, Lupin stated that: "*[…] When we got the MHRA letter in November, there was a lot of internal discussion around what that meant for us […]. We were spending money and it's a serious amount of money that we were spending in litigation […] and it was clear at that time, that because of this letter* [MHRA letter] *we were not going to be able to, even if we won, […] to enter the market once a decision came out. […] [W]e decided we had two options before us. One was to cut our losses and stop litigation and the other was to try and settle. And if we had not been able to settle we would have* ***probably*** *cut our losses and stop litigation*"[2541] (emphasis added). Servier concluded from this statement that the reasons Lupin had to interrupt litigation were "*perfectly legitimate*".[2542] However, on 25 October 2006, Lupin was trying to obtain financial support from [name of Lupin business partner]* for the patent litigation in the UK.[2543] Lupin did not withdraw this request after receiving the MHRA deficiency letter. On the contrary, Lupin left this request lingering until the agreement with [name of Lupin business partner]* was terminated, even though this request was a serious point of disagreement between the companies,[2544] and it was listed as one of the reasons [name of Lupin business partner]* wanted to terminate the agreement with Lupin.[2545] Furthermore, on 14 November 2006, after receiving the MHRA letter, Lupin considered among its options to move forward "*continue litigation and seek launch at earliest opportunity*", as well as to "*seek partners for litigation cost sharing*", even if the latter was considered a "*remote possibility*".[2546] Therefore, despite the MHRA letter and after "*a lot of internal discussions*" within Lupin, contemporaneous documents indicate that Lupin still considered litigation a viable option.

(1898) In its reply to the Statement of Objections, Lupin also declared that [confidential].[2547] However, contemporaneous evidence indicates that Lupin indeed considered launching perindopril at risk.[2548] Similarly, the evidence shows that Servier's claim

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Objections, Lupin also mentioned without specific supporting evidence the risk of litigation involving the Lupin's patent applications and the Krka's patents that Servier had purchased (Lupin's economic annex by Oxera, paragraph 2.29, ID8753, p. 16).

2540 Servier's reply to the Letter of Facts, paragraphs 682 - 683, ID10324, p. 184-185.

2541 Oral Hearing, recording of 18 April 2013, Lupin's intervention, at 01:26:31; transcription provided by Servier in its reply to the Letter of Facts, paragraph 682, ID10324, p. 184 - 185.

2542 Servier's reply to the Letter of Facts, paragraphs 682 - 683, ID10324, p. 184 - 185.

2543 Servier's reply to the Letter of Facts, paragraph 737, ID10324, p. 196, referring to ID0535, p. 32.

2544 [Name of Lupin business partner]'s* reply to Lupin's request was that the "*additional undertakings that you are looking for in order to look at your patent strategy for the UK MA […] are not acceptable to us*" (ID0535, p. 32.).

2545 ID6757, p. 45.

2546 ID0054, p. 144 - 148; see also paragraph (1020).

2547 Lupin's reply to the Statement of Objections, paragraph 21, ID8752, p. 13; Lupin's reply to the Letter of Facts, paragraph 27, ID10247, p. 7.

2548 See paragraphs (990), (992) and (993). While Lupin discarded entry at risk in its reply to the Statement of Objections (paragraphs 44 - 45, ID8752, p. 17) as unlawful, entry at risk is unlawful only if a court decides that a valid patent has been infringed. There was no such finding by the date of the Lupin Settlement Agreement. Lupin in its reply to the Letter of Facts (paragraph 24, ID10247, p. 6) alleged that the possibility of launching at risk reflected "*Lupin's business strategist's optimistic views in January 2006. It does not […] reflect Lupin's position at the time of the conclusion of the Lupin*

that Lupin was pretending to be confident in front of its commercial partners is unfounded.[2549] While Servier also highlighted that apart from Apotex "**all market players were waiting and watching and none planned to launch at risk*",[2550] Lupin and Apotex were according to Servier's own contemporary assessment the two remaining "*hostile players*"[2551] and several patent settlement agreements had already been concluded by Servier at the time of the evidence quoted (September and October 2006). Servier further argued that launching at risk would have been "**suicidal*" for Lupin due to the financial risk. Lupin was nevertheless considering the option in its strategy documents as set out above. Moreover, generic companies have ways of mitigating risk exposure.[2552]

Production difficulties

(1899) In its reply to the Statement of Objections[2553], Lupin argued that it faced production difficulties with the manufacture of perindopril in its plant in Mandideep, India; and Servier, in its reply to the Letter of Facts,[2554] also referred to the difficulties encountered by Lupin to supply [name of Lupin business partner]*.[2555] However, the so-called production difficulties, by Lupin's own account, were primarily the result of business choices (i.e., Lupin shifted priorities between the various "prils" API),[2556] and not from Lupin's inability to produce perindopril. In any event, the said difficulties concerned "*the period 2007 to 2009*" and are therefore not relevant to the *ex ante* assessment.[2557]

(1900) Last but not least, to assess Lupin as a potential competitor it is interesting to note that Lupin preferred – even after the settlement agreement – to launch its own product over the possibility to enter into a distribution agreement with Servier, to which it was entitled according to the settlement agreement.[2558]

Settlement Agreement". However, on 5 October 2006, launching at risk was still considered an option (see paragraph (992)) and, on 14 November 2006, producing at risk was also being considered (ID0054, p. 144). Moreover, Lupin could again reconsider the option of entering at risk once the marketing authorisation was granted.

2549 Servier's reply to the Statement of Objections, paragraph 1191, ID10114, p. 367.

2550 Servier's reply to the Statement of Objections, paragraph 1270, ID10114, p. 403.

2551 See paragraph (1024).

2552 For instance, the financial risk of launching at risk could be mitigated by a limited price reduction or by limiting sale volumes (see, for example, paragraph (889)).

2553 Lupin's reply to the Statement of Objections, paragraph 167, ID8752 p. 45; and Lupin's economic annex by Oxera, paragraph 1.14, ID8753, p. 8.

2554 Paragraph 703, ID10324, p. 189.

2555 ID6602, p. 21

2556 Lupin's reply to the Statement of Objections, paragraph 168, ID8752, p. 45.

2557 In view of the settlement agreement, Lupin could have a reduced incentive to prioritise perindopril as it was tied as to the possibility of launch.

2558 See paragraphs (1071) to (1073). Lupin in its reply to the Letter of Facts confirmed that it "*[…] actively engaged with the MHRA in order to obtain a marketing authorization*" (paragraph 65, ID10247, p. 15), and despite the issues encountered after the signature of the Settlement agreement (see, for example, email from [employee name of Lupin]* of 18 July 2007 in which Lupin anticipates bad news from MHRA, ID7074, p. 60), Lupin persevered until it obtained its marketing authorisation on 22 July 2008. These problems, together with those faced by Lupin after obtaining the marketing authorisation (paragraph 66, ID10247, p. 15) are not relevant for an *ex ante* assessment. On the other hand, Servier considered in its reply to the Letter of Facts that Lupin's ability to "**pursue both options [negotiating with Servier and pursuing its own product] in parallel […] confirms the pro-competitive effects of the agreement between Lupin and Servier*" (paragraph 744, ID10324, p. 198); however, as discussed in sections 5.6.1.3.2.2 and 5.6.1.3.2.3, the non-compete clause impeded Lupin to launch on the European markets until generic entry from third parties effectively occurred or could occur; and the supply

(1901) Based on the above, the Commission considers that Lupin was a potential competitor which had the intention and ability to enter the market within a foreseeable time frame. In summary, Lupin had taken all the necessary steps to enter the market and was a close potential competitor to Servier in the production and supply of perindopril on the EU markets at the time the settlement with Servier was concluded. Lupin was close to having a viable product, which would have been marketed by Lupin and/or through distribution partners in various EU markets. Equally important, Lupin was one of only two remaining challengers to Servier's '947 patent in the UK, after a series of other patent settlements described above.

5.6.1.3 Terms of the Lupin Settlement Agreement

5.6.1.3.1 An agreement between undertakings

(1902) The investigated contractual arrangement between Servier and Lupin[2559] consists of a single contract with provisions concerning the terms of the patent settlement, the sale of Lupin's perindopril process patent applications, and a commitment to use all reasonable endeavours to conclude at a later date a distribution agreement whereby Servier would supply perindopril to Lupin.

(1903) Lupin concluded a written legally enforceable contract with obligations for both parties which, in view of the case law mentioned in section 5.2.1.3.1] clearly qualifies as an agreement. Lupin and Servier can be considered as undertakings within the meaning of Article 101 of the Treaty. The Lupin Settlement Agreement is therefore an agreement between undertakings within the terms of Article 101(1) of the Treaty.

5.6.1.3.2 Restrictions of the settlement agreement disabling or hampering Lupin's ability to enter the market in a timely and viable manner

(1904) Before the Lupin Settlement Agreement was concluded, Lupin was free to continue its commercial activities to enter the market in a timely and viable manner, including by pursuing legal actions against Servier. The Lupin Settlement Agreement contains in particular two key restrictions of this ability to compete, namely a (i) non-challenge obligation, and (ii) a non-compete obligation. These restrictions were obtained in exchange for an inducement in the form of a very significant reverse payment from Servier to Lupin. This section further looks at (iii) the envisaged option of concluding a supply agreement as an alleged procompetitive feature of the agreement stressed by the parties in the course of the investigation.

5.6.1.3.2.1 The non-challenge obligation

(1905) The non-challenge obligation for Lupin is contained in clauses 1.1 and 1.3 to 1.5 of the Lupin Settlement Agreement. Lupin essentially commits not to "*directly or indirectly seek or assist or procure any third party to revoke, invalidate or otherwise challenge the Patents or any patent owned by Servier or its affiliates covering the*

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agreement as envisaged by Servier was an exclusive distribution agreement by which Lupin would not be able to sell its own products or those of third parties but only Servier's products. Moreover, the supply agreement was never signed, and even if it would have been signed, it would not have resulted in an earlier generic entry since Lupin would have only been able to enter the market once the market was (already) open to generic competition.

2559 See section 4.3.4.7.1.

Products in any country other than [a non-EEA jurisdiction] (the "Servier Patents)" (clause 1.3).[2560]

(1906) Pursuant to clause 1.1 of the agreement, the non-challenge obligation thus encompasses the need for Lupin to withdraw from the existing patent challenges: its UK invalidity action and the EPO opposition against the '947 patent. Moreover, Lupin was bound to refrain from any new challenges of any of Servier's patents on perindopril in the EU (or elsewhere).

5.6.1.3.2.1.1 The non-challenge obligation relating to the '947 patent

(1907) The Lupin Settlement Agreement contained a non-challenge obligation concerning Servier's '947 patent, which formed the subject matter of the patent litigation leading to the settlement, and was perceived as by far the main barrier for Lupin's generic entry. [2561]

(1908) The non-challenge obligation had two main consequences. First, it prevented Lupin from establishing its technology as a *de iure* non-infringing technology for the production of perindopril products (API and formulations). Second, the non-challenge obligation also prevented the objective legal review of the validity of the '947 patent based on Lupin's existing legal actions, disabling the possible benefit for Lupin and other generic producers in case the patent was finally to be invalidated.

5.6.1.3.2.1.2 The non-challenge obligation relating to other patents owned by Servier covering perindopril goes beyond the scope of the settled litigation

(1909) In addition to the commitment not to challenge the '947 patent, Lupin also committed not to challenge "*any [*other*] patent owned by Servier or its affiliates covering the Products*" (clause 1.3).

(1910) Lupin and Servier were asked[2562] to explain their interpretation of one of the operative terms of the agreement, "*any patent*". Servier claimed that this refers to any of its patents on "*the Products*" (the other operative term of the agreement). While recital A of the agreement defines "*the Products*" as "*pharmaceutical products containing, as an active ingredient, perindopril terbutylamine (also known as perindopril erbumine)* ***and any salt thereof***" (emphasis added), Servier claims the scope of the agreement is limited to the erbumine (tertbutylamine) salt of perindopril. Servier's narrow *ex post* interpretation (which admits that the terminology in the agreement is imprecise[2563]) is in contradiction with the wording of the definition, which explicitly refers to "*any salts thereof*", and not to "any other form" of the perindopril erbumine salt. A reasonable method of interpretation of legal texts is to assume that a particular phrase is meaningful and/or purposeful rather than meaningless and/or useless. Moreover, the Lupin Settlement Agreement was negotiated by the parties with the benefit of legal and financial advice; hence, the reasonable inference is that the key operative terms were deliberately drafted in the way they appear in the agreement. Therefore, the extension of the definition from perindopril erbumine to perindopril erbumine and "*any salt thereof*" can only be meaningful if other salts of perindopril were to be included in the definition in

2560 See paragraph (1038).
2561 See, for example, paragraphs (982) and (994).
2562 See section 4.3.4.7.2.
2563 See paragraphs (1043) and (1047).

addition to the erbumine salt.[2564] This has been expressly confirmed by Lupin, which argued that in addition to the '947 patent, "*the Products*" related to: "*any pharmaceutical product containing, as an active ingredient (i.e. API), Perindopril Tertbutylamine (also known as Perindopril Erbumine), and any alternative salt of Perindopril"*.[2565]

(1911) The non-challenge obligation thus goes far beyond the commitment not to challenge the '947 patent, which was the subject matter of the settled litigation.[2566] The obligation not only extends to Servier's three process patents '339, '340 and '341, but also to all other patents filed by Servier protecting perindopril in any salt, including those filed in the period 2001 to 2003, many of which were internally classified by Servier as "barrage patents" – "**paper patent*" and some were even described as "**zero inventive step*".[2567] The obligation relates to other salts, and therefore can be interpreted (as Lupin confirmed) to also cover the '873 patent for Servier's second generation product, the arginine salt of perindopril, which would expire in 2023 and which was the subject of opposition proceedings before the EPO by another generic producer, Teva.[2568]

(1912) Therefore, the Commission considers that the wording of the settlement agreement prohibits launching litigation procedures against any of Servier's patents covering perindopril. This also includes patents that were not under dispute. Even if Servier's narrow interpretation of the obligation were to be accepted (*quod non*), the agreement would at any rate generate significant uncertainty as to the scope of the non-challenge obligation (and the non-compete obligation assessed in the subsequent heading) and thus reduce incentives to challenge Servier's patents.

2564 Servier in its reply to the Statement of Objections (paragraphs 1216 - 1229, ID10114, p. 393 – 395) argued that the Commission was erring in its interpretation of "*any salt thereof*". According to Servier, "**the most plausible interpretation of the term 'Products' is that it indicates perindopril tert-butylamine salt or perindopril tert-butylamine salt of alpha form*". As for the ambiguity, acknowledged by Servier, "**it is surely a drafting error*" due to the short timeframe in drafting the agreement. To support its claim, Servier relies on the fact that the wording in the Heads of Agreement was clear (see paragraphs (1043) - (1045)). However, this all the more fails to explain why a change of the definition (including that of "Patents") was then actively pursued to arrive at the one espoused in the actual agreement, which left wider scope for uncertainty, to Servier's benefit.

2565 See footnote 2575. In their replies to the Letter of Facts, Servier and Lupin confirmed their previous interpretations of the operative terms of the agreement, "Product" and "Patents". Regarding the term "Product", Servier does not seem to (still) consider the final agreement ambiguous (see paragraph (1043) - (1044)). Servier considered that interpreting this term as covering any salts would be illogical since it would mean that "**Servier accepted to supply perindopril arginine to Lupin* " (paragraph 748, ID10324, p. 198). Servier's interpretation conflicts with Lupin's that in its reply to the Letter of Facts stated that "*the Heads of Agreement was no more than a step in the pre-contractual negotiations between the parties and, as such, should not be used to interpret the Lupin Settlement Agreement […]*" (paragraph 76, ID10247, p. 17). Furthermore, Lupin claimed that according to English law (*Prenn v Simmonds* [1971] 3 All ER 237 at 240): "*It is only the final document which records a consensus*" (paragraph 73, ID10247, p. 17). However, such consensus seems to be missing, which is particularly surprising considering that the definition of the "Patents" and "Products" were allegedly the key operative terms of the agreement.

2566 Lupin in its reply to the Statement of Objections (paragraph 317.3, ID08752, p. 78) stated that the only circumstances in which a reverse payment settlement might have anti-competitive effects are when the restrictions go beyond the "*exclusionary scope of the patent*".

2567 See section 4.1.2.1.1.

2568 See paragraphs (230), (1045) and (1046).

(1913) In its reply to the Statement of Objections,[2569] Servier argued that even if the non-challenge clause covered other patents, it would not be harmful to competition as "**such a clause is not disproportionate to the objective of preventing future disputes*", "**whether it is a new dispute concerning the '947 patent or a dispute over another patent of Servier on perindopril erbumine*".[2570] Servier further alleged that "**this is especially true in the context of a settlement as in this case where the parties have entered into a distribution agreement*". First, it is recalled that no such distribution agreement was in fact concluded (see paragraph (1041) and section 4.3.4.9.1.). Second, Servier claims that Lupin did not have "**the intention or need to challenge other patents of Servier*". This statement contradicts Servier's own statement on the need to prevent future litigation. One could not preclude other challenges by Lupin in other countries.[2571]

(1914) Finally, Servier argued that the non-challenge clause did not prevent the legal review of the '947 patent.[2572] Servier faced several other opponents in the EPO proceedings, and Apotex in the UK proceedings. First, the non-challenge clause in fact left no scope for Lupin's patent challenge of any of Servier's perindopril-related patents. Second, relying on the benefit of hindsight, Servier stresses that the remaining proceedings were pursued until the very end. This claim will be further addressed in section 5.6.2. It is nevertheless already noted that, at the time of the Lupin Settlement Agreement, there was no certainty that the Apotex proceedings would be maintained, especially in view of Servier's pattern of concluding settlement agreements. Then, even if there were parallel proceedings, for example before the EPO, a specific challenging party may present evidence, carry out experiments, or develop arguments that could not be replicated by other, parallel, claimants. Servier further argues that the non-challenge clause "**did not prevent any interested third party from challenging themselves the patent in question*".[2573] However, there was no infinite number of potential challengers to Servier's patents.

(1915) To conclude, the non-challenge obligation granted Servier a 100% certainty that Lupin would not represent a competitive threat through its challenge to Servier's patent position. As the obligation not only covered the actual patent in-suit ('947), but encompassed all Servier's patents concerning perindopril, this restriction not only covered the scope of the underlying litigation, but had a significantly broader scope in preventing Lupin from future challenges of virtually all remaining perindopril patents of Servier. This is a clear indication that the purpose of the settlement agreement was not only to put an end to the pending patent litigations but to impose on Lupin commitments that the exclusionary power of the patent in suit was unable to impose.

2569 Servier's reply to the Statement of Objections, paragraphs 1249 -1254, ID10114, p. 399 - 400.

2570 Lupin similarly stated in its reply to the Statement of Objections (paragraphs 265 – 274, ID8752 p. 67 – 69) that "*the scope of the non-challenge clause in the Lupin Settlement Agreement was necessary and justified in order to conclude the dispute*".

2571 Servier alleged that "**Lupin was sensitive to the cost of litigation and was not even considering challenging the '947 patent in the jurisdictions which were of strategic importance to it (e.g. France)*" (Servier's reply to the Statement of Objections, paragraph 1252, ID10114, p. 400). Lupin was however actively challenging the '947 patent. Evidence on Lupin's commercial strategy also shows that Lupin had envisaged launch in several countries (see section 4.3.4.2). Concerning France, the possibility of litigation had been mentioned (see paragraph (990)).

2572 Servier's reply to the Statement of Objections, paragraphs 1232 -1238, ID10114, p. 396 - 397.

2573 Servier's reply to the Statement of Objections, paragraph 1243, ID10114, p. 398.

5.6.1.3.2.2 The non-compete obligation

(1916) Clause 1.6 of the Lupin Settlement Agreement provides that: "*Neither Lupin nor any of its affiliates shall directly or indirectly sell or offer for sale any Products in any country (excluding [non-EEA jurisdiction]) (a 'Relevant Jurisdiction'), either by themselves or in collaboration with any third party, always provided that with effect from the date that the conditions set out in Clause 4.1(a) or (b) or (c) (or any of them) apply in respect of any Relevant Jurisdiction Lupin may sell and/or offer to sell Servier supplied Products and/or Products manufactured by Lupin or its affiliates in such Relevant Jurisdiction*".[2574]

(1917) Clause 4.1 sets three alternative conditions under which the non-compete obligation is partially lifted. Lupin could start marketing its own perindopril, but not products of third parties, in the respective jurisdiction if and when: (1) an authorised generic is on the market, or (2) all relevant patents protecting perindopril expired in the relevant jurisdiction, or (3) an independent third party sells perindopril and Servier does not request interim injunctions against such sales.[2575]

(1918) The non-compete provision did not only relate to Lupin's perindopril as developed at the time of the settlement, but also to any other perindopril whether developed anew or acquired from third parties (including non-infringing perindopril).[2576] The entry limitations did not only relate to perindopril erbumine in alpha crystalline form as protected by the patent-in-suit ('947), but, as explained in the preceding section, extended also to other forms of the erbumine salt (also beyond the protected crystalline forms invented or acquired by Servier) as well as other salts of perindopril, including perindopril arginine (*"perindopril terbutylamine […] and any salt thereof"*) and combination products (*"products containing, as an active ingredient, perindopril"*, e.g. perindopril indapamide or perindopril amlodipine). In the same way as the non-challenge clause, also the non-compete clause went significantly beyond the scope of the patent-in-suit.

(1919) The non-compete obligation prevented Lupin from launching its own perindopril on the European markets (including launch at risk) until generic entry from third parties effectively occurred or could occur. In addition, in view of the scope of the non-compete obligation (which covered alternative forms of perindopril erbumine and also other salts of perindopril), Lupin had no incentive to develop an own version not covered by the alpha patent, or source such perindopril from third parties (although previously it showed interest in finding a second source of API[2577]). It thus had no

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2574 See paragraph (1038).

2575 Lupin clarifies in its submissions of 19 August 2010 that the definition of "*The Products*" includes "*any pharmaceutical product containing, as an active ingredient (i.e. API), Perindopril Tertbutylamine (also known as Perindopril Erbumine), and any alternative salt of Perindopril. As at the date of the Settlement Agreement, the only other salt was Perindopril Arginine and this position has not changed up to the present day*". See section 4.3.4.7.2.

2576 Servier in its reply to the Letter of Facts claimed that if this interpretation was to be accepted it would mean that "**the agreement included an additional pro-competitive component, namely Servier's commitment to supply perindopril arginine to Lupin*" (paragraph 749, ID10324, p. 198 - 199). However, as explained in this section, the non-compete clause would prevent Lupin from entering the market with any sort of perindopril. Furthermore, the Lupin Settlement Agreement did not warranty entering into a distribution agreement. Moreover, as mentioned above, the supply agreement would not have resulted in an earlier generic entry since Lupin would only be able to enter the market once the market was (already) open to generic competition (see section 5.6.1.3.2.3).

2577 See paragraphs (1018) and (1038).

option but to wait until other generic operators overcame the obstacles to entry for the large part owned or influenced by Servier in each of the jurisdictions concerned. In other words, Lupin made its market launch of perindopril fully dependent on either Servier's decision to allow third parties to enter the market with perindopril or on the inability of Servier to stop such generic entry.[2578] In this respect it is noteworthy that Lupin was fully aware of Servier's past efforts to remove generic threats by commercial arrangements (settlements and patent acquisitions).

(1920) It needs to be borne in mind that at the time, certain companies were developing non-alpha perindopril, for example by developing new salts (Krka) or amorphous perindopril erbumine (Sandoz). As the restriction also related to other salts of perindopril, it removed Lupin's incentives to develop a new form/salt of perindopril,[2579] or to enter into a co-development, supply or other partnership concerning non-alpha perindopril.

(1921) In response to the Statement of Objections, both parties argued that (i) non-compete clauses in general are a normal feature of such agreements, and (ii) the non-compete clause in the agreement at hand did not restrict Lupin.

(1922) Firstly, Servier submitted that this clause ensured "**the effectiveness of the settlement*" and that "**this type of clause is quite conventional in the context of a settlement and also generally accepted by the Commission*".[2580] For Lupin,[2581] "*non-compete obligations are perfectly acceptable, even recommended*" notably in the framework of the Vertical Guidelines. In the Commission's view, the assessment of the non-compete clauses cannot be detached from the existence of a significant inducement in the agreement at hand (see section 5.6.1.3.3). Moreover, the Vertical Restraints Guidelines are inapplicable insofar as the agreement was an agreement

2578 See, for example, paragraph (1090). Prior to launching in France, Lupin informed Servier in a letter dated 17 March 2009 of its intention to launch, as Sandoz had already launched a generic on the market, and asked Servier whether Servier had any "*proper reason*" to object. Servier replied in a letter of 31 March 2009. In the reply to the Letter of Facts, Lupin considered this type of communication as a standard practice that "*should not be taken to indicate anything beyond usual, and prudent, commercial practice*" (paragraph 77, ID10247, p. 18). Servier seemed to share Lupin's opinion (Servier's reply to the Letter of Facts, paragraph 751, ID10324, p. 199). However, contemporaneous documents show that Lupin looked for further confirmation from Servier in a letter of 3 April 2009 in which it requested further clarification to Servier's reply of 31 March (ID1078, p. 3). This behaviour is not consistent with the statement included at the end of Lupin's letter of 3 April 2009 that stated "*Lupin does not believe it has any obligation to write to notify Servier of its plans*". Moreover, the correspondence exchanged between the parties does not support Servier's claim that "*Servier did not express disagreement […] which confirms that Lupin was free to enter the market […]*" (Servier's reply to the Letter of Facts, paragraph 753, ID10324, p. 199). On the contrary, the absence of a clear reply from Servier created uncertainty that Lupin tried to solve with its letter of 3 April 2009.

2579 Servier argued in its reply to the Statement of Objections (paragraphs 1272 - 1276, ID10114, p. 404 – 405) that there is no proof that Lupin had any intention to develop a non-infringing perindopril product, that development would have taken time, and that nothing indicates that Lupin considered getting supply from Sandoz or Krka. Those options can conversely not be excluded. Previously, Lupin showed interest in finding a second source of API (see paragraph (1018)). The development time mentioned ("**one to two years if one refers to Krka's product* ") (it was rather two-three years) would certainly imply a delay, but at least not exclude the possibility of all future competition. Finally, the fact that Lupin was not looking for other sources after the Lupin Settlement Agreement can illustrate the decreased incentives in the wake of the agreement.

2580 Servier's reply to the Statement of Objections, paragraph 1258, ID10114, p. 401. Note is taken of the fact that Servier mentions "**if […] Lupin had been authorised to market its product in violation of Servier's patents […]*" using the plural form.

2581 Lupin's reply to the Statement of Objections, paragraphs 253 – 260, ID8752 p. 64 – 66.

between competitors and not a vertical one. Neither do these Guidelines, in the Commission's view, provide any useful analogy. In any event, the option to conclude a distribution agreement was never exercised.

(1923) Lupin also argued that it was allowed to continue with the development of its product as it obtained the licence back for its three process patents applications and it was allowed to continue with the marketing authorisations procedures. [2582] While this is not disputed, any product to come out of Lupin's development, be it an existing or even a new version of perindopril would still be caught by the non-compete restriction, and could therefore not limit its impact. Lupin itself admitted that the obligation covered other patents which weren't the subject matter of the dispute (see section 4.3.4.7.2.). The wording of the obligation is open ended and seems to cover all forms of perindopril, and is certainly not limited to the subject-matter of the dispute, i.e. the '947 patent (in contrast to, for example, the Krka patent settlement agreement). If paragraph 205 of the Technology Transfer Guidelines were to be applied by analogy, the broad non-compete restriction covered situations where it was "clear that no blocking position exists" (see paragraph (1187)).

(1924) Lupin hence found itself *de facto* in Servier's hands regarding its product launch. Regarding France, Servier argued that it allowed Lupin to launch, [2583] even when the '947 patent was still valid. However, Lupin's letter informing Servier of its intention to launch pointedly illustrates Lupin's limited scope of action. [2584] It is noteworthy that Lupin received its marketing authorisation in France on 9 July 2008, and only sent the letter to Servier on 17 March 2009 after Sandoz's product launch in the country. The market for perindopril erbumine was as such already considered "lost" to Servier, which had switched its focus to perindopril arginine before generic entry. [2585] While Servier stated that "**the third exception to the non-compete obligation allowed Lupin to enter the market with a product infringing the '947 patent*" following entry by another non-infringing generic product, any such entry would be strictly limited to countries already "lost" to Servier. While Lupin's communications to third parties show that Lupin continued its activities, "*taking cognisance of existing patents rights*", [2586] the above also confirms that Lupin's commercial activities were necessarily dependent on Servier and/or its remaining generic rivals.

(1925) Servier further claimed that making Lupin's entry dependent on events that would take place before Lupin was ready to launch its product remove the scope for possible effects, as it would not be ready to launch before the EPO appeal decision or

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2582 In contradiction with its statement that "*Lupin negotiated the non-compete to ensure that it was limited to only what was necessary for the specific purposes of the settlement agreement*", Lupin acknowledges that "*the Lupin Settlement Agreement, in hindsight, is not well drafted and there is scope for ambiguity*" (Lupin's reply to the Statement of Objections, paragraphs 262 – 264, ID8752 p. 66 – 67).

2583 Servier's reply to the Statement of Objections, paragraphs 1283 - 1284, ID10114, p. 406 - 407. Servier also formulated in its reply (paragraph 1204, ID10114, p. 391), that "**the main objective of the agreement was to end the litigation and enable Lupin, under certain conditions, to enter the national markets where Servier still had patent protection*,", acknowledging that entry was subject to conditions.

2584 See paragraph (1090).

2585 ID1346, p. 26.

2586 ID0797, p. 65. Servier in its reply to the Statement of Objections (paragraphs 1259 - 1263, ID10114, p. 401 - 402) mentioned other pieces of communication. For completeness sake, it is noted that ID0503, p. 1 refers to a country outside the EU. On the UK, ID6752, p. 127 dates from 21 August 2007, and not July 2007 as mentioned by Servier, i.e. after the '947's invalidation by the High Court.

the launch of other generics.[2587] The Commission reiterates that Servier's argument relies on hindsight. It relies on the actual course of events, posterior to the Lupin Settlement Agreement, which was however far from certain at the time of the settlement (see paragraph (2023)), and in any event only focuses on the UK. The actual course of events was only but one in a range of possibilities that existed at the time of the agreement. Elsewhere, it could not even *ex post* be excluded that, absent the settlement, would be possibly able to launch before the EPO appeal decision in May 2009. Besides, nothing indicates either that entering after the other generic companies would be completely unattractive for Lupin.

(1926) From the above, the Commission concludes that the non-compete obligation thus disabled Lupin's market entry with the existing product, but in addition also removed the incentives to come onto the market with other possibly non-infringing products (its own or developed by a third party). Therefore, the non-compete obligation limited Lupin's ability to compete to the fullest extent, and Lupin accepted commitments going far beyond the commitments required for terminating the pending litigation between the parties to the settlement agreement.

5.6.1.3.2.3 The possibility of concluding a supply agreement as an alleged pro-competitive feature of the Lupin Settlement Agreement

(1927) Lupin argued that the settlement with Servier was expected to accelerate its market entry under the prevailing patent situation,[2588] in particular as its terms envisaged the conclusion of a distribution agreement allowing Lupin to enter sooner. The Commission considers that this argument cannot be sustained. First, the distribution agreement – even if concluded - would only allow for distribution rights of perindopril by Lupin once the conditions for Lupin's independent generic entry are fulfilled. In other words, again Lupin made the market entry dependent on either Servier's decision to allow third parties to enter the market with perindopril, or on the inability of Servier to stop such generic entry. Therefore, Lupin's entry with Servier's supplies would be no earlier than at a time when, eventually, entry by independent generics would be possible. Second, such a distribution agreement was never concluded between the parties despite an explicit provision in the agreement (clause 4.2) stipulating that the parties agreed to use "*all reasonable endeavours*" to enter into a supply agreement within four weeks from the conclusion of the settlement agreement.[2589] A contemporaneous document of August 2007[2590] and the *ex post* explanations provided by Lupin and Servier point to an important disagreement as the reason why the parties did not sign the distribution agreement.[2591] Such disagreement concerned the exclusive nature of the agreement, while Servier envisaged an exclusive agreement by which Lupin would only distribute Servier's products; Lupin understood that the agreement would allow it to distribute its own products. If Servier would have prevailed then the distribution agreement would not have accelerated Lupin's market entry. Instead, the distribution agreement was not concluded, as Lupin preferred to continue with the development of its own product.

2587 Servier's reply to the Statement of Objections, paragraphs 1290 - 1292, ID10114, p. 407 - 408.

2588 See paragraph (1050).

2589 ID0053, p. 92.

2590 ID0033, p. 66 - 67.

2591 See section 4.3.4.9.1, in particular paragraphs (1068) – (1070).

(1928) For the same reasons, Servier's claim that the possibility of concluding a supply agreement as "**a central element of the agreement*"[2592] appears doubtful, at the very least. Insofar as there is no supply agreement, Servier's argument that "**distribution agreements benefit in general from block exemption*" cannot be sustained. Moreover, even if the agreement would have been signed, it would not have been benefited from an exemption since it was an agreement between competitors, and not a vertical one (see paragraph (1922)).[2593]

5.6.1.3.3 Financial or other considerations for the restriction

(1929) The assessment of the Lupin Settlement Agreement as a restriction of competition by object requires an identification of the value transfers to Servier and/or Lupin. The aim of the assessment is to establish whether there was a net value transfer from Servier to Lupin and to quantify that value transfer with a view to establishing its importance in the agreement.

(1930) This section is divided into five sub-sections. First, the Commission will assess the net value transfer itself and its precise purpose. Second, this section will verify whether the value transferred by Servier was justifiable as remuneration for Lupin's patent applications transferred to Servier. Third, various methods for establishing the value of Lupin technology will be used. Fourth, it will be examined whether the payment constituted an inducement for Lupin. Fifth, the significance of the quantum transferred by Servier to Lupin will be assessed.

(1931) The parties' arguments regarding the value transfer will be addressed in the relevant sub-sections. The two main arguments raised were the following:

- The technology acquisitions were not dependent on the payment, which did not constitute an inducement (see sub-sections 1 and 4);
- The patent acquisitions had commercial value for Servier (see sub-sections 2 and 3).

5.6.1.3.3.1 Identification of value transfers

(1932) As indicated the Lupin Settlement Agreement consists of three main elements: the settlement provisions (containing the non-challenge and non-compete clauses), the provisions on the sale of Lupin's patent applications, and the envisaged distribution contract.[2594] Whilst the envisaged distribution contract might be of value in its own right, it will not be included in the present assessment. First, its value cannot be determined, as the distribution agreement was neither entered into nor implemented. Second, if established, the value from a distribution deal could further increase the quantum of value transferred to Lupin. In view of the latter, omitting the potential distribution deal from the analysis of the value transfer could be beneficial, or at the very least neutral, for the parties' interests.

(1933) Besides the inherent exclusionary value of the restrictive settlement provisions, the value flow in the Lupin Settlement Agreement is formally limited to Servier's

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2592 Servier's reply to the Statement of Objections, paragraph 1150, ID10114, p. 378.

2593 Servier's reply to the Statement of Objections, paragraph 1370, ID10114, p. 425. On a similar note, the same paragraph argues that "**agreements for the assignment of intellectual property rights, in that they merely transfer a right, do not a priori distort competition, especially where a free licence for use is granted in return*", while there was no technology transfer within the meaning of the Technology Transfer Guidelines in the Lupin Settlement Agreement.

2594 See section 4.3.4.7.1.

acquisition of three patent applications, and the corresponding remuneration to Lupin.[2595] The Lupin Settlement Agreement does not mention any other specific cost or performance on the side of Lupin, and to the benefit of Servier, which would be capable of explaining Servier's payments.

(1934) The sale of Lupin's patent applications foreseen in the Lupin Settlement Agreement essentially consisted of the sale and transfer of three process patent applications from Lupin to Servier for a payment to Lupin of EUR 40 million.[2596] The patents transferred were (i) WO 2004/075889 (EP 1603558B1) for EUR 20 million, (ii) WO 2006/097941 (EP 1861367 A) for EUR 10 million, and (iii) WO 2005/037788 (EP 1675827 A1) for EUR 10 million. Lupin received a royalty free back-licence on these applications for its own use only.

(1935) The date of transfer of WO 2004/075889 was the date of the signature of the agreement (30 January 2007). The EUR 20 million payment was staggered in two phases: the first EUR 10 million was paid on 2 February 2007 and the second tranche was paid on 26 February 2007. The date of purchase and the payment of the two remaining patent applications were however deferred until 1 October 2007.

(1936) The question is whether the payment was a consideration for the sale of the patent applications only, or whether it was, in addition, an inducement for Lupin to enter into the settlement agreement.

(1937) In their replies to the Statement of Objections, both Servier and Lupin denied that the settlement depended on the terms of the assignment of patent applications.[2597] However, Lupin had previously confirmed that: "*the assignment of Lupin's three process patent applications was an integral part of the settlement discussions*".[2598] Although Lupin argued that this was because "*the patent transfer depended on the settlement agreement, not vice versa*", the Commission notes that Lupin itself described the payments received as "*settlement monies*" or "*settlement sums*".[2599] Besides, Lupin does not provide any alternative plausible explanation for the payment of EUR 40 million to the explanation provided by the Commission. It was Lupin who had initiated litigation against Servier, and could withdraw it at any time. Finally, as will be set out below the value of the payment was higher than the profits Lupin expected to make from perindopril, and was hence not likely to be dependent on the settlement.

(1938) The Lupin Settlement Agreement thus contains a transfer of value in both directions. Therefore, the Commission will examine if the magnitude of the payment significantly differs from the value of the transferred rights in the given economic context.

(1939) The first part of the assessment will examine the inherent value of the transferred Lupin patent applications for Servier. The second part will verify if the magnitude of the payment for the patent applications could be considered to represent a significant

2595 In addition, Servier grants to Lupin a license for free.

2596 See paragraphs (1040) and (1041).

2597 Lupin's reply to the Statement of Objections, paragraph 331, ID8752, p. 81; Servier's reply to the Statement of Objections, paragraph 1149, ID10114, p. 378. See also paragraph (929).

2598 See paragraph (1053). Lupin stated that it would only agree to the sale of the patent applications being part of the patent settlement agreement if Lupin was granted a licence back (ID1039, p. 45).

2599 See paragraph (1053).

inducement for Lupin to accept the overall terms of the Lupin Settlement Agreement. The third part will compare the sums of money transferred by Servier to Lupin with the levels of profits which were contemporaneously expected by each of the parties in the alternative scenario of generic market entry. On the basis of the first three parts, the formal valuation of the patent applications sold by Lupin and acquired by Servier will be carried out in line with the generally accepted valuation methods.

5.6.1.3.3.2 Inherent value of transfer for Servier

(1940) Servier, in the course of the investigation, advanced a general claim that the acquisitions pursued the goal of improving manufacturing processes.[2600] Servier contests the Commission assessment that these patent applications had no commercial value to Servier, and essentially served to induce Lupin into accepting the settlement terms.[2601] From the outset, the Commission recalls that the Court of Justice held in *Aalborg Portland* that "*[i]n most cases, the existence of an anti-competitive practice or agreement must be inferred from a number of coincidences and indicia which, taken together, may, in the absence of another plausible explanation, constitute evidence of an infringement of the competition rules*".[2602]

(1941) The analysis will first look at the evidence on expected gains from the declared goal of the purchase, i.e. commercial exploitation. Second, the extent of actual benefits to Servier will be examined. Third, any other elements indicative of the value of Lupin technology for Servier will be taken into consideration.

(1942) The *ex ante* expectations of gains from an improved manufacturing process should serve as the benchmark for establishing whether the payment to the generic company significantly exceeded the expected gains from the acquired rights and thus constitute a covert reverse payment to Lupin.

(1943) However, Servier has, despite repeated attempts by the Commission,[2603] not been able to submit any contemporaneous documents,[2604] which would lend credence to its posterior explanations of the objectives of the acquisition.[2605] Neither has Servier been able to report any specific practical use of Lupin's patents applications in the manufacture of perindopril.[2606] On the other hand, reference can be made to Servier's document from 1999 outlining the strategy to prepare a high number of patent

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2600 See paragraph (1054).

2601 Servier's reply to the Statement of Objections, paragraph 1312, ID10114, p 411 - 412.

2602 Joined Judgments in *Aalborg Portland and Others v Commission*, C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P, EU:C:2004:6, paragraph 57.

2603 Commission's RFI of 15 January 2009, questions 24 and 25; RFI of 6 August 2009, question 33; RFI of 9 April 2010, question 25; RFI of 7 February 2011, questions 23, 24.

2604 Contemporaneous documents such as investment plans, technical feasibility studies, cost-benefit analysis, due diligence reports, financial plans, etc.

2605 Servier explained in its reply to the Statement of Objections (paragraph 1319, ID10114, p. 413) that it relied on internal knowledge. This is according to an expert statement (Annex 00-07, paragraphs 10 – 31, ID9054, p. 4 - 10) not unusual in the industry. The statement also claims that investment plans and such documents are scarcely used for patent application acquisitions. However, the expert statement does not distinguish such acquisitions depending on the amount at stake, and it failed to explain why investment into IPR should be any different than investments in other assets in that they did not prompt an elaborated and documented economic rationale. On a side note, the Commission observes that the expert opinion failed to declare that [name of expert]* had worked for Bristows UK, one of Servier's external counsels.

2606 See paragraph (1055).

applications in the period 2000-2003. However, the goal pursued by this "**cluster of patents*" was not to discover and patent more efficient production processes, but to block all alternative ways of producing perindopril to prevent generic entry.[2607]

(1944) In a situation where potential exculpatory evidence can only come from the parties themselves, and the parties are unable to produce such evidence despite several requests from information, the Commission is entitled to draw inferences from that. Against this background, the analysis can only focus on actual documented cost related benefits, namely optimised production costs and increased production capacity.

(1945) Servier has explained (*ex post*) that the objective pursued by the acquisition was the optimisation of the synthesis of perindopril erbumine and/or arginine (WO 2004/075889), of the purification process and the reduction of crystallisation time for the perindopril erbumine (WO 2005/037788, WO 2006/097941). Additionally, in its reply to the Commission's RFI of 16 January 2009, Servier explains that "**Alternative purification methods, in particular recrystallisation in Dimethoxyethane (Lupin WO 2005/037788A1), will be of great help for the success of this future optimisation"*. However, in the same document Servier states that *"*has been unable to identify within the time allowed documents on the value of LUPIN's patent applications acquired*".[2608]

(1946) Servier's explanations as to the intended use of the Lupin technology reveal a degree of incoherence. In March 2011, Servier stated that its current manufacturing process did not rely on Lupin's patent applications. Servier maintained, however, that it would use the patent applications for research and development purposes.[2609] In May 2011, Servier contradicted this with its explanation that certain savings which allegedly accrued from 2005 were based on Krka's, Lupin's and Azad's technology. This, in turn, directly contradicted Servier's earlier statement that the alleged savings (of around EUR 0.3 million a year) were based only on Krka's technology. In any event, Servier failed to answer the question from the underlying RFI (i.e., how could Servier already in 2005 benefit from a technology it only acquired in 2007?).[2610]

(1947) Thus, there is no evidence that the objective behind the transfer of patent applications was genuinely acquiring technology expected to improve Servier's manufacturing processes (and provide a return on the very significant investment amounting to EUR 40 million). This is corroborated by the non-existence of credible evidence as to the attempts to use this technology in practice. Servier never substantiated any of the claims that it saved money through the acquisition. Moreover, the circumstances of the acquisitions and the language of the settlement agreement also suggest that Servier's interest in commercial exploitation of the patent applications did not play a primary role.

(1948) Firstly, Servier appears to have had limited knowledge of the acquired patent applications. Following a lunch during which [employee name]* (Servier) expressed interest in Lupin's patent applications[2611] [Employee name]* of Lupin sent an email on 10 January 2007: *"It was a pleasure to meet you yesterday - thank you for a*

2607 See, for example, paragraphs (115) and (123).
2608 See paragraph (1055).
2609 See paragraph (1055).
2610 See paragraph (952).
2611 See paragraphs (1026) - (1027).

delightful lunch. Please see below the patent applications that may interest you". The information provided to Servier on each patent application is a succinct summary encompassing title, dates of publication, filing and priority and status of the application. In addition, details of patentability reports were included. It is also peculiar that, while it was allegedly Servier who expressed interest in patent acquisition, it was up to Lupin to identify the specific patent applications to Servier. From the negotiation history it can be deduced that Servier's decision to acquire the patent applications would appear to have been taken on the basis of scarce information and over a short period of time. Servier conducted no due diligence at the time of the Lupin Settlement Agreement, unlike in the case of Azad and Sandoz, where transaction did not concern a patent settlement, but a pure IPR purchase. In both of these cases, the due diligence process itself took several weeks, and Servier was interested in the know-how from the practical implementation of the technology in the manufacturing process over and beyond the disclosure in the patents themselves. The absence of due diligence at the time of the Lupin Settlement Agreement is all the more unusual in view of the fact that the Lupin patent applications overlapped to a significant degree with a patent application that Servier had acquired from Krka only weeks before, also in January 2007.[2612]

(1949) In its reply to the Statement of Objections,[2613] Servier referred to evidence on file and provided new evidence to argue that it did not have only a limited knowledge of the acquired patent applications (see paragraph (1005)). This evidence concerns its follow-up of application WO 2004/075889, known "**in the context of its activity of monitoring the Perindopril patent*", and also scientific knowledge of WO 2005/037788. None of these documents explains the basis to calculate the amount paid to Lupin (even less so of the magnitude of EUR 40 million).[2614] Concerning patent application WO 2006/097941, Annex 00-04 dates from 2013 with no reference to contemporaneous evidence.

(1950) Secondly, Servier did not insist on the validity (patent grant) or functionality (industrial applicability) of the patents as a (pre)condition for its purchase. Section 2.2 of Lupin Settlement Agreement states that: "*(a) Lupin gives no assurance that any patent comprising the Lupin IPR shall be granted or that any patent is or shall be valid or that any product or process claimed in the Lupin IPR is non-infringing […]*".[2615] Servier even accepted to pay if the patent applications would have never been granted. Indeed, pursuant to clause 2.2(b) of Lupin Settlement Agreement, Servier "*shall be obliged to pay the sums falling due on 1 October 2007 regardless of the status (or non status as the case may be) and/or validity of the Lupin IPR to be assigned on that date*".[2616] Lupin received EUR 40 million from Servier, even though Lupin did not offer any representations or warranties, and was

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2612 See paragraph (953).

2613 Servier's reply to the Statement of Objections, paragraphs 1315 - 1318, ID10114, p. 412 - 413.

2614 Servier in its reply to the Letter of Facts referred to Lupin's correspondence of February 2005 (ID0055, p. 78 - 82) to support its claim that "**Servier was of the opinion that there was every chance that the patent applications would be accepted*" and added that "**just because a patent application is refused, that does not mean that the underlying technology loses all relevance* " (paragraphs 766 - 767, ID10324, p. 202 - 203). Yet, Servier fails to indicate how it intended to use Lupin's patents; and the explanations provided in previous occasions reveal a degree of incoherence (see paragraph (1946)).

2615 ID0053, p. 92.

2616 See paragraphs (1034) and (1040).

not liable in case of invalidity.[2617] Servier had no claim against Lupin in case of non-validity of the patent applications. This provision is the most conspicuous instance that the sale of patent applications paid little attention to the inherent future value of the acquired rights. This strongly suggests that the acquisition was not made at arm's length, and that Servier' was ready to pay the full price even if the patent applications were not granted. Moreover, Servier did not request a transfer of any know-how from Lupin to Servier that would allow Servier to make optimal use of the patent applications.[2618] It is noted that Servier had asked for know-how in the context of the Azad acquisition.[2619]

(1951) In its reply to the Statement of Objections,[2620] Servier claimed that it was confident in the validity of the applications, and did not need know-how as it had internal knowledge. It relies on Annex 00-07 arguing it is not uncommon to rely on "*a few knowledgeable and experienced people*" for such decisions.[2621] Nevertheless, with the Lupin Settlement Agreement, the risk was passed to Servier even before the applications were transferred. Moreover, Lupin was under no obligation to use its best endeavours to support the applications until these would be transferred to Servier. Thus, Servier bore the risk for the success of the applications, but could not even influence the application process for a number of months.

(1952) Another element that contests the acquisition being made at arm's length was that Lupin would receive a royalty free back-licence on the three patent applications acquired by Servier for Lupin's own use only.[2622] Therefore, the terms of the Lupin Settlement Agreement prevented Servier from receiving any royalties from these patents, from Lupin or other parties; as well as from having an exclusive access to the benefits derived from their application.[2623] The above strongly suggests that the payment had another purpose.

(1953) Thirdly, Servier deferred the acquisition of patent applications WO 2006/097941 and WO 2005/037788 by eight months in order to adapt the cash flow to Servier's financial planning. Lupin explains that the reason for the staggered transfer "*was to assist Servier by splitting the consideration to be paid in respect of the three patent applications, pursuant to the terms of the Settlement Agreement, over two financial years*".[2624] Servier confirmed without more details a financial interest in splitting the

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2617 In the reply to the Letter of Facts, Lupin stated that "*the inclusion of such an exclusion clause [clause 2.2] [...] reflects standard industry practice*" (paragraphs 90 - 92, ID10247, p. 20). Servier did not seem to consider that this exclusion clause was a standard practice (see paragraph (1030)). In its reply to the Letter of Facts, Servier indicated that "**the allocation of risks may […] vary from one contract to another*" and that the presence of a warranty clause depended on several factors, in particular: (i) the internal expertise of the buyer; (ii) the buyer's confidence on the soundness of the patent applications; (iii) the negotiation power of the parties; and (iv) the financial soundness of the parties, among others (paragraphs 768 - 769, ID10324, p. 203). However, contemporaneous documents do not show how these elements were taken into account to allocate the risk of the agreement entirely to Servier (see paragraph (1055)).

2618 See paragraph (1056).

2619 See paragraph (370).

2620 Servier's reply to the Statement of Objections, paragraphs 1321 – 1322, ID10114, p. 413.

2621 It is noted that said Annex 00-07 is widely relying on the opinion of [employee name]* of Servier. See regarding validity Servier's reply to the Statement of Objections, Annex 00-07, paragraphs 83, 85 and 86, ID9054, p. 23 - 24.

2622 See paragraph (1053).

2623 See paragraph (1056).

2624 See paragraph (1052).

payments.[2625] It is curious that a rational operator would not insist – absent exceptional circumstances which were not claimed– on the immediate transfer of the patent applications to make use of them as early as possible, also in view of the limited remaining patent term and the fact that their prosecution remained within Lupin's remit until the actual transfer. Servier fails to explain why accounting considerations would have mattered more than having the two applications. This is amplified taking into account that Servier sought no warranties until the actual assignment of the patent application.[2626] Consequently, Lupin was not under a legal obligation to undertake steps necessary for due maintenance or prosecution of the patent with the EPO. And yet, Servier was definitely committed to purchase the patent applications (irrespective of the grant and the validity, as said above). Furthermore, Servier showed little interest to register patent application WO 2004/072889 (transferred on 30 January 2007) as its property, and had to be reminded by Lupin in August 2007.[2627]

(1954) Fourthly, Servier's product manager for perindopril confirmed that Servier' normal policy in acquiring IPRs would be to prepare a feasibility study prior to the acquisition itself:[2628] "**I find it hard to imagine that there is no clause, if indeed the case is as you describe it, which specifies that any contract signed takes effect without such analyses [feasibility studies] having been made*". However, no such feasibility studies have been submitted by Servier concerning Lupin's patent applications. [2629] Lupin pointed out that *"Servier would have had sight of the relevant know-how associated with Lupin's patent applications/manufacturing process"* during the course of the litigation procedure between the two companies.[2630]

(1955) Fifth, in view of the above, it is not surprising that neither Servier nor Lupin were able to provide a plausible description of the factors determining how the final sum of EUR 40 million was reached. Unlike the payment structure in the actual agreement, the negotiation documents reveal that the specific payment was not allocated according to the perceived value of the patent applications, but rather reflected the payment schedule. Moreover, it appears that, while the overall amount of EUR 40 million remained the same, the proposals how to structure the payments per patent application varied up to 90% from one proposal to another.[2631] This all suggests that the patent applications were not financially evaluated according to their respective commercial/industrial value for Servier and Lupin. While both parties argued that the price was negotiated as a package,[2632] this puts further emphasis on

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2625 Servier's reply to the Statement of Objections, paragraph 1323, ID10114, p. 414.

2626 In certain agreements for the transfer of patent application not examined in this Decision, Servier sought such warranties. See, for example, paragraph (1782).

2627 See paragraph (1086).

2628 See paragraph (288).

2629 Servier claimed that "**it has been shown […] that analyses had been made previously within Servier on two of the patent applications*" (Servier's reply to the Statement of Objections, paragraph 1324, ID10114, p. 414). However, only evidence of scientific tests applications has been demonstrated. Servier further alleged that more elaborate analyses were not possible due to the short timeframe. Servier fails to explain why the acquisitions could not be postponed if as it alleges the settlement was a prerequisite for the acquisitions and independent from them, and, in any event, Servier's financial interests dictated a later transfer.

2630 See paragraph (1028).

2631 See paragraph (1034).

2632 Lupin's economic annex by Oxera, paragraph 3.37, ID8753, p. 28. Servier's reply to the Statement of Objections, paragraph 1325, ID10114, p. 414. While Servier's Annex 00-07 (paragraphs 83 - 93) presumes that the value EUR [10–25]* million was allocated to one patent application because "*the first*

the fact that efforts were directed towards the timing of payments (see paragraph (1953)). Lastly, the value of the acquisitions for Servier can be questioned in view of their timing, since Servier had already shifted its priority to the arginine salt. Annex 00-04 clarifies the timing of this shift:[2633] "*the stabilities of […] other perindopril salts including […] arginine were studied as early as 1983*"; "*the idea of using arginine instead of ter-butylamine resurfaced in 1999/2000*"; "*following extensive research we launch our […] manufacturing process for perindopril arginine in accounting year 2005/2006*". Servier has also stressed several times in its replies that perindopril tert-butylamine salt […]*.[2634]

(1956) Servier's above statements unequivocally confirm that (1) the perindopril erbumine technology was acquired at the time when Servier had already made the decision to switch to perindopril arginine; and (2) even though perindopril erbumine can be used […]*, Servier did not commence any meaningful development activities on the basis of the Lupin technology.[2635] This directly disproves Servier's explanation that "*given the change in […] prioritisation of the arginine project following the purchase of Lupin 1, it was also decided to abandon research in that area for the time being"*.[2636] It also casts further doubts on the stated, yet undocumented objectives for acquiring the Lupin technology. What in the Commission's view nonetheless clearly flows from the above is that the acquired Lupin technology was, in spite of the alleged haste in preparing the transaction,[2637] not a priority for Servier and thus not the subject of further research.

(1957) In its reply to the Statement of Objections, Servier argued that the first Lupin patent application to grant was "*particularly important for Servier, as it related to technology which was very close to one of the patent applications that Servier had previously purchased from Krka (WO 2005/113500)*".[2638] [Employee name of Servier]* "*therefore wished to ensure Servier's freedom to operate with the Krka technology that it had already acquired*". Lupin made the similar point that "*the Krka patents were known to be at a high risk of infringing one of the Lupin patents*" and hence "*some part of Servier's €40m payment is likely to have been for the protection*

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of the three patents (which had an application date of 2004) was likely to grant sooner than the other two", this claim is not supported by the course of the negotiations.

2633 Servier's reply to the Statement of Objections, Annex 00-04, paragraphs 70 - 79, ID9054, p. 27 - 30. In its reply to the Letter of Facts, Servier referred to the statement of the head of the Oril plant (Annex 00-04 of Servier's reply to the Statement of Objections) which indicated that Lupin's technology "**contains interesting aspects which might be exploited in future*" (paragraph 755-757, ID10324, p. 200). Servier failed to mention that the same Annex evidences that Lupin's process patent applications were not interesting to the manufacturing process that Servier used and/or that application of Lupin technology would require a substantial investment in research at a time when Servier had already decided to give priority to the arginine project (see paragraph (1956)). Therefore, Annex 00-04 fails to show that Servier had interest in the commercial exploitation of Lupin's technology (see paragraph (1949)). Servier finally stated that " **it would have been irrational on the part of Servier to pay Lupin for a settlement without the guarantee of a settlement with Apotex*" (paragraph 758, ID13024, p. 200). Yet, Servier had several strategies in place to address the litigation with Apotex (see paragraph (1266), as well as paragraphs (179) and (191)).

2634 See for instance Servier's reply to the Statement of Objections, paragraph 1326, ID10114, p. 414, and Servier's reply to the Letter of Facts, paragraph 757, ID10324, p. 200.

2635 Servier moreover acknowledged that "*similarly to the Krka2 application, transposing this technology to production on an industrial scale would require a substantial investment in research and development*".

2636 Servier's reply to the Statement of Objections, Annex 00-04, paragraph 97, ID9054, p. 35.

2637 See paragraph (1035).

2638 Servier's reply to the Statement of Objections, Annex 00-03, paragraphs 40 - 44, ID9054, p. 13 - 14.

of Krka's patent applications".[2639] Firstly, this further casts doubt on the value of the Krka technology for Servier, for which there is also no *ex ante* evidence on the commercial objectives sought (see section 5.5.3.4.2). Besides, this statement not only raises the question of Servier's interest in acquiring the Krka technology, but also the question why it sought freedom to operate (in view of the EUR 40 million entailed by this "freedom to operate" purchase) without actually having any concrete plans to exploit Krka technology. Moreover, Servier could start a patent challenge, or seek a licence in case Servier ever decided to commercially exploit Krka technology, and Lupin asserted its patent applications against Servier.

(1958) Servier also argued that the objective of its purchase was to safeguard possible future development avenues. However, it does not appear plausible from the facts of the case and is not confirmed by the subsequent product developments carried out by Servier.

(1959) Thus, the evidence at hand suggests that, at the time of the acquisition, Servier was ready to pay EUR 40 million to Lupin whatever the validity or the usefulness of the acquired patent applications. The inherent commercial value of the patent applications for Servier was negligible,[2640] as it was unchecked by Servier at the time of the Lupin Settlement Agreement. Moreover, Servier accepted to partially forgo potential future income derived from royalties of the patent applications from Lupin by giving a royalty-free licence back of the patent applications to Lupin. Therefore, the Commission can conclude that the payment was in consideration for something other than the patent applications. The Commission considers that the Lupin Settlement Agreement entailed, at most, a negligible value transfer from Lupin to Servier and the payments were primarily an inducement for settling as explained below.

5.6.1.3.3.3 Value of Lupin's patent applications

(1960) Taking into account the fact that the Lupin Settlement Agreement included the sale of Lupin's patent applications, the Commission also finds it necessary to relate the amount paid by Servier to possible proxies for the value of Lupin's patent applications.

(1961) For the purpose of the present investigation, out of the three main methods generally proposed for patent valuation, i.e. cost approach, income approach and market approach,[2641] only the cost and income approaches can provide for reasonable valuation of the patent applications in question. The Commission considers that the market approach cannot be applied because it is virtually impossible to find a comparable market transaction where the conditions would be sufficiently similar to those of the present case but for the value that the incumbent allocates to excluding its potential competitor.

(1962) Based on the cost approach, the value of Lupin's patent applications was not higher than the amounts Lupin invested into its perindopril development programme. As Lupin was unable to provide an estimate of total cost, including its internal costs of

2639 Lupin's economic annex by Oxera, paragraphs 1.15 and 3.23, ID8753, p. 8 and 25.

2640 The value that the patent applications had, specifically in the context at hand, for Servier is of great importance to assess whether the payment made to Lupin was in consideration for something else than the patent applications.

2641 For a brief description of each method, see: http://www.epo.org/searching/essentials/business/valuation/faq.html#faq-144

developing perindopril (external costs amounted roughly to EUR [0.35-0.75] million),[2642] the cost of comparable development projects can serve as an appropriate benchmark. Reference is thus made to costs of Krka's perindopril development, which amounted to around EUR [1-4] million.[2643] It is unlikely that Lupin's cost exceeded the Krka benchmark,[2644] as these costs also included the costs for obtaining marketing authorisation in a large number of Member States. It is safe to assume that the development programme also covered other aspects such as building up of necessary know-how that was not revealed in the patent applications in question; hence the development programme's cost constitutes an upper boundary for the cost-based value of the traded rights.

(1963) The income approach leads to two different valuations for each of the parties. With respect to Lupin, it is reasonable to equate the value of the patent applications with the profits expected from marketing independently generic perindopril.[2645] This being said, the same caveat must apply as in the above discussion of the cost approach. Since Lupin's perindopril development programme in all likelihood also covered other tangible and intangible assets, therefore the total expected profits must be regarded as an upper boundary for the income-based value of the traded rights. As established earlier, the gross margins[2646] forecasted by Lupin fall far short of the payment made by Servier. Therefore, from Lupin's perspective, the income-based value of the traded rights must be considered as substantially lower than Servier's offer.

(1964) With respect to Servier, the patent valuation based on the income approach must take into account the fact that the application of Lupin's patents could only bring about an incremental improvement for Servier's production process. As already mentioned, Servier was unable to produce any contemporaneous documents that would be informative as to the amount of savings expected from acquiring Lupin's technology. Such savings would have to be considerable in order to warrant the payment of EUR 40 million. The Commission estimates the annual cost of perindopril API manufactured by Servier at EUR [20–30]* million.[2647] Given the 2007 production level, in order to break even on the investment in Lupin's technology, Servier would have to be confident to achieve savings in the region of 20-24% of the API production cost.[2648] For the sake of comparison, according to Servier's own

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2642 See paragraphs (1058) - (1059).

2643 See paragraph (920).

2644 Lupin questioned why Krka was chosen as a good comparator (Lupin's economic annex by Oxera, paragraph 3.10, ID8753, p. 23). Krka serves as the closest comparator because of a similar timing and the in-house nature of the development programme.

2645 There are no indications that Lupin was expecting a separate income from transferring its technology to any third parties. Lupin's main options were between settling and marketing after the way would be cleared (see paragraphs (1020) - (1022)).

2646 See paragraph (1974).

2647 The estimation is based on the following assumptions: (a) Servier's worldwide production of [1,000–10,000]* million DDDs of product containing perindopril (this represents approximately the production level achieved by Servier at its peak in 2007), (b) full shift of the production to the arginine salt, i.e. DDD equals 5 mg, and (c) the API cost of EUR 2,000 per kilogram.

2648 The calculation of required savings assumes: (a) annual cost of manufacturing perindopril API at the level of EUR [25–50]* million, (b) [10–20]* % discount rate, and (c) [0–20]* year repayment period. The discount rate is in the lower range of internal rates of return (IRR) reported for the sector (see, for example, Peter Mansel, *Output-based measures needed for pharma R&D investment*, PharmaTimes Online, 2 December 2010). The repayment periods assume a full implementation of Lupin's technology within one or five years from the acquisition as well as the continuous exploitation until 2021, i.e. the

submission, the technology acquired from Krka allowed for savings of [1.5-2]%.[2649] It must be also noted that in the overall calculation, Lupin's technology was not as cost efficient as the one used by Servier. Lupin estimated the perindopril erbumine API cost at USD [2,800 - 5,500] (EUR [2,230 - 4,380]) per kilogram with a potential decrease to USD [1,700 - 3,400] (EUR [1,350 - 2,710]),[2650] while Servier was able to manufacture its own perindopril erbumine API at the level of EUR [1,300 - 1,700] (year 2007 - 2008) and less.[2651] The potential of Lupin's technology to deliver any meaningful savings that would be in the range required to substantiate the price paid by Servier must be further put into doubt by the fact that in its manufacturing process Servier did not do any specific development based on Lupin's patent applications even four years after their acquisition.[2652]

(1965) In view of the foregoing, the Commission considers that at the time of concluding the settlement both Lupin and Servier could not reasonably value the transferred patent applications at EUR 40 million, except for assigning to those patent applications the value of shielding Servier's profits that would have been lost if Lupin's technology had led to a generic entry. This is consistent with the terminology Lupin itself employed: the payments were referred to as "*settlement monies*" and "*settlement sums*".[2653] Likewise, handwritten notes taken in the course of negotiation suggest that the payments were not necessarily linked to patent applications, as the following proposal to stagger the payments suggests: "*Heads - €10; Agreement - €10; October - € 20*".[2654]

(1966) Since Lupin's patent applications were transferred within the framework of the patent settlement agreement preventing Lupin from entering the market, any amount of the payment that cannot be reasonably derived from a pro-competitive use of the patent applications, such as a market entry for Lupin and an increase in productivity for Servier, must be regarded as a reverse payment, an inducement for Lupin to accept the restrictions flowing from the settlement agreement.

5.6.1.3.3.4 Payment as a significant inducement for Lupin

(1967) For the reasons already developed above (course of negotiations, content of the agreement including the deferral of acquisition, weak warranties, and unconditional payment), Lupin was in a position to understand that the transaction was at odds with a patent acquisition where the purchaser would have a genuine interest in exploiting the transferred technology.

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expiry date of the alpha patent. Lupin claimed in its economic annex that a longer repayment period of 25 years would result in a different result (Lupin's economic annex by Oxera, paragraph 3.18, ID8753, p. 24). However it cannot be assumed that Servier would be able to generate substantial savings after 2021 (even assuming 2023 in view of the arginine patent, this would not alter substantially the calculation). The alpha patent was already litigated at the time relevant for valuation of the patent applications at stake. Moreover, it is not realistic to assume that Servier would be able to profit from its monopoly after 2021. After the patent expiry, it is safe to assume that the incumbent is replaced with generic substitutes.

2649 Servier reported (see paragraph (952)) that Krka's technology led to the savings of EUR [30-40] per kilogram of API. This corresponds to a [1.5-2]% reduction in the production cost calculated from the API price of EUR 2,000 per kilogram which is assumed here for the purpose of comparison.

2650 See footnote 2659 and paragraph (1022), the USD-EUR conversion was applied at EUR 1 = USD 1.2556, i.e. the ECB exchange rate for 2006.

2651 See reference in paragraph (301).

2652 See paragraph (1055).

2653 See paragraph (1053).

2654 See paragraph (1034).

(1968) As already mentioned, according to Lupin itself, the sale of its patent applications to Servier was integrally linked to the settlement negotiations.[2655] The present subsection along with the subsequent assessment of quantum will in addition demonstrate that the payment received in the framework of the Lupin Settlement Agreement represented a significant inducement for Lupin to accept the restrictive terms of that agreement. The subsection will first examine whether the payment could also be explained as remuneration for costs incurred by Lupin, and second, whether the quantum of the payment was likely to represent a significant advantage over other competitive scenarios.

(1969) The below analysis will show that the net value transfer by far exceeded any "costs" for Lupin allegedly stemming from the settlement.

(1970) Lupin reported about two cost factors that can be associated with its previous efforts to enter the perindopril market, namely its litigation costs (GBP [310,000 - 570,000]) and its past external development costs (approximately EUR [350,000 - 750,000]).[2656] Even if these cost factors were to be considered legitimate and deductible cost factors (which is not the case[2657]), and if in turn the costs would need to be deducted from the value transfer previously established (EUR 40 million), the value transfer to Lupin would still be substantial.

(1971) Moreover, the development costs would not be entirely foregone due to Servier's acquisition of patent applications, as Lupin was granted a licence back in the Lupin Settlement Agreement and was thus able to continue to use the technology for its own production. Hence, Lupin's investments into the technology were still subject to amortisation by on-going and future sales of Lupin's perindopril products, and thus any additional income from their commercial use represented windfall profits for Lupin, rather than a break-even compensation. It needs to be considered that Lupin had the intention to continue its perindopril project.

(1972) Furthermore, with respect to the litigation costs it should also be noted that the Settlement Agreement explicitly stipulates that each of the parties were to bear its own litigation costs.

5.6.1.3.3.5 Assessment of quantum

(1973) It is central to the assessment of the Lupin Settlement Agreement that the amount of the net value transfer was very significant and induced Lupin to conclude the agreement. The quantum of the net value, and its significance to the parties, is assessed below.

(1974) Lupin received EUR 40 million from Servier and a royalty-free license. Lupin's strategy documents focus primarily on the two biggest markets for perindopril worldwide, France and the UK, and that Lupin was, at the time, not considering taking legal action in other Member States;[2658] however, should Lupin's entry have taken place, it would have had a broader geographical character with Lupin also being present on the EU markets through its licensed partners.[2659] According to Lupin's profit forecast from July 2006, Lupin planned to achieve a gross margin of

2655 See paragraph (1053).

2656 See paragraphs (1058) – (1060), at the following exchange rates: 1/2/2007 USD/EUR 1.3, GBP/EUR 0.75; average 2009 - 2011 INR/EUR 64.47.

2657 Servier received no commercial benefit from Lupin's sunk development costs, or litigation costs.

2658 See paragraphs (990), (992), (994) and (1020).

2659 See section 4.3.4.2.

USD [4.02 - 6.8] million (EUR [3.18 - 5.38] million) on its perindopril worldwide sales in the financial year 2007/08 and USD [3.45 - 7.03] million (EUR [2.77 - 5.65] million) in the financial year 2008/09. In the UK, Lupin was, shortly prior to the settlement, expecting to earn EUR [3.7 - 10.5] million over the first 3 years in the case of annulment of the '947 patent in the UK.[2660] [2661] The Commission notes that Lupin's profit forecast concerned the first two to three years of commercialization when the first generic entrant can usually benefit from the highest margins which are later competed away with subsequent generic entries. Therefore, the Commission considers that the sum of monies received from Servier is likely to considerably exceed the profits that Lupin could rationally expect from its independent entry on the market for perindopril during the aforementioned two to three years following the launch, while still having access to the transferred technology to which the payment allegedly related. The importance of the quantum of money to Lupin can be seen in the significant difference between the overall value and the expected/foregone profits. Instead of earning those gross profits by taking the risk of competing on the market, Lupin received them from the incumbent originator. This appears to be confirmed by the performance review of [employee name of Lupin]* who personally negotiated the agreement with Servier. The review drafted by [employee name and function with Lupin]*, states: *"[i]n Q3'07[cit] we decided to pursue a transaction with Servier to sell our IP. [Employee name of Lupin]* pursued Servier, presented the IP and Lupin's position and negotiated what turned out to be the largest deal for the company*". Lupin considered that the payment "*[w]ill make for this year being stellar also"*.[2662]

(1975) In turn, this payment was a way for Servier to reduce uncertainty in the market,[2663] avoiding the risk of Lupin possibly prevailing in patent litigation and/or launching generic perindopril and negatively affecting Servier's profits from perindopril. Undertakings should not be entitled to avoid the uncertainty and risks related to competition on the market by transferring money to prevent market entry.[2664]

(1976) Servier reported an EBIT profit of EUR [150 - 350] million from the sales of perindopril on its top thirteen EU markets in 2007.[2665] At least a significant part of

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2660 See paragraph (1022). The annex to the cover letter also shows an even more optimistic scenario of finding of non-infringement, although this was less likely as Lupin itself was aware its perindopril was in the alpha crystalline form. According to these projections, Lupin expected to achieve a gross margin of EUR [9.4 - 17.8] million over the first five years of its presence on the UK market. The underlying scenario assumed a lower API cost of USD [1,700 - 3,400] (compared to a higher cost of USD [2,800 - 5,500]) and the non-infringement situation, in which Lupin would be among relatively few generic entrants. The said projection as well as all other projections assumed diminishing profits over the time. The projections were not discounted for the value of money in time. If a modest, 5% discount was applied, Lupin's most optimist projection would yield EUR [8.9 - 16.9] million. If the projection period was extended to 14 years (until 2021. i.e. the alpha patent's expiry date) without further diminishing of profits after year five, the net present value would be EUR [13.5 - 25.1] million.

2661 Lupin's economic annex by Oxera builds scenarios based on an assumption of EUR 10 million (paragraph 2.30, ID8753, p. 17).

2662 See paragraph (1087).

2663 See, for example, Judgment in *T-Mobile Netherlands and others*, C-8/08, EU:C:2009:343, paragraph 35; Judgment in *Thyssen Stahl v Commission*, C-194/99 P, EU:C:2003:527, paragraph 81.

2664 Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraphs 33-34.

2665 Member States included for the purpose of this calculation are: Belgium, Greece, the Netherlands, the UK, the Czech Republic, Hungary, Poland, France, Ireland, Portugal, Germany, Italy and Romania. The calculation is based on the underlying data of section 6.4.5.3.

that profit would have been lost for Servier, if Lupin managed to enter the market with its generic perindopril. Moreover, and as already noted with respect to the settlements between Servier and other generic companies (Niche and Krka), the inclusion of the non-challenge and non-compete clauses referring explicitly to the '947 patent in the settlement agreement demonstrates that Servier concluded the agreement with Lupin with an intention to secure its market position for a multi-year period, possibly even until the '947 patent expiry in 2021. Therefore, the sum of money transferred to Lupin must be regarded as a small fraction of the total profits that Servier hoped to protect by entering into the settlement in question.

(1977) In view of the foregoing, the Commission considers that both Servier and Lupin were better off in agreeing the settlement than in an alternative scenario of generic entry and resulting competition.

5.6.1.3.3.6 Conclusion on the financial consideration

(1978) In the light of the above, it is concluded that the settlement agreement stipulating a payment of EUR 40 million comprised a reverse payment to Lupin. In view of the absence of evidence of Servier' commercial interest in the transferred Lupin technology, and the quantum of payment significantly exceeding Lupin's expected profits from competition, the Commission concludes that this reverse payment represented a significant inducement tantamount to a rent sharing arrangement between Servier and Lupin in return for the obligations limiting Lupin's ability and incentives to compete.

5.6.1.3.4 The parties' intentions

(1979) The intention of the parties can be an additional indication of the object of a given agreement. A description of respectively Lupin's and of Servier's intentions will be made in the following paragraphs.

5.6.1.3.4.1 Lupin's intentions

(1980) In the period leading to the settlement in January 2007, Lupin was at an advanced stage of perindopril development and was one of only two remaining companies with a potentially viable product which were seeking the annulment of the '947 patent in the courts of the Union (the other one being Apotex).

(1981) Already in its 2005/2006 strategy plan, Lupin anticipated that it would be in a position to enter the market in 2006/2007, and directly compete with Servier's branded perindopril.[2666] In November 2006, after having launched its legal action before the High Court, Lupin still envisaged possible entry in April 2007, but also considered steps to find an advantageous commercial arrangement with Servier and avoid competing on the merits. A strategy document from November 2006[2667] sets out, amongst others, an option to "*actively seek settlement with Servier*", including a threat to enter in Servier's home market, France. This appeared to be the prominent alternative to entry envisaged for April 2007 following the expected annulment of the '947 patent. In the competitive scenario of generic entry, Lupin expected to be rivalled by Apotex (and its partners), Krka (and its partners) and Servier's authorised generics (Teva, and another generic company). The same document contains an

[2666] See paragraph (993). In an internal communication between [employee name of Lupin]* and [employee name of Lupin]* of December 2005 perindopril was included among the four products representing Lupin's best product development opportunities.

[2667] See paragraphs (1019) - (1023).

insightful overview of the settlements Servier concluded earlier with Niche, Matrix, Teva and Krka, which further indicates that Lupin was seriously considering this option.

(1982) The above suggests that Lupin considered that generic entry could be less beneficial for itself and harmful for Servier, and that it was willing to reach an arrangement with Servier to prevent this.

(1983) The statement by [employee name and function with Lupin]* as cited in The Economic Times (an Indian newspaper) is fully consistent with the remainder of the Commission's conclusions concerning the Lupin Settlement Agreement: *"Although Servier's original patent on Perindopril has expired in most European countries, this move will allow the French company to prevent generic players from entering the market and continue to enjoy exclusivity"*.[2668] Although the authenticity of this statement was disputed by Lupin in the context of the present proceedings, the Commission considers that Lupin's arguments fail to deny its evidentiary value.

(1984) Separately, the evidence on the file shows that Lupin was confident in the strength of its position in the patent litigation against Servier concerning the invalidity of the '947 patent, but also concerning the non-infringement of Servier's process patents (see paragraphs (1891) - (1898)). Despite this confidence, it opted to abandon this litigation in return for the significant payment from Servier. This shows an intention to avoid competition on the market.

(1985) According to Lupin's *ex post* explanations, several considerations led it to believe that it would not benefit from the litigation anymore.[2669] Among those considerations, Lupin formulated that it seek to enter market as a first mover (see paragraph (1051)) but was concerned it might not obtain such status in view of production difficulties (see paragraph (1899)), and difficulties in finding a commercial partner (see paragraph (1886) – (1890)). Apotex might hence be in a position to "*free-ride*" on Lupin's litigation. Moreover, Lupin was concerned there was a risk of not recouping the "*high levels of expenditure on research and development and litigation*". However, Lupin fails to point to contemporaneous evidence showing that such a conclusion had been reached prior to settling. As far as Apotex is concerned, from an *ex ante* perspective, it could not be excluded that Servier would also settle with Apotex. Additionally, if Apotex remained, there would indeed be competition between Apotex and Lupin, but Lupin could still benefit from an early mover status, potentially also in other European countries than the UK.

(1986) Lupin's statement further stresses the role played by the financial incentive: "*Lupin factored in the various and diverse considerations it faced at the time and weighted the relative advantages and disadvantages of continuing to litigate or settling with Servier, concluding that it was in Lupin's best interests […] to settle with Servier*".[2670] The terms discussed in the course of the negotiations, including the payment of EUR 40 million, were instrumental in Lupin's decision to settle. This statement, Lupin's emphasis on the importance of recouping its investments and the

2668 See paragraph (1082).

2669 Lupin's reply to the Statement of Objections, paragraphs 26 - 32, ID8752, p. 13 - 14. Servier brought forward similar arguments (see Servier's reply to the Statement of Objections, paragraph 1206, ID10114, p. 392).

2670 Lupin's reply to the Statement of Objections, paragraph 30, ID8752, p. 14.

presence of a very significant payment in the settlement at hand undermine Lupin's claim that its intention might have been to settle regardless of financial incentive.

(1987) While Servier claims that "**the desire to secure a supply agreement with Servier*"[2671] played a part in Lupin's consideration of settling with Servier, this is not supported by the evidence mentioned nor by other elements from Lupin. In fact Lupin's strategy note from 14 November 2006 describes in rather negative terms Teva's deal: "*Servier has pulled back from allowing early entry since Krka has settled. I have learnt from within Teva that the terms are not very attractive, the transfer price and restriction on number of packs they can sell significantly reduces their competitiveness*".[2672] Nor is Servier's claim corroborated by Lupin's attitude in the negotiations of a potential supply agreement following the Lupin Settlement Agreement (see section 5.6.1.3.2.3).

(1988) In light of the above, it can be concluded that Lupin opted for a patent settlement in exchange for a substantial sum of money instead of continuing litigation which it considered it had chances to win, and pursuing the independent launch of its generic perindopril.

5.6.1.3.4.2 Servier's intentions

(1989) Turning to Servier's intentions, the following facts describing the contextual situation before the conclusion of the patent settlement are illustrative of Servier's limited belief in the strength of its remaining patent protection as well as the set of options that it had in mind shortly before the conclusion of the settlement.

(1990) The assessment of earlier agreements demonstrated that Servier was aware of a real concrete possibility that the '947 patent would be invalidated.

(1991) The fact that patent settlements were a part of Servier's anti-generic strategy clearly flows from Servier's internal document "*Coversyl: defense against generics*" (by [employee name of Servier]*, who also negotiated and signed the agreement for Servier). The document, dated 19 June 2006, just days after the conclusion of the Teva Settlement Agreement, explicitly points to the Niche and Matrix patent settlements under the meaningful heading "*Did it work?*" In addition, the document also points to a "partnership" with Teva. Thus, all the patent settlements concluded by Servier before the document was created were referred to in the presentation of actions and results in the context of Servier's anti-generic strategy.[2673] Servier argued that "**if settlements were effectively a quasi-systematic defense tool used by Servier against generics, Servier would have taken the initiative to contact Lupin in order to offer it a settlement*".[2674] First, the assessment of whether an agreement is restrictive pursuant to Article 101(1) of the Treaty does not depend on which of the contracting parties initiated the negotiations of the agreement as a whole, or of any specific terms thereof. Second, in any event, the parties gave contradictory statements as to who took the initiative. Then, were it established that Lupin contacted Servier, the knowledge Lupin had of Servier's pattern of settling could have led it to this move, without making Servier's pattern any less meaningful.

2671 Servier's reply to the Statement of Objections, paragraph 1198, ID10114, p. 390.

2672 See paragraph (1023).

2673 See, for example, paragraphs (886) and (1007).

2674 Servier's reply to the Statement of Objections, paragraph 1364, ID10114, p. 424.

(1992) Servier put forward in its reply to the Statement of Objections that facing several litigations on the same question was costly and that it naturally preferred an additional commercial partnership "**allowing it to optimise its sales of perindopril with a view to a generalisation of the market*".[2675] Servier further submits that it actively negotiated the supply agreement even though it was not achieved and blames some of the delay on Lupin.[2676] While there indeed were discussions between the parties concerning a potential supply agreement for the UK,[2677] those discussions took place after the conclusion of the Lupin Settlement Agreement when Lupin's ability and incentives to compete were already restricted. As for the interest of having another generic partner to maintain turnover, Servier had indeed, as it acknowledges, other partners. Servier claims that it was relying on partnerships "**to sell generic perindopril on the other generic markets*"[2678] other than France and Eastern European countries, and hence might need Lupin. It is noted that in the UK Servier had already concluded agreements with Teva[2679] and GUK. As for the other European countries other than France, the UK and the Eastern European countries, Lupin did not have commercial capacities on its own. It is therefore unclear how Servier could benefit from such a partnership. As has been demonstrated the Lupin Settlement Agreement did not aim at preparing for generic entry, but rather at postponing such entry and "**a likely drop, in the months/years to come, in Servier's turnover*".[2680]

(1993) Finally, Servier submitted that it knew the agreement could not impact the litigation with Apotex nor the EPO proceedings, and hence "**did not guarantee in any way the maintenance of Servier's position*".[2681] Such a lack of impact has not been established. First, it is not excluded that Servier could also settle with Apotex. Second, even if there were parallel proceedings, a specific challenging party may be in possession of evidence, carry out experiments, or develop arguments that could not be replicated by other, parallel, claimants. Then, the Lupin Settlement Agreement aimed at removing one potential competitor in the EU, one of the two "*hostile players*" remaining (with no certainty on Apotex' challenge). This agreement was a restriction of competition by object, which took place in the wider context of Servier's strategy to maintain its position, and in any event reduced the uncertainty for Servier, eliminating one of only two remaining actions for annulment of the

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2675 Servier's reply to the Statement of Objections, paragraphs 1206 - 1207 and 1366 - 1367, ID10114, p. 392 and 424. In its reply to the Letter of Facts, Servier mentioned the litigation with Lupin in a [non-EEA jurisdiction] regarding patent '947, as one of the costly litigations that would be terminated with the signature of the settlement agreement with Lupin (paragraph 662, ID10324, p. 179) (see also paragraph (1035)).

2676 Servier's reply to the Statement of Objections, paragraphs 1298 - 1306, ID10114, p. 409 - 410. For instance, "**it would appear that the agreement had, at the time, been delayed by difficulties met by Lupin regarding its artwork and its inability to supply Servier with the necessary maquettes*", relying on emails from August 2007 (ID0055, p. 136, and ID6756, p. 1). Conversely, an email from July 2007 indicates for example, delays on Servier's side ("*the process has not moved forward (despite numerous requests*", ID0503, p. 24).

2677 See section 4.3.4.9.1.

2678 Servier's reply to the Statement of Objections, paragraph 1345, ID10114, p. 419.

2679 Servier stated that Teva "**was a particularly well-connected company in the UK market*" with significant resources, experience and a good reputation. (Servier's reply to the Statement of Objections, paragraph 671, ID10114, p. 261 - 262). It is further claimed by Servier that Teva was covering the retail channel in the UK, while GUK was covering hospital sales.

2680 Servier's reply to the Statement of Objections, paragraph 1345, ID10114, p. 419.

2681 Servier's reply to the Statement of Objections, paragraph 1367, ID10114, p. 424.

'947 patent in the UK. According to the case law, it is unnecessary to analyse the effects of the agreement when the restriction is by object. The Commission nonetheless, for the sake of completeness, analysed such effects below, in section 5.6.2.

5.6.1.3.5 Conclusion - Lupin Settlement Agreement restricts competition "by its very nature"

(1994) Concerning the Lupin Settlement Agreement, the following assessment is made, in line with the general approach set out above (see paragraph (1154)):

- Lupin was at least a potential competitor of Servier.
- Lupin committed to limit its ability to compete through non-compete and non-challenge obligations.
- In the context of the same settlement agreement, Servier transferred EUR 40 million for three patent applications assigned by Lupin. The agreement, and the context in which it was concluded, demonstrate that this payment constituted a significant inducement for Lupin to accept the restrictive settlement terms and constrain its independent efforts towards a possible effective and legitimate market entry until up to 2021.

(1995) Furthermore, the restrictions went beyond the scope of the underlying litigation concerning the validity of the '947 patent and extended to a number of patents for which, concerning the actual Lupin product, there was no apparent, or alleged blocking patent position. Moreover, Lupin was precluded from selling any perindopril independently of Servier, as the non-compete obligation covered not only the various perindopril forms protected by Servier's patents, but also any other forms.[2682]

(1996) In the present case, the Commission's view based on the evidence described in this section is that the payment to a potential competitor of a significant amount of money is the central and essential consideration for the conclusion of the agreement, even if formally in consideration for an assignment of three patent applications. The economic context of this assignment establishes that the payment very significantly exceeded the expected or inherent value of the patent applications for the parties. Lupin confirmed that the assignment was an integral part of the settlement discussions – this allows the conclusion that the settlement was, amongst others, also depending on the reverse payment to Lupin.

(1997) If such a reverse payment were not deemed necessary to reach the same negotiating outcome, it is reasonable to assume that Servier would behave as any profit maximising economic operator and not pay out such a significant amount of cash. By the same token, Lupin would have thus either insisted on more favourable settlement terms allowing for earlier market entry or narrower restrictions, or would have continued litigation and could have become an actual competitor with its generic perindopril.

[2682] Lupin cannot argue that the settlement had no effect on the market. The fact that another operator, Apotex, pursued its litigation against Servier's '947 patent and ultimately prevailed, which in turn led to the generic entry of Apotex, Teva and another generic company in July 2007, post-dated the conclusion of the agreement, and is thus irrelevant for the purpose of establishing the infringement. Such facts may, however, be taken into account for determining the duration of the infringement.

(1998) Both parties to the settlement, Servier and Lupin, were better off in agreeing the settlement than in an alternative scenario of generic entry and resulting competition. The mutually beneficial arrangement was ultimately to the detriment of consumers, who as a consequence lost another potential generic supplier of perindopril and were thus faced with the prospect of continuing to pay higher prices than in the scenario of competitive entry. In economic terms, the Servier-Lupin settlement must be considered as a classic rent sharing agreement by which the interests of the counterparties are aligned.

(1999) Finally, at the time of conclusion of the settlement agreement, both parties' intentions were clear as evidenced by a number of facts assessed above in section 5.6.1.3.4. First, the generic company decided to forego the competitive commercial incentives in exchange for "*the largest deal for the company*", which, as the above analysis shows, exceeded what Lupin expected to earn from selling perindopril on the market.[2683] Second, Servier had by then pursued a pattern of patent settlements with generic competitors in the framework of its anti-generic strategy, while its own belief in the validity of the '947 patent was limited.

(2000) Given the above assessment of the agreement concluded between Servier and Lupin, the Lupin Settlement Agreement should be considered as a restriction of competition by object. The Commission refers to sections 5.1 (and in particular to paragraph (1112)) and 5.6.1 for its considerations on the appreciable degree to which the agreement in question restricted competition and to section 5.6.2.6 for its analysis of effect on trade between Member States. The analysis in those sections shows that for a restriction by object that may affect trade between Member States, the Commission does not have to prove an appreciable restriction of competition, but that in any case the Lupin Settlement Agreement did restrict competition to an appreciable degree.

5.6.2 Lupin Settlement Agreement is a reverse payment settlement which restricts competition by effect pursuant to Article 101(1) of the Treaty

(2001) The previous section concluded that the Lupin Settlement Agreement was a restriction of competition by object. Although in those circumstances, and according to the case law, it is unnecessary to analyse the effect of the agreement, the Commission will nonetheless, for the sake of completeness, show in the present section that the agreement was also likely to cause restrictive effects on competition between Servier and Lupin, as well as on competition between Servier and other generic companies, which would source perindopril from Lupin. For the general framework for assessment of restrictive effects, reference is made to section 5.1.7 above.

(2002) To determine if the Lupin Settlement Agreement was likely to entail restrictive effects on competition, the following elements need to be considered: (i) Servier's market position, (ii) whether Lupin was an actual or potential competitor of the originator company; (iii) content of agreement (significant reverse payment changes the incentives of the generic party to accept the exclusive clauses of the agreement), and (iv) competition that would have existed in the absence of the agreement. The latter point will focus on the competitive behaviour that Lupin would have been likely to engage in, absent the agreement, and on the other relevant sources of competition to Servier thereby demonstrating the importance of Lupin as a competitive threat to Servier.

[2683] See paragraph (1087).

(2003) For points (i) to (iii), the analysis in this section will rely on the preceding conclusions of the present Decision, which will be shortly summarised for ease of reference. Thus, the present section will focus in more detail on point (iv).

(2004) While the findings of this analysis are limited to the markets where Servier has been, in the preceding analysis, found to hold significant market power (i.e., France, the Netherlands, Poland, the UK), this does not imply that such or similar effects would not be likely for other territories covered by the assessment of the Lupin Settlement Agreement as a restriction by object.

(2005) The parties' main arguments in respect to the restriction by effect analysis of the Lupin Settlement Agreement can be summarized as follows, and will be addressed in the relevant sections:

- The Commission's framework for assessing effects is incorrect (see section 5.1.7);
- The parties were not potential competitors and Lupin was not able to launch (see section 5.6.1.2 and section 5.6.2.2);
- The non-challenge clause did not prevent the legal review of the '947 patent, since Apotex in the UK and several generic challengers before the EPO continued the litigation and were successful (see section 5.6.2.4);
- As for the non-compete clause, the Commission's counterfactual is wrong since it is not certain that Lupin would have continued with the litigation, prevailed in the litigation and launched. Lupin would not have been able to launch on time. Also, Lupin's activities towards launching generic perindopril were not discontinued (see section 5.6.2.4).

5.6.2.1 Servier's competitive position

(2006) In the framework of the dominance assessment under the standards of the Article 102 analysis, it was established that Servier held a dominant position on the final perindopril product market and the upstream perindopril API technology market (see sections 6.5 and 7.3). According to the Horizontal Guidelines, these findings are directly transposable to the assessment of market power under Article 101(1) of the Treaty.[2684]

(2007) In the context of the Lupin Settlement Agreement, Servier had an interest in protecting its significant market power, as there had been virtually no launch of generic perindopril and therefore its supra-competitive rents were intact. This also afforded the means to protect its significant market power: continued inflow of rents in the absence of price competition from generics provided the "deep pocket" to Servier from which it was able to finance rent sharing with generics in return for their withdrawal from competition. To illustrate the significant financial incentive from the originator company, one can compare the transfer of EUR 40 million pursuant to the Lupin Settlement Agreement to the EUR [3.7-10.5] million Lupin was expecting to earn over the first three years in the UK[2685] in the case of annulment

2684 Horizontal Guidelines, point 42.

2685 One of Lupin's main target markets (Lupin's document dated 14 November 2006 did not contain estimates for other markets but referred to possible pre-launch activities in France, see paragraph (1022)).

of the '947 patent.[2686] This comparison shows that the overall payment amount in all likelihood significantly exceeded profits Lupin would have made under any competitive scenario.

5.6.2.2 Lupin is a prominent potential competitor of Servier

(2008) Based on the facts in section 4.3.4 and the assessment in section 5.6.1.2, it was possible to conclude that Lupin was a potential competitor to Servier in the production and supply of perindopril on the EU markets at the time the settlement with Servier was concluded.

(2009) In fact, the efforts and investments made by Lupin show the intentions of the company to enter the EU perindopril market. More importantly, Lupin was able to enter within a short period of time, if it was not for the settlement agreement, with an already developed perindopril technology and an advanced development of a potentially viable product, which would have been marketed by Lupin and/or through distribution partners in the EU markets. Lupin also perceived that there were good chances that Servier would not prevail in the annulment proceedings and was actively clearing the way for its product through litigation.

(2010) Servier in its reply to the Statement of Objections[2687] claimed that it was not established that Lupin was a potential competitor to Servier for the EU markets, especially since Lupin had not applied for a marketing authorisation in Poland and the Netherlands. While the UK and France were indeed seen as a priority by Lupin, note is taken of Lupin's product development and regulatory file (section 5.6.1.2), of the wide geographic scope envisaged for launch,[2688] and of its active search for partners.

(2011) Basing itself on the duration of the infringement (see section 5.8.5), Servier further argued that "**Lupin was not in a position to enter the UK market before July 2008, therefore the agreement had no effect on this market"*.[2689] Similarly, "**Lupin was not*

2686 It must be noted that the initial period for which Lupin's profit projection was made is by far the most profitable period for generic operators, since later on the prices are often driven down to more competitive levels at which some generic companies may even need to exit the market to avoid generating losses.

2687 Servier's reply to the Statement of Objections, paragraphs 1393 - 1397, ID10114, p. 430 - 431.

2688 19 EU countries were mentioned in Lupin's documents and its correspondence with partners from 2006. See, for instance, paragraphs (993), (996) and (997). Servier in its reply to the Letter of Facts (paragraphs 692 - 693, ID10324, p. 187 - 188) pointed out that in the email of 13 December 2006 from [name of Lupin business partner]* to Lupin regarding the Letters of Access (see paragraph (997)), [name of Lupin business partner]* informed Lupin that because of the delay it had "*decided to cancel the proposed parallel DCP*". Servier interpreted this statement as a confirmation of the regulatory difficulties that Lupin was facing. However, [name of Lupin business partner]* had already decided on 30 November 2006 not to go ahead with the parallel national decentralised procedure and they apologised to Lupin for the change of plans ("*I really must apologise, our company have made a change to the regulatory strategy, we are no longer submitting a parallel national DCP […]. I am looking forward to receiving confirmation of your submission timelines*" (ID6755, p. 48-49). As Lupin indicated in its reply to the Letter of Facts, [employee name of Lupin]* replied on 1 December 2006 indicating he would "*let our regulatory guys know and revert ASAP*" (ID6755, p. 48). Therefore, the reply received from [name of Lupin business partner]* on 13 December 2006 does not seem consistent with the rest of the email trail; in any case it is clear from this reply that [name of Lupin business partner]* did not terminate its relationship with Lupin and was willing to move forward with Lupin's product (Servier's reply to the Letter of Facts, paragraphs 693 - 695, ID10324, p. 187 - 188) (see paragraphs (1099) - (1101)).

2689 Servier's reply to the Statement of Objections, paragraphs 1400 - 1419, ID10114, p. 431 - 435.

able to enter the French, Polish and Dutch markets throughout the period of the alleged infringement". This line of reasoning is flawed insofar as it is entirely based on contingencies posterior to the settlement, for which there was no certainty from an *ex ante* perspective. Lupin's incentives could also have been influenced in the wake of the agreement, for instance the decision to prioritize other prils.[2690]

5.6.2.3 Content of the Lupin Settlement Agreement

(2012) As indicated in the above section 5.6.1, Lupin committed not to enter with (any salt) perindopril in the whole of the EU but also to no longer challenge relevant Servier perindopril patents. The total payment from Servier to Lupin of EUR 40 million was claimed to be a consideration for Servier's purchase of Lupin's patent applications.

(2013) On this basis, it was concluded that, against significant reverse payment, Lupin thus contractually bound itself not to do what would have been possible for it to do under patent law (in addition to patent invalidity or non-infringement actions, to launch at risk, or to supply other companies), which disabled or hampered Lupin's ability to enter the market in a timely and viable manner and restricted competition by object. It also affected Lupin's incentives to restart the development of a possibly non-infringing form of perindopril.

5.6.2.4 Competition that would have existed in the absence of the Lupin Settlement Agreement and the importance of Lupin in view of the remaining competition

(2014) This section will examine the competition that would have existed in the absence of the restrictive provisions of the Lupin Settlement Agreement. The section will focus on the competitive behaviour that Lupin would have been likely to engage in, absent the agreement, and on the other relevant sources of competition to Servier thereby demonstrating the importance of Lupin as a competitive threat to Servier.

5.6.2.4.1 Lupin's likely competitive behaviour

(2015) In the absence of the restrictive provisions of the Lupin Settlement Agreement, Lupin which has been considered by Servier, after the settlements with Krka and Teva, as one of only two "hostile players" (together with Apotex),[2691] would have remained a competitive threat as a potential generic entrant with perindopril in the UK and in other markets. Lupin would have retained significantly more ability and incentives to compete and challenge Servier's market position if it had not settled or had settled on less restrictive terms in the absence of the reverse payment.

(2016) Firstly, absent the non-challenge obligation, Lupin would have remained one of only two remaining generic challengers to the validity of the '947 before the courts in the UK (Apotex being the other one).[2692] Lupin considered litigation a viable option even after the EPO decision of 27 July 2006 and after receiving the MHRA deficiency letter on 13 November 2006.[2693] Patent litigation in France was also contemplated.[2694] Considering the central role the '947 patent played for Servier's

2690 See paragraph (1899).

2691 See paragraph (1024).

2692 The two sets of legal actions were not identical but the claim made by the generic company is essentially the same in both cases. Servier brought an infringement action against Apotex, and Apotex counterclaimed that the '947 was invalid for lack of novelty and inventive step. The Lupin case was initiated by Lupin against Servier, and Lupin claimed that the '947 patent was invalid for similar reasons.

2693 See paragraph (1897).

2694 See paragraph (990).

continued product exclusivity, this threat was crucial for Servier. Such threat would normally only be maintained under the hypothesis the parties did not settle.

(2017) Secondly, in the absence of the non-compete obligation, Lupin would have remained a potential competitor due to its advanced development of perindopril, either as a direct supplier of perindopril API and/or formulations or through distribution partners.[2695] It is recalled that Lupin had considered aggressive competitive strategies, including launching perindopril at risk.[2696] Absent the agreement, Lupin would have retained the ability and incentives to compete and pursue commercial strategies independently of Servier, taking into account the patent situation.

(2018) Thirdly, absent the non-compete and non-challenge obligations going beyond the scope of the patent-in-suit, i.e. the '947 patent, Lupin would have retained the incentive to potentially invest into development (or sourcing) of patent-free perindopril formulations (of either other forms of erbumine or another salt of perindopril), as an alternative to challenging the validity of the '947 patent. This is not a merely hypothetical scenario as Lupin had, shortly before the conclusion of the settlement agreement, considered including a second source of API in its regulatory file to make Lupin's "*offering more attractive*".[2697] Although two to three years behind Sandoz' development, there were other projects to develop non-infringing forms of perindopril where generic partners were sought and which could have potentially allowed for a viable entry in case the '947 patent were ultimately upheld.[2698] Besides the impossibility to develop a patent-free product, Lupin could not, in view of the scope of the restrictions, contest the validity of other perindopril patents besides the '947 patent.[2699]

(2019) Fourthly, in the absence of the non-compete obligation, Lupin would have retained the freedom to sell or license out the rights to its three patent applications relating to perindopril to third parties.

(2020) In the absence of the above obligations (save for the non-challenge obligation) the competitive threat from Lupin would normally be maintained irrespective of whether the parties would have not settle or would have settled on less restrictive terms, notably allowing earlier generic entry. Even if Lupin's entry at risk or continued patent challenge absent the agreement could potentially fail, there was nonetheless a significant enough likelihood that Lupin's course of actions would be successful so that prospects for actual competition would have been better in the absence of the agreement.

(2021) During the investigation, both Servier and Lupin suggested that the settlement had no effect on the market, as Apotex pursued its litigation against Servier's '947 patent in the UK and ultimately prevailed, which in turn led to the generic entry of Apotex, Teva, and another generic company in July 2007. Lupin claims it was lagging behind Apotex and had no interest to remove the '947 patent with *erga omnes* effect *("Lupin felt that the arguments regarding the validity of Servier's patents were more than adequately covered by Apotex in the UK and the other parties before the EPO. These*

2695 See paragraphs (1899) and (1089).
2696 See paragraph (1898).
2697 See paragraph (1018).
2698 See section 7.3.3.1.3.
2699 See paragraph (1912).

factors made continuing with the proceedings an unattractive proposition for Lupin").[2700]

(2022) Firstly, it is obvious that this claim only concerns the UK, where effective generic entry indeed came at an earlier point than in other Member States, while the restrictions of the Lupin Settlement Agreement covered the entire EU. In France, the Netherlands and Poland, amongst others, Lupin could have remained amongst the most important generic challengers to Servier, either through patent invalidation actions (explicitly contemplated for France),[2701] or launches at risk. [2702] For example, no injunction was granted in the Netherlands against Katwijk/Apotex for infringement of the '947 patent in proceedings initiated only months after the UK revocation;[2703] and in Poland, the national equivalent of the '947 patent had not been granted at the time. Lupin could not only pose a direct threat in the other Member States, but also an indirect one, as a supplier of perindopril formulations, API and/or technology to other generics which could follow a similar course of action. This would be the case even taking into account the actual timing of regulatory approval, which had been delayed in comparison to Lupin's contemporaneous expectations from the period when the settlement agreement was discussed and concluded.

(2023) Secondly, the parties' claim that there were no actual or potential effects in the UK market enjoys the benefit of hindsight, and relies on the actual course of events posterior to the settlement which was however far from certain at the time of the settlement. It relies on the fact that Apotex pursued litigation until final judgment, and prevailed in that litigation. However, at the time of the settlement, neither Servier nor Lupin had the certainty that this would be the case. On the contrary, Lupin was well aware of the fact that Servier was systematically entering into settlement agreements,[2704] an aspect which appears to have also led Lupin to consider settling as one of the commercial scenarios. Therefore, it was in a position to understand that also Apotex litigation with Servier could be settled.[2705] Moreover, it appears that Servier has attempted to neutralise Apotex' generic challenge through a combination of proceedings in Canada and an attempt to discontinue (rather than settle) the UK litigation.[2706] Therefore, there was uncertainty not only about the

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2700 See paragraph (1050).

2701 See paragraph (1893).

2702 See paragraph (1898).

2703 See Table 5 (paragraph (156)).

2704 See, for example, paragraph (1023).

2705 For example, Teva was hoping such a settlement between Servier and Apotex would materialise, as it could "*keep other generics off the market in the UK*" allowing Teva to maintain the "present arrangement" with Servier, i.e. monthly payment of Liquidated Damages. See paragraph (773).

2706 See paragraphs (179), (191) and (2720). Servier in its reply to the Statement of Objections (paragraph 1236, ID10114, p. 397) "**firmly denies*" that there were attempts to settle the UK litigation. "**It is wrong to claim that Servier tried to reach a settlement with Apotex in the UK litigation. No settlement was discussed with Apotex. […] The only contacts Servier had with Apotex for a possible settlement and to which [employee name of Servier]* refers, occurred in June 2008 as part of the proceedings in Canada*". However, in its reply to the Commission's questions during the inspections (ID3442 p. 6), [employee name of Servier]* refers to "**an indication that perhaps Apotex could consider a settlement. But there were no negotiations. [...] We were absolutely convinced of our intellectual property right we still are, the British judge held differently*". Later on, Servier envisaged discontinuance rather than settlement because, according to [employee name of Servier]* "**[…] we [Servier] anticipate a decision unfavourable to us in the context of proceedings in the UK*" (ID0102, p. 266). In any case it is reminded that Lupin had knowledge of Servier's pattern to settle and that there was no certainty that Apotex would see the litigation to its end.

outcome of the proceedings, also as to the question whether proceedings would at all lead to a judgment on the merits. Hence, although the latter course of events by a third party, Apotex, might have avoided anticompetitive effects from the Lupin Settlement Agreement to actually materialise in the UK, this does not mean that such effects were not likely at the time of the conclusion of the settlement agreement.[2707] On the contrary, there was appreciable likelihood that Servier could further delay generic entry.

(2024) More broadly, Servier claimed in its reply to the Statement of Objections that "**the Commission's theory is based on the assumption that the litigation would have resulted in an invalidation of the patent"*.[2708] Further to that, had the '947 patent been validated, Lupin would not have launched and the validation would not be favourable to other third parties *"*since it would have confirmed the validity of the patent erga omnes"*.[2709] Lupin similarly argued that "*the Commission's effects analysis is based on the incorrect and unsupported assumption that in the counterfactual Lupin would have: continued with the '947 litigation; prevailed in the '947 litigation; and entered the perindopril market*".[2710] The Commission's assessment does not rely on the certainty of invalidation, but on the existence of a genuine patent dispute and the real concrete possibility that Lupin would actually have entered absent the agreement. Servier aimed at reducing uncertainty in the market,[2711] avoiding the risk of Lupin possibly prevailing in patent litigation and negatively affecting Servier's profits from perindopril.

(2025) Turning to the non-compete restriction, Lupin further argued that there could be no effect since "*Lupin could not, as a matter of irrefutable fact, have entered […] before it was lawfully able to do so*",[2712] notably in the UK where Lupin was not able to enter until July 2008 or more likely only in 2009. However, according to the terms of the Lupin Settlement Agreement, Lupin could have been obliged to stay out of the market at least until 2021. Thus, in the absence of intervention from other generics, Lupin could have been effectively barred from the EU markets for at least 12 years by virtue of the agreement. Lupin's statement relies on an *ex post* analysis which does not adequately reflect what was at stake at the time of the conclusion of the agreement. In any event, even the *ex post* argument only holds true for the UK, while Lupin's product could have still been launched amongst early entrants in other countries. Lupin further claimed that it could not have entered any EEA market prior to the EPO Technical Board of Appeal's revocation on 6 May 2009.[2713] However, it is possible that Lupin would, either directly or through its commercial partners, launch litigation in France and/or other markets, or launch at risk where there was a lesser risk of injunction. Further to its obtaining of a marketing authorisation in 2008, a launch by Lupin in one or more countries other than the UK would therefore still be possible before the revocation of the '947 patent by the EPO BoA.

2707 The General Court took a similar approach under Article 102 of the Treaty in the Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraphs 360 and 605.

2708 Servier's reply to the Statement of Objections, paragraph 1241, ID10114, p. 398.

2709 Servier's reply to the Statement of Objections, paragraphs 1241 and 1271, ID10114, p. 398 and 404.

2710 Lupin's reply to the Statement of Objections, paragraph 366, ID8752, p. 90.

2711 See, for example, Judgment in *T-Mobile Netherlands and others*, C-8/08, EU:C:2009:343, paragraph 35; Judgment in *Thyssen Stahl v Commission*, C-194/99 P, EU:C:2003:527, paragraph 81.

2712 Lupin's reply to the Statement of Objections, paragraph 368, ID8752, p. 90.

2713 Lupin's reply to the Statement of Objections, paragraphs 400 – 401, ID8752, p. 96.

(2026) In its economic annex,[2714] Lupin sets out three counterfactual scenarios: (i) "*Lupin would not have supplied perindopril in the counterfactual*" due to its lack of marketing authorisation, (ii) "*[t]here are plausible scenarios where Lupin would not have had an incentive to litigate even without having signed the Agreement*" due to a new costs / expected benefits balance,[2715] and (iii) "*[t]here are plausible scenarios where Apotex may not have litigated if Lupin had continued its litigation*" hence further delaying generic entry.

(2027) As for (i), reference is made to section 5.6.1.2 (Product development and regulatory position).

(2028) As for (ii), it is correct to expect that the litigant continues the litigation only if the expected benefits of doing so are higher than the expected costs of dropping the case and agreeing with the counterparty's position. The strategy document (see paragraph (1020)) did mention the possibility of Lupin withdrawing litigation. However, this possibility was considered much less likely given that the strategy document omits to give this option any further consideration, and that the litigation was launched by Lupin only a month earlier. There is no other contemporaneous document showing that Lupin considered pulling out of litigation as a serious option. In any event, the counterfactual analysis of the Commission established that, even in the absence of litigation, Lupin would be still free, and have the incentive to develop, or source, non-infringing forms of perindopril and thus continue to compete with Servier.

(2029) As for (iii), Lupin claims that "*if Lupin did not conclude the Agreement, Apotex may not have had strong incentives to continue the litigation owing to this coordination problem*", i.e. to avoid occurring the costs and still reap the benefits.[2716] Hence "*there is a plausible scenario in which the Lupin Settlement Agreement may have led to earlier generic entry into the market for perindopril*". As set out in the general section and in following of the *AstraZeneca* judgment (see paragraph (1220)), Lupin cannot rely on third party's behaviour which was yet unknown at the time of the investigated practice. The scenario is based on highly hypothetical speculations as to Apotex's behaviour. The past record of settlements between Servier and generic contenders actually reinforces the idea that there could be no certainty as to another challenger litigating until the final resolution of the case.

(2030) Overall, the presented scenarios appear as speculations that find little support in the case facts. Until the Lupin Settlement Agreement, Lupin actively pursued the market entry path.

(2031) The parties also claimed that Lupin was not prevented from continuing with its preparation for perindopril launch and actually did so.[2717] However, Lupin had placed itself in the hands of Servier for effective launch (see section 5.6.1.2.2.).

(2032) In the reply to the Statement of Objections, Lupin tries to show that the Lupin Settlement Agreement had no actual effect on competition;[2718] however, the Commission does not make any inferences that Lupin would be an actual competitor

2714 Lupin's economic annex by Oxera, paragraph 2.5, ID8753, p. 10.

2715 A similar argument was formulated by Servier (Servier's reply to the Statement of Objections, paragraph 1422, ID10114, p. 436).

2716 Lupin's economic annex by Oxera, paragraphs 2.35 – 2.45, ID8753, p. 18 - 21.

2717 See, for example, Servier's reply to the Statement of Objections, paragraph 1409, ID10114, p. 365.

2718 Lupin's reply to the Statement of Objections, paragraphs 397 – 402, ID8752, p. 96 – 97.

absent the agreement. The counterfactual is that Lupin would remain a potential competitor to Servier.

(2033) Therefore, in the absence of the restrictions in the agreement, Lupin would have remained a prominent potential competitor to Servier through its challenge to patent validity and/or its advanced product development, and its perindopril technology.

5.6.2.4.2 Other relevant sources of competition

(2034) Given the removal of Lupin as a potential source of competition to Servier, the subsisting market structure at the time of the conclusion of the agreement will be examined, in particular by identifying other relevant sources of competition and whether they could be perceived as capable of sufficiently constraining Servier to offset the effects of the agreement. The analysis will focus on generic competition which was by far the most important source of constraint on Servier's prices and volumes for perindopril. The analysis relies on the presentation of the competitive landscape made in section 5.1.7.

(2035) There was no generic perindopril on the market at the time the agreement was concluded, and there was no effective generic entry afterwards until May 2009, with only few exceptions, such as the UK (annulment in July 2007), and the Netherlands (entry at risk in December 2007, followed by patent annulment in June 2008).

(2036) In the context identified in section 5.1.7, an internal contemporaneous document providing an update as of October 2006 on Lupin's main products and projects observes in relation to perindopril that a few companies had developed generic versions but either had settled or were in a legal battle with Servier. It is mentioned that some companies had developed novel polymorphs but were late in developing a formulation. In view of the difficulties, Lupin even considered adding a second API source in order to have a more attractive product to offer to potential customers.[2719]

(2037) From the first group, after reverse payment patent settlements with Teva and Krka, the only remaining patent challengers in the UK (where all litigations/disputes directly leading to the investigated settlements took place) were Lupin and Apotex. Teva was only a potential challenger in other Member States not covered by the Teva Settlement Agreement.[2720] Servier's anti-generic strategy document identified the main sources of competition Servier was facing in June 2006. Apart from Teva and Krka, which were removed as a threat through the settlements,[2721] Servier only mentioned Glenmark, Apotex and [name of Lupin business partner]* (which was in fact sourcing its API from Lupin). Glenmark's development was less advanced at the time and was fraught by possible infringement of Servier's process patents. Accordingly, Glenmark's attitude was a passive one, as it did not challenge the '947 before national courts, in contrast to Apotex and Lupin, and was thus a less direct threat to Servier.

(2038) From the second group, only Sandoz and Cipla remained. Cipla's project, while advanced, appeared to possibly infringe Servier's patents, and as no legal action was started by the company, the same reasoning applies as for Glenmark, and Cipla needs not to be regarded as a direct threat to Servier.

2719 See paragraph (1018).

2720 See section 4.1.2.4.2.2.

2721 Merck/GUK, also mentioned in the report, did not have an advanced perindopril project and also concluded a distribution agreement with Servier. See section 4.1.2.5.1.

(2039) As mentioned in section 5.1.7, this assessment of the competitive landscape coincides with the one by Lupin in its strategy document "*Perindopril UK competitive scenario*" dated 14 November 2006.[2722] Based on the marketing authorisation status, Lupin expected that Lupin (including [name of Lupin business partner]* with a Lupin product), Apotex (including Sandoz with an Apotex product) and Krka would be ready to enter with an independent generic product broadly within a year. Lupin also briefly mentioned Glenmark and Ranbaxy without further elaboration.

(2040) The above strongly suggests that, from the perspective of both Lupin's and Servier's perception of the competitive structure prior to the conclusion of the agreement, as well as of the Commission's market investigation, Apotex appeared to be the most important competitive threat to Servier in addition to Lupin.

(2041) In addition to Apotex' invalidation action, Sandoz' advanced development of non-infringing perindopril was another serious threat to its market position, although not as imminent. This concurs with the assessment in Servier's documents from December 2006 that the only remaining hostile players were Apotex and Lupin.

(2042) To conclude, apart from Lupin, and following the patent settlement agreements between Servier and Niche/Unichem, Matrix, Krka and Teva, there were only two other direct generic threats to Servier with advanced perindopril development, either actively contesting the validity of the '947 patent (Apotex), or with non-infringing forms of perindopril (Sandoz). Hence, where there has been no actual generic entry, and there is only a very limited number of potential competitors with prospects of a viable launch in view of the persisting barriers to entry (in particular patent and regulatory compliance), the removal of a single competitor significantly reduces the likelihood of a timely and effective generic entry (and therefore increases the probability generic entry will be delayed to the detriment of consumers).

(2043) In addition, one needs to recall Servier's expected/prospective actions to confront generic entry, which posed an additional source of uncertainty as regards the likely behaviour of the remaining potential competitors.

(2044) Thus, the Lupin Settlement Agreement was part of a consistent series of "amicable" solutions between, on the one side, Servier, and on the other, Servier's close generic rivals, whereby agreements involving a significant financial transfer to generic operators (either reverse payment patent settlements or acquisitions of API technology) or another inducement at the same time removed the latter from competing with Servier. Lupin was aware of the existence of these settlement agreements.[2723] Given Servier's overall defensive strategy against generics, the market generally suspected that Servier would try to buy out all possible sources of competition, and that Servier had already concluded a patent settlement agreement with Niche/Unichem, Matrix, Teva and Krka, and there was a strong possibility that Servier would attempt to reach similar agreements with Apotex and/or Sandoz.

(2045) The Commission infers from Servier's contemporaneous documents[2724] that Servier at least considered the settlement option in the Apotex litigation. However, following the analysis of Apotex' products, Servier considered that Apotex had a strong case in

[2722] See paragraphs (1020) - (1023).
[2723] See paragraph (1023).
[2724] See paragraphs (179) and (191).

the UK. As a consequence, Servier envisaged discontinuing, rather than settling, the litigation. Servier requested its lawyers to analyse the consequences of the discontinuance option. Apotex was additionally constrained by a parallel action by Servier for infringement of the perindopril compound patent in Canada, where Apotex was producing perindopril products for the EU markets in 2006. Servier eventually prevailed in the Canadian litigation in July 2008 (but only after Apotex had succeeded in obtaining the annulment of the '947 patent in the UK and had launched there, and after Apotex had transferred its production to India).[2725]

(2046) As regards Sandoz, in the period mid-2007 to mid-2008, Servier was in intense discussions to acquire its entire perindopril technology for a total of USD [40–55]* million and to turn Sandoz into a distributor of Servier. Sandoz eventually abandoned the negotiations with Servier and launched its perindopril but only in May 2008, after the '947 patent had been annulled and a number of generics, including Apotex and Teva, already entered certain markets.[2726]

(2047) Thus, even for the already very limited competition from the two remaining sources identified above, there was, at the time of the Lupin Settlement Agreements, a strong possibility that Servier would try to reach an agreement with them or otherwise remove them from competition.

5.6.2.5 Conclusion – the Lupin Settlement Agreement was likely to entail restrictive effects for competition

(2048) The above analysis established that Servier held significant market power in the market for perindopril formulations and the upstream market for perindopril API technology, in which also Lupin was active.[2727] As the incumbent facing no price related constraints, and thus charging supra-competitive prices, Servier had the commercial interest and the financial means to offer significant inducements for close potential competitors to withdraw from competition. Thus, by inducing Lupin with a payment of EUR 40 million for the terms of the Lupin Settlement Agreement (as compared to the expected aggregate three years profits of EUR [3.7 - 10.5] million for the UK, Lupin's major target market), Servier effectively removed Lupin from competition on perindopril. Lupin was no longer able to pursue its patent challenges against Servier as a key avenue for a viable generic entry, and was also not able to enter "at risk".

(2049) The Lupin Settlement Agreement thus reduced competition between the parties to the agreement, Servier and Lupin. Lupin could no longer compete with Servier the way it would have in the absence of the agreement – neither with its existing development nor by engaging in new development (as all forms/salts of perindopril were covered by the non-compete clause), or as a source of independent perindopril technology. As Lupin was also an actual or potential supplier of perindopril products to other generic companies, the agreement also affected competition between Servier and these additional potential competitors to Servier.

(2050) In the period of the conclusion of the Lupin Settlement Agreement, its likely effects on competition were appreciable, as Lupin was an important source of competition to Servier. It was likely ready to launch perindopril during the period coinciding with

[2725] While filed for in 1981, Servier's perindopril compound patent would, due to specificities of the Canadian patent system, run until 2018. See paragraphs (2717) - (2721).

[2726] See section 4.2.2.8.4.

[2727] See paragraph (991). In 2005, Lupin was already active in the perindopril API market.

that covered by the Lupin Settlement Agreement and also supply other generic operators. Equally importantly, it was actively clearing the way for its product by litigating against the '947 patent (for which it was advised that it seemed to have a strong case). There were only two other potential competitors posing a comparable competitive threat (advanced product development and actively addressing patent situation by invalidity actions or non-infringing product), and therefore the likelihood of generic delay increased appreciably. To complement this, there was considerable uncertainty as to whether the remaining sources would subsequently also reach an agreement with, or be otherwise blocked by Servier. The removal of Lupin thus likely affected the overall competitive structure concerning perindopril.

(2051) The assessment of the likelihood of restrictive effects corroborates the above findings since it elucidates the factual circumstances in which Servier was willing to share its rents with a competitor in exchange for the competitor's commitment to withdraw from competition. If, unlike in the present circumstances, there were a host of other competitors representing a similar competitive challenge to Servier (advanced product and a patent challenge) as Lupin in the relevant period, it is doubtful whether Servier, as a rational economic operator, would conclude a settlement agreement with a significant payment to the generic party.

(2052) On the basis of the foregoing considerations, the Commission finds that the Lupin Agreement was such as appreciably to restrict potential competition among Servier and the generic companies and barred "*real concrete possibilities*" for Servier and Lupin to compete between each other or "*for a new competitor to penetrate the relevant market and compete with the undertakings already established*".[2728] By discontinuing Lupin's patent challenge, removing the possibility of launch at risk with Lupin's product or transfer of Lupin's technology to other generic companies, the Lupin Settlement Agreement appreciably increased the likelihood that Servier's significant market power would remain uncontested for a longer period of time and that consumers would forego a significant reduction of prices that would ensue from timely and effective generic entry.

5.6.2.6 Effects on trade within the meaning of Article 101 of the Treaty

(2053) Article 101(1) of the Treaty only applies to agreements and practices "*which may affect trade between Member States*".

(2054) This criterion has three basic elements.[2729] First, "*trade between Member States*" must be affected. The concept of trade covers all forms of economic activity including establishment. According to settled case law,[2730] an agreement that has an impact on the competitive structure in more than one Member State is by its very nature capable of affecting trade between Member States. Trade between Member States may be affected also in cases where the relevant market is national.[2731]

2728 Joined Judgments of 15 September 1998, *European Night Services and Others v Commission*, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198,paragraph 137.

2729 *Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81 - 96, point 18.

2730 Joined Judgment of 8 October 1996, *Compagnie maritime belge transports and Others v Commission*, T-24/93, T-25/93, T-26/93 and T-28/93, ECR, EU:T:1996:139, paragraph 203; Joined Judgment in *Commercial Solvents v Commission*, C-7/73 and C-6/73, EU:C:1974:18, paragraph 23.

2731 *Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ C 101, 27.4.2004, p. 81 - 96, points 19 - 22.

(2055) Second, it is sufficient that the practice "*may affect trade*", i.e. that it is sufficiently probable that the practices are capable, based on an objective assessment (as well as subjective elements, if any), of having an effect on the patterns of trade, or on the competitive structure.

(2056) Third, the effect on trade of the agreement must be appreciable. This element requires that the effect on trade between Member States must not be insignificant and it is assessed primarily with reference to the position of the undertaking(s) on the market for the products concerned.

(2057) By discontinuing Lupin's activities to viably enter the market independently of the incumbent, Servier, either on its own or through a cooperation partner, the economic activities in which such undertakings were engaging in several Member States were affected. The restriction of Lupin's right to commercialise, directly or indirectly, its generic perindopril, disrupted the market structure and also implied a ban on intra-community trade. The example of the significant price decrease following the annulment of the '947 patent in the UK illustrates the actual and potential effect on the competitive structure in the Member States.[2732]

(2058) By removing Lupin as a potential competitor to Servier,[2733] the Lupin Settlement Agreement, actually or at least potentially affected trade between the Member States. In view of the magnitude of perindopril sales in the Member States concerned (see paragraph (2129)) the actual or potential impact on trade can be said to be appreciable.

5.6.3 Conclusion – the Lupin Settlement Agreement restricts competition within the meaning of Article 101(1) of the Treaty

(2059) The above analysis has demonstrated that the Lupin Settlement Agreement constituted a patent settlement agreement between Servier and Lupin with reverse payment to the latter company, which had as its object to restrict competition by removing Lupin as one of the closest potential competitors approaching product launch at the time of settlement. Lupin was prevented to continue efforts for a viable and timely generic entry, either on its own or as a supplier of perindopril formulations, API or technology to other generic companies. Lupin thus discontinued its competitive challenge to Servier's market position, and in return received a reverse payment, which effectively amounts to rent sharing. The Lupin Settlement Agreement thus constitutes a restriction by object in terms of Article 101(1) of the Treaty.

(2060) At the same time, the Lupin Settlement Agreement also included restrictions beyond the scope of the patent further reinforcing the restriction of competition by object pursuant to Article 101 (1) of the Treaty.

(2061) In addition, it has also been shown that, given the prevailing market conditions at the time of the settlement, and considering its content, the Lupin Settlement Agreement was also capable or likely to entail restrictive effects on competition pursuant to Article 101(1) of the Treaty.

2732 See section 6.5.1.2.6.

2733 Lupin was able to obtain marketing authorisations in, for example, France and the UK one and a half, and two and a half years, respectively (ID1039, p. 12 and 15).

5.7 Application of Article 101(3) of the Treaty

(2062) In case where a restriction of Article 101(1) of the Treaty is found, *"Article [101(3)] of the Treaty sets out an exception rule which provides a defence to undertakings against a finding of infringement […]"*.[2734] Article 1(2) of Regulation 1/2003 provides that agreements caught by Article 101(1) of the Treaty which satisfy the conditions of Article 101(3) of the Treaty shall not be prohibited, no prior decision to that effect being required. Guidelines on the application of Article 81(3) of the Treaty explain as follows:[2735]

"The application of the exception rule of Article 81(3) is subject to four cumulative conditions, two positive and two negative:

(a) The agreement must contribute to improving the production or distribution of goods or contribute to promoting technical or economic progress,

(b) Consumers must receive a fair share of the resulting benefits,

(c) The restrictions must be indispensable to the attainment of these objectives, and finally

(d) The agreement must not afford the parties the possibility of eliminating competition in respect of a substantial part of the products in question.

(2063) When these four conditions are fulfilled the agreement enhances competition within the relevant market, because it leads the undertakings concerned to offer cheaper or better products to consumers, compensating the latter for the adverse effects of the restrictions of competition".

(2064) Pursuant to Article 2 of Regulation 1/2003, *"[t]he undertaking […] claiming the benefit of Article [101(3) of the Treaty] shall bear the burden of proving that the conditions of that paragraph are fulfilled"*.[2736]

(2065) Whether an agreement constitutes a restriction by object or by effect does not prejudge the possibility for it to be exempted under Article 101(3) TFEU. In the *Matra* case, the Court of First Instance held that "*in principle, no anti-competitive practice can exist which, whatever the extent of its effects on a given market, cannot be exempted, provided that all the conditions laid down in Article [101(3)] are satisfied […]*".[2737] However, severe restrictions of competition such as price fixing or limiting, controlling and sharing markets are unlikely to fulfil the conditions of Article 101(3) of the Treaty, because, as the Commission has explained in its Guidelines on the application of Article 81(3) of the Treaty (now Article 101(3) of the Treaty), usually they "*neither create objective economic benefits nor do they benefit the consumer*".[2738] Instead, they may lead to "*transfers [of] value from consumers to producers […] without producing any countervailing value to*

2734 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 1.

2735 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 34 (note that the order is different in Article 101(3) of the Treaty).

2736 See also *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 11.

2737 Judgment of 15 July 1994, *Matra Hachette v Commission*, T-17/93, ECR, EU:T:1994:89, paragraph 85.

2738 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 46.

consumers…."[2739] Whether the conditions of Article 101(3) of the Treaty are met requires a specific analysis for each continuing agreement/infringement of Article 101(1) of the Treaty.

(2066) Guidelines on the application of Article 81(3) clarifies that claims need to be substantiated to allow the verification of the following elements:[2740]

- the nature of claimed efficiencies;
- the causal link between agreement and claimed efficiencies;
- the likelihood and magnitude of each efficiency;
- how and when efficiency would be achieved.

(2067) In the case of claimed cost efficiencies, a party must as accurately as reasonably possible calculate or estimate the value of the claimed efficiency gain and describe in detail how the amount has been computed. A party must also describe the method by which the efficiency gain has been achieved. Data submitted must be verifiable.[2741]

(2068) In line with the *GlaxoSmithKline* case, the Commission took into account the legal and economic context, such as that characteristic of the pharmaceutical sector. Here the Commission considered the legal and economic aspects of the pharmaceutical sector insofar as they affect generic entry. The Commission carefully examined, "*as specifically as possible, in the context of a prospective analysis, whether, in the particular circumstances of the case and in the light of the evidence submitted to it, it seemed more likely that the advantages described by [the parties] would be achieved or, on the contrary, that they would not*".[2742]

(2069) The Commission has identified[2743] the following claims why the investigated agreements should be exempted under Article 101(3) Treaty:

(a) an alleged efficiency gain from avoided litigation cost;[2744]

(b) an alleged efficiency gain from improving Servier's perindopril production processes by acquiring technology from generic companies;[2745]

2739 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 46.

2740 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 51.

2741 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 56.

2742 Judgment of 27 September 2006, *GlaxoSmithKline Services v Commission*, T-168/01, ECR, EU:T:2006:265, paragraph 301.

2743 In their replies to the Statement of Objections, explicit efficiency claims were raised by Teva, Niche and Krka. The replies of Matrix and Lupin did not relate to the application of Article 101(3). Servier refused to raise efficiency claims, claiming that "**Servier considers that the agreements in question do not infringe Article 101 (1)* of the Treaty, *so that it is not necessary to examine in detail each of the conditions of Article 101 (3)* of the Treaty*"*. (Servier's reply to the Statement of Objections, paragraph 153, ID10114, p. 106). The Commission nonetheless identified certain efficiency claims, and included them in the list. Even if it did not submit any formal claim based on Article 101(3) of the Treaty, Servier argues that the patent settlement agreements have pro-competitive effects and finds support in an economic report entitled "*The consumer welfare effects of value transfer settlements*" (reply to the Statement of Objections, Annex 00-01B, ID9054). This report is discussed and rebutted above in paragraphs (1202)-(1206).

2744 For example, Servier's reply to the Statement of Objections, paragraph 446, ID10114, p. 198. Niche's reply to the Statement of Objections, ID8524, p. 59.

(c) an alleged efficiency gain from improving distribution of Servier's products (Krka in seven Central and Eastern European markets[2746] and Teva for the UK;[2747])

(d) an alleged efficiency gain consisting in Teva's claim that the agreement facilitated and expedited Teva's early entry;[2748]

(e) an alleged efficiency gain from Krka's licence for seven Central and Eastern European markets;[2749]

(f) an alleged efficiency gain from Niche's continued commercial existence and investment into development of new generic products other than perindopril;[2750]

(g) an alleged efficiency gain consisting in Teva's claim that reverse payment patent settlement agreements secures the incentives to challenge patents and favour generic entry.[2751]

(2070) The Commission has clarified in the Guidelines on the application of Article 81(3) of the Treaty that in its analysis of whether parties have succeeded in proving that all four conditions have been met, the Commission may consider the conditions in a different order, without there being any obligation to address all four conditions if one or more of them should not be met. [2752] When the parties claim efficiencies from agreements which restrict competition by their very object, the Commission will assess the extent of the likely harm in order to balance the efficiencies against the harm, unless it is clear that the efficiencies are insufficient or that some of the four conditions are not met.

(2071) However, none of the parties submitted the evidence necessary to show that all four conditions for the application of Article 101(3) of the Treaty had been met for the claimed efficiencies from any of the restrictions found under Article 101(1). Indeed, no party even substantiated in the required detail the claimed efficiency gains within the meaning of paragraph (2066) above. Without such substantiation of each claimed efficiency gain and submission of sufficient evidence that all four conditions of Article 101(3) of the Treaty have been met for an infringement, the exemption of Article 101(3) of the Treaty is not applicable.

(2072) The Commission considers, in any case, that the restrictions by object identified in this Decision were not necessary to achieve any claimed efficiencies. In the case of Niche, Matrix, Teva and Lupin agreements, any of the claimed efficiencies could also have been achieved through a settlement agreement without any value transfers and based purely on each party's assessment of the strength of Servier's patents in relation to the generic product concerned (and only that product), for example, an

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2745 Servier's reply to the Statement of Objections, paragraph 1329, ID10114, p. 415.

2746 Servier's reply to the Statement of Objections, paragraph 955, ID10114, p. 332-333.

2747 Servier's reply to the Statement of Objections, paragraph 828, ID10114, p. 302.

2748 Teva's reply to the Statement of Objections, paragraph 696-702, ID8495, p. 138-140.

2749 Krka's reply to the Statement of Objections, paragraph 174, ID8742, p. 87.

2750 Niche's reply to the Statement of Objections, ID8524, p. 59. In the reply to the Statement of Objections (p. 58), Niche states that "*precedent on the successful application of Article 101(3) to restrictions by object is scant, particularly in horizontal situations*". Niche mentions several precedents. None of them is relevant for the present case (see section 5.7.6).

2751 Teva's reply to the Statement of Objections, paragraph 731-732, 755, ID8495, p. 145, 148

2752 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 38.

early entry agreement, and/or by concluding a distinct distribution or technology transfer agreement without restricting competition between the parties. In the case of Krka Settlement Agreement, the settlement could have been structured in a way so as not to amount to market sharing, whereby Krka conceded to be excluded from competition in most markets in return for a licence from Servier granting it commercial and legal certainty in seven markets. Servier could also benefit from Krka's technology without engaging in an exclusive transfer of rights. Moreover, none of the parties has submitted sufficient evidence that consumers in the restricted markets would have received a fair share of any claimed efficiency.

(2073) For the sake of completeness, with respect to each of the alleged efficiencies the Commission makes the following additional observations.

5.7.1 Alleged efficiency gain from avoided litigation costs

(2074) The parties claim that the settlements sought to avoid significant litigation costs: "**Servier's intention to settle also stems from the rational desire to avoid very significant costs*".[2753] In the case of Niche, such costs were allegedly even menacing the company's existence: "*In the absence of the settlement agreement, Niche would have continued to spend money on litigation with Servier until it could no longer afford to do so and go out of business*".[2754]

(2075) As mentioned above, the parties did not substantiate the alleged savings from avoided litigation. Moreover, they also failed to demonstrate the objective nature of efficiency gains in accordance with settled case law of the Court of Justice,[2755] in particular whether such cost reductions produce any pro-competitive effect on the market instead of just increasing the companies' profits.[2756] As the facts of the present case show, litigation forms a key part of competition between originator and generic companies. Avoided litigation costs are basically savings achieved due to a reduction of output into (litigation) activity needed to possibly successfully challenge the patent and thus enable a viable generic entry into the market. The parties failed to show how such savings would lead to pro-competitive effects on the market.

(2076) Moreover, in the case of settlements with Niche, Matrix, Teva and Lupin it has been shown that the cash payment to the generic company exceeded litigation costs. If Servier indeed sought to save litigation costs, it is unclear how this would be achieved by paying the settling parties even more than it would have spent in litigation.

(2077) As already mentioned above, none of the reverse payment patent settlements with Niche/Unichem, Matrix, Teva, Lupin and Krka was indispensable to achieve the claimed the alleged savings. If, for example, Niche's objective was indeed only to avoid debilitating litigation cost, this could have been achieved in a settlement without a reverse payment being paid to Niche.

2753 Servier's reply to the Statement of Objections, paragraph 446, ID10114, p. 198. See similar argument by Krka, reply to the Letter of Facts, ID10202, p. 32-33, Lupin, reply to the Statement of Objections, paragraphs 359, 500, 502, ID8752, p. 88, 119-120, Matrix, reply to the Statement of Objections, paragraphs 5.11, 3.20, 4.17, ID 8835, p. 62-63, 33, 45, and Teva, reply to the Statement of Objections, paragraph 72, ID8495, p. 21.

2754 Niche's reply to the Statement of Objections, ID8524, p. 59 and Matrix's reply to the Statement of Objections, paragraph 5.11, ID 8835, p. 63. See also section 5.7.6.

2755 Judgment in *Consten and Grundig v Commission*, C-56/64 and C-58/64, EU:C:1966:41.

2756 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 49.

5.7.2 Alleged efficiency gain from improving Servier's perindopril production processes

(2078) A further efficiency claimed by Servier is that the Lupin Settlement Agreement and the Assignment and Licence Agreement with Krka enabled it to acquire intellectual property rights which in turn aimed at possibly advancing technical progress and reducing cost: "**patent applications were acquired by Servier particularly for their potential to optimise Servier's production techniques*".[2757]

(2079) According to the wording of these agreements Servier acquired five patent applications from Krka and Lupin for a total sum of EUR 70 million. For four out of five patent applications thus acquired, Servier reported no use to date. One patent application has reportedly allowed Servier to reduce by one step its production process, achieving savings of EUR [0–5]* million over a period of six years.[2758]

(2080) Throughout the investigation, including in its reply to the Statement of Objections, Servier was unable to provide any contemporaneous documents demonstrating expected savings from the use of these patent applications, or documents capable of proving that the teachings of the said patent applications have in fact been used and have led to the claimed savings. Likewise, Servier provided no contemporaneous documents to the agreements which would set out the economic rationale for the acquisition of the patent applications. This being said, Servier's product manager for perindopril did confirm that its normal policy in acquiring IPRs would be to prepare a feasibility study concerning the benefits of use of such IPRs prior to the acquisition itself: "**I find it hard to imagine that there is no clause, if indeed the case is as you describe it, which specifies that any contract signed takes effect without such analyses [feasibility studies] having been made"*.[2759]

(2081) While a transfer of technology can in principle yield efficiencies from the integration of assets, for example by allowing for a more efficient production process, Servier failed to substantiate such claims and provide the underlying evidence in line with its burden of proof.

(2082) In any event, the conditions in the agreement were not indispensable. If Servier's objective with the Lupin Settlement Agreement was indeed to acquire Lupin's technology to improve its own production processes, technology could be transferred in an agreement that would not impose a non-compete and a non-challenge obligation for Lupin. In the case of both Lupin and Krka technology, which was substitutable to the technology Servier already controlled, it is unclear why Servier needed to transfer such technology on an exclusive basis, moreover in the form of patent assignment. Claimed production improvements for its existing production processes could have been achieved by Servier by a non-exclusive licence.

5.7.3 Alleged efficiency gain from improving distribution of Servier's products

5.7.3.1 Teva

(2083) Servier claims that the Teva Settlement Agreement allowed it to improve distribution of Servier's perindopril by generic companies in the UK: "**the patent settlement allowed the conclusion of a supply agreement with Teva (which Servier was*

2757 Servier's reply to the Statement of Objections, paragraph 1329, ID10114, p. 415.

2758 See paragraph (952).

2759 See paragraph (288).

considering since 2001/2002), which was the best generic partner possible for Servier".[2760]

(2084) It should be recalled that Servier sought a generic partner to launch generic perindopril only once Servier would have lost patent exclusivity. Entry of Servier's authorised generics was referred to in Servier's internal documents as a "*nuclear weapon*". The strategic use of friendly generics was made clear in the instruction: "*be prepared (registration, production)*", "*but launch only in case of absolute necessity*".[2761]

(2085) In view of the analysis under Article 101(1) of the Treaty, it is evident why having Teva, one of the closest challengers to Servier's market position, as an authorised generic distributor, instead of as a competitor, was commercially attractive to Servier. Once it lost the '947 patent and generic entry occurred in the UK, Servier could maintain a certain volume of perindopril sales through "wholesale" supply of finished perindopril product to generics. Servier does not explain why the distribution arrangements with Teva would produce objective qualitative efficiencies. The Guidelines on the application of Article 81(3) of the Treaty[2762] clarify that efficiencies could arise in case of specialised distributors or distributors who have a significantly broader outreach and could e.g. enable access to perindopril for patients that would otherwise remain unserved. No such claims have been made or appear plausible against the facts of the case (also in view of the fact that Servier authorised another generic company to distribute Servier perindopril).

(2086) The restrictions in the agreement, for example that Teva could not sell perindopril other than that supplied by Servier even if the latter opted not to supply Teva, were not indispensable conditions to achieve the claimed efficiencies from having a distribution partner once Servier would decide to start selling through generic partners. Most notably, the same claimed distribution efficiencies could have been achieved by Servier if it concluded a stand-alone distribution agreement with Teva or another generic company with a well established commercial presence in the UK, as has been done with another generic company for the UK market or with generics in other Member States.

5.7.3.2 Krka

(2087) For the seven CEE markets, Servier granted a licence for the '947 patent to Krka, which sold its own, and not Servier's, perindopril. Servier claims that, although Krka did not distribute Servier's perindopril, Krka's generic penetration with perindopril nonetheless brought about efficiencies for Servier, as it contributed to the overall promotion of perindopril compared to other antihypertensive agent: "**the licence agreement had a potential for developing Servier's sales in the CEEC "where Krka has a very strong distribution network, which enables it to develop the market share of perindopril as opposed to the competitor medicines". Servier could thus benefit from the promotional effort of Krka for perindopril (with a consequent increase in the "share of voice" of perindopril compared with ACE inhibitors and ARBs)*".[2763] Servier failed to further substantiate this efficiency in line with its burden of proof.

2760 Servier's reply to the Statement of Objections, paragraph 828, ID10114, p. 302.

2761 See paragraph (203).

2762 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 72.

2763 Servier's reply to the Statement of Objections, paragraph 955, ID10114, p. 332-333.

(2088) It remains unclear how the licence could create efficiencies for Servier in the relevant markets in view of the following. First, prior to the agreement with Servier, Krka had already launched generic product in five of these markets. While Krka itself could conceivably draw some benefit from the licence (see section 5.7.5 below), Servier could enjoy the alleged benefits of Krka's presence without concluding the agreement in the five markets where Krka had already marketed perindopril. Therefore, the causal link between the Krka Settlement Agreement and the alleged efficiencies from Krka's presence has not been demonstrated.

(2089) Second, Servier's seems to find support for its claims in an internal presentation from 2006, which lays out a strategy to counter Krka's promotional efforts in view of Krka's perindopril launch in the Czech Republic in April 2006.[2764] In the Commission's view, the link between the claimed efficiency and the settlement, as allegedly demonstrated by this document, is not apparent. The document does not discuss how to harness Krka's share of voice (Krka has a strong sales force in the CEE), but lays out a plan how to defend Servier's sales from a "*massive attack*" and "*aggressive communication*",[2765] which presented a "*high risk for Servier*". The remainder of the document presents Servier's reaction – intensified activities of Servier's own sales representatives "*to decrease the risk of substitution from [Servier's] Prestarium to [Krka's] Prenessa*". This resulted in a "*low take-off of Prenessa*", while "*Prestarium keeps its trend*".[2766] The document does not refer to competitive constraints from other antihypertensive agents and possible efficiencies from Krka's promotional efforts, as Servier appears to suggest. On the contrary, instead of examining possible efficiencies from Krka's presence, it presents Servier's success in defending its sales from the threats related to Krka's entry. More generally, Servier's document is consistent with its overall strategy to prevent, or limit generic substitution, which it also pursued through the launch of perindopril arginine. It remains unexplained how Krka's promotional efforts for perindopril erbumine could benefit Servier's sales of perindopril arginine, given that perindopril erbumine could not be substituted by perindopril arginine, and vice versa.

(2090) In view of the above, Servier's argument that it sought to achieve efficiencies from Krka's promotional efforts for perindopril does not appear convincing. In any event, to achieve the alleged efficiency, it was not indispensable for Servier to impose restrictions on Krka – Krka was already present on five markets and Servier could simply abstain from patent enforcement to prevent Krka's marketing. Alternatively, it could also enter into the licensing agreement for the seven markets without restricting Krka's ability and incentives to compete in the remaining 20 markets.

5.7.4 Alleged efficiency gain consisting in Teva's claim that the agreement facilitated and expedited Teva's early entry

(2091) Teva claims that the Teva Settlement Agreement should be analysed as a vertical supply arrangement, which facilitated and expedited Teva's early entry[2767] in view of delays with regulatory approval and possible infringement issues with Krka's

2764 ID9970, p. 191-197.

2765 ID9970, p. 191.

2766 ID9970, p. 196.

2767 Teva's reply to the Statement of Objections, paragraph 696-702, ID8495, p. 139-140. Teva also claimed that, even if assessed as a reverse-payment settlement, the agreement would merit an exemption under Article 101(3) of the Treaty, as such agreements stimulate generic investment and patent challenges. For the rebuttal of this general argument, reference is made to paragraphs (1207) and (1208).

product: "*Servier's supply option was, from Teva's perspective, the best option to enter the UK perindopril market at the earliest possible date*". The Commission disagrees, as it has found that Teva was a potential competitor of Servier in view of Teva's development of perindopril product and its activities to overcome patent barriers and obtain marketing authorisation. The Teva Settlement Agreement therefore cannot be assessed as a vertical supply agreement, but as a horizontal agreement between competitors.[2768] Notwithstanding, the alleged efficiency gain will be analysed in what follows.[2769]

(2092) As explained by Servier, the Teva Settlement Agreement was not meant to result in early generic entry, that is to say entry occurring while Servier still enjoyed patent protection.[2770] Accordingly, the Teva Settlement gave Servier the option to postpone the distribution at its discretion, an option which Servier actually exercised and kept Teva off the market and on its payroll for additional 11 months. As already mentioned, Servier viewed the entry of authorised generics as a *"nuclear weapon"*: "*be prepared (registration, production)*", "*but launch only in case of absolute necessity*".[2771]

(2093) The claimed efficiency is thus limited to facilitating Teva's entry once the market would eventually anyway open up for generic competition. This could happen during the term of the agreement if another generic company overcame Servier's patents and launched (as Apotex, following EPO's upholding the '947 patent, eventually did), or not, in which case Teva would continue to collect liquidated damages for not selling any perindopril, be it Servier's, its own, or a third party's. It is therefore incorrect to present the agreement as securing the "earliest possible date" to Teva. In case the '947 patent remained in force following the EPO opposition decision, Teva could no longer continue to follow its independent activities to enter the UK market, which could allow for an earlier entry than that based on Servier's choice between the option to supply and the option not to supply pursuant to the agreement.

(2094) Therefore, the nature and scope of the efficiency gains as adduced by Teva remain unclear, and appear to only consist in granting Teva a good starting position once generic entry by third parties would occur. As Teva would not be the only supplier of generic perindopril in such a scenario (apart from the independent entrant, generic perindopril would also be sold by another authorised generic of Servier), it would need to explain which objective qualitative efficiencies would flow from it distributing perindopril (specialised distributors or distributors who have a significantly broader outreach and could e.g. enable access to perindopril for patients

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2768 See *Communication from the Commission: Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, OJ C 11, 14.01.2011, page 1, point 12.

2769 Regarding the Lupin Settlement Agreement, Servier and Lupin made similar claims that the agreement was procompetitive as it could facilitate Lupin's entry on the perindopril market (Servier's reply to the Statement of Objections, paragraph 1150, ID10114, p. 378, Lupin's reply to the Statement of Objections, paragraph 288, ID8752, p. 72). Given that the parties have not substantiated this argument in view of the four conditions under Article 101(3) of the Treaty, the Commission cannot carry out a meaningful assessment. At any rate, it appears unlikely that the main conclusions of this heading would not also apply to the Lupin Settlement Agreement. This is all the more so as no distribution agreement was concluded between Servier and Lupin.

2770 See, for example, paragraph (772).

2771 See paragraph (203).

that would otherwise remain unserved).[2772] No such claims have been made or appear plausible against the facts of the case.

(2095) The agreement contained conditions that are not indispensable to achieve the claimed efficiencies. Most notably, the exclusive purchasing obligation for Teva prevented Teva from selling any perindopril erbumine product not produced by Servier, even if Servier failed to supply Teva as envisaged by the agreement. Neither could Teva terminate the agreement for such failure to supply. Such a restriction cannot be claimed indispensable for a distribution agreement, as it effectively made Teva fully dependent on Servier's discretion, kept Servier's significant market power untouched, and actually reduced Teva's incentives to supply perindopril at all.[2773]

5.7.5 Alleged efficiency gain from Krka's licence for seven Central and Eastern European markets

5.7.5.1 The Krka Settlement Agreement is not exempted pursuant to the Technology Transfer Block Exemption Regulation and the Technology Transfer Guidelines

(2096) The parties claim that the Krka Settlement Agreement was pro-competitive, as it allowed Krka to compete in a situation where, absent the licence, competition from Krka would be excluded to the detriment of consumers. Accordingly, Article 101 of the Treaty should not apply to the Krka Settlement Agreement[2774] by virtue of paragraphs 204 and 205 of the Technology Transfer Guidelines, which state that licensing "*in the context of settlement agreements and non-assertion agreements is not as such restrictive of competition since it allows the parties to exploit their technologies post competition […] In cases where it is likely that in the absence of the licence the licensee could be excluded from the market, the agreement is generally pro-competitive"*. Furthermore Krka argues that patent holders are fully entitled as to how to exploit/licence their patents: whether to grant it to a third party, to which extent, for what territories etc.[2775] In the same vein, Servier claims that the Licence Agreement, which only grants the licence for seven out of 25/27 markets covered by the Settlement Agreement, should be exempted by virtue of Article 4(1)(c)(ii), of the Technology Transfer Block Exemption Regulation[2776] (hereafter: "TTBER") which exempts licensing agreement containing field of use limitations on the licensee, in this case Krka.[2777]

(2097) The Commission notes, on a preliminary basis, that the Krka Settlement Agreement contains restrictions which remove Krka from competition with Servier in territories where it was previously present as a potential competitor, and for which no enabling licence was provided. The Krka Settlement Agreement could not benefit from an exemption for a number of reasons.

2772 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 72.

2773 See paragraph (773): "*If the settlement keeps other generics off the market in the UK, then we keep our present arrangement with Servier [i.e. no supplies but monthly liquidated damages payment]".*

2774 Krka's reply to the Statement of Objections, paragraphs 139-142, ID8742, p. 69-72, Servier's reply to the Statement of Objections, paragraph 1008, ID10114, p. 346.

2775 Krka's reply to the Statement of Objections, paragraph 145, ID8742, p. 73-74.

2776 Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, Official Journal L 123, 27.04.2004, p. 11-17 (later references to the Technology Transfer Block Exemption Regulation, or TTBER, should be understood as referring to this 2004 Regulation).

2777 Servier's reply to the Statement of Objections, paragraph 1006, ID10114, p. 345.

(2098) First, the agreement does not meet the conditions for the TTBER to apply. In the vast majority of Member States, Servier held a monopoly in perindopril, and was free of any price competition. In the remaining five Member States, where Krka was already present with its perindopril, the parties together accounted for all perindopril sales. Servier thus enjoyed significant market power well in excess of the market share threshold from Article 2 TTBER, and together or with Krka (in five Member States) held 100% of perindopril sales.[2778] Moreover, due to the restrictions in the 18/20 Member States going beyond the field of use restrictions and the restrictions on active sales, the Krka Settlement Agreement would not fall under any of the exceptions to Article 4(1)(c) TTBER. The agreement would thus be qualified as a hard-core restriction having as its object the allocation of markets. Finally, the Krka Settlement Agreement could also be seen as a hard-core restriction in the sense of Article 4(d) TTBER, consisting in "*the restriction of the licensee's ability to exploit its own technology*". In the 18/20 markets, the non-compete and non-challenge obligations of the Krka Settlement Agreement indeed restrict the licensee's, Krka's, "*ability to exploit its own technology*" as they remove Krka's ability to potentially enter and compete with its existing product.

(2099) Second, the scope of the guidance in the Technology Transfer Guidelines is explicitly limited to situations where licensing may serve as a means of resolving disputes, allowing the parties to exploit their technologies post agreement.[2779] The Guidelines therefore do not apply to the situation in the 18/20 Member States concerned by this Decision,[2780] where Krka needed to withdraw from competing with its product, including the UK as the focal market for national litigation for both Servier and Krka. In these 18/20 markets, there was no licensing which would enhance competition between Servier and Krka. On the contrary, the non-compete and non-challenge restrictions reduced competition from Krka, which represented a "*serious threat*" to Servier.[2781]

(2100) Third, the restrictions of Krka Settlement Agreement cannot be mistaken for field of use restrictions which limit the ways in which the licensee can use its licence,[2782] or for prohibiting active sales into a non-licensed territory. On a preliminary note, the Technology Transfer Guidelines state that "[t]*he main competitive concern in the case of such restrictions is the risk that the licensee ceases to be a competitive force outside the licensed field of use"*.[2783] In this respect, it is recalled that Krka was not only prevented from selling products from licensed into non-licensed territories, but was prevented from competing in these non-licensed territories based on its own technology and resulting products. Namely, in the 18/20 markets not covered by the licence, the non-compete and non-challenge obligations of the Settlement Agreement barred Krka not only from selling a product based on its own technology but also from attempting to remove any remaining patent barriers to entry with its own technology.[2784]

2778 See sections 6.5. and 7.3.

2779 Technology Transfer Guidelines, point 204.

2780 The Commission's legal assessment does not extend to seven Member States covered by the Licence Agreement.

2781 See paragraph (912).

2782 Servier's reply to the Statement of Objections, paragraph 1011, ID10114, p. 347.

2783 Technology Transfer Guidelines, point 183.

2784 This also addresses Servier's comment: "**One can also wonder what would have been the Commission's position if the licence agreement had been concluded in 2005, regardless of any*

(2101) What matters is that, before the settlement agreement, Krka was an actual or potential competitor to Servier on the 25/27 markets. After the Krka Settlement Agreement, Krka remained Servier's competitor only on the seven licensed markets. The scope and nature of competition between the settlement parties was clearly reduced in the remaining, restricted 18/20 markets. This is so because the Krka Settlement Agreement not only limits the licence to seven markets, but prevents Krka from contesting Servier's market position in all other markets not covered by the licence. These restrictions thus not only deny consumers in the 18/20 markets from sharing possible benefits from the licence in the seven markets, but in addition deprive the consumers of any benefit from Krka's potential market entry in the 18/20 markets.

(2102) In view of the foregoing, the Krka Settlement Agreement is not exempted pursuant to the TTBER, and the claimed efficiency gains therefore need to be examined individually under Article 101(3) of the Treaty.

5.7.5.2 Individual examination of the alleged efficiency gains

(2103) Krka claims that "*the licence granted […] enabled Krka to offer its product in EU7 markets as an additional choice to the incumbent original product*".[2785] According to Krka, the licence enabled it "*to sell form* [sic] *3,4 million to 5 million packs annually in the period 2007-2009 what with the price decrease of 30% to 40% due to generic entry and an average price of the original product in EU7 markets of €5-8/pack resulted in savings for healthcare public in 7 countries in approximately 5- 9 million EUR annually*".[2786] Krka also claims that the restrictions from the Settlement Agreement were indispensable for Krka to obtain a licence from Servier.[2787] Likewise, Servier claims that the settlement and the licence allowed Krka to remain or launch on the seven markets covered by the licence.[2788]

(2104) By the time of the Krka Settlement Agreement, Krka had already entered five of its core CEE markets[2789] with generic perindopril, including the biggest one, Poland. Krka remained undeterred even in the aftermath of the decision of the EPO Opposition Division upholding the '947 patent and continued to market its perindopril, it successfully averted Servier's application for interim relief in Hungary, which was rejected by the court only weeks before the settlement. Having regard also to Krka's counterclaim for annulment of the '947 patent in the UK, Krka thus distinctly manifested that it would oppose the grant and/or the enforcement of the '947 or its national equivalents. Therefore, while the licence indeed provided Krka

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litigation: would that have also been a market-sharing agreement?" (Servier's reply to the Statement of Objections, paragraph 970, ID10114, p. 337).

2785 Krka's reply to the Statement of Objections, paragraph 174, ID8742, p. 87.

2786 Krka's reply to the Statement of Objections, paragraph 188, ID8742, p. 91.

2787 Krka's reply to the Statement of Objections, paragraph 176, ID8742, p. 88. As to Krka's arguments that it was not the one to request a sole licence for the seven Member States, and that nothing prevented Krka and Servier from competing with one another (see paragraphs 177 and 179 of the reply), the Commission observes that the decision does not contain any conclusion as to the existence or not of an infringement of Article 101 of the Treaty in the seven Member States covered by the licence. The Commission in addition observes that the question who proposed the arrangement is not of relevance. Krka considered the agreement with Servier as means to prevent that the market would be opened for everybody (paragraph (1756)). Krka also acknowledged that the PSA enabled a "minor number of competitors" (paragraph (914)). In any event, both parties had a common interest to limit the number of competitors in these markets.

2788 Servier's reply to the Statement of Objections, paragraphs 1068, 1071, ID10114, p. 360-361.

2789 Czech Republic, Hungary, Lithuania, Poland and Slovenia.

with legal certainty that Servier would not continue to assert its patents, or commence to assert them in the future[2790] it is incorrect to claim that Krka *a priori* would not have been in a position to maintain itself on or enter the seven markets.[2791] While the licence undisputedly provided a subjective advantage to Krka, as it avoided the patent risks inherent to competition between originator and generic company, it failed to explain why its presence in the 7 markets should be attributed to the licence, and not Krka's predating commercial and other activities. It thus remains uncertain whether the public healthcare savings to which Krka points could not be achieved in any event.

(2105) Concerning Krka's claim that "*the possibility to supply EU7 market overweighs the elimination of the three main countries of the EU18/20 markets*",[2792] the Commission takes the view that even if it were accepted that the licence produced positive effects in the licensed markets, such efficiencies cannot offset anticompetitive effects in the remaining 18/20 markets, where Krka had to withdraw from competition with its current pipeline product.

(2106) Any claimed efficiencies generated in a relevant product and/or geographic market should be sufficient to offset any restrictive effects within that same market. In the *Mastercard* case,[2793] the General Court further clarified that "*the appreciable objective advantages to which the first condition of Article 81(3) EC relates may arise not only for the relevant market but also for every other market on which the agreement in question might have beneficial effects, and even, in a more general sense, for any service the quality or efficiency of which might be improved by the existence of that agreement*". The Court however clarified that "*the very existence of the second condition of Article 81(3) EC necessarily means that the existence of appreciable objective advantages attributable to the MIF [card payment fees] must also be established in regard to them [merchants]*". As there was no proof that merchants, one of the two groups of users affected by payment cards, could benefit from the alleged advantages, the second condition of Article 101(3) TFEU was not fulfilled. According to the Guidelines on Application of Article 101(3), "*[n]egative effects on consumers in one geographic market or product market cannot normally be balanced against and compensated by positive effects for consumers in another unrelated geographic or product market. However, where two markets are related, efficiencies achieved on separate markets can be taken into account provided that the group of consumers affected by the restriction and benefiting from the efficiency gains are substantially the same…*".[2794]

2790 Of the seven CEE markets, only three were covered by the EPO '947 patent (Latvia, Lithuania, Slovenia). In the Czech Republic, Hungary, Poland and Slovakia, Servier applied for national equivalents of the '947 patent. (ID0119, p. 29) At the time of the settlement, such a national equivalent was only granted in Hungary in August 2006, whereas in the Czech Republic, Slovakia and Poland, Servier had no valid patent yet (in Poland as long as until 2010). (ID0363, ID4968, p. 3-4)

2791 This addresses Krka's claims that the licence increased rather than eliminated competition, and that "*some competition is always better that* [sic] *no competition*" (Krka's reply to the Statement of Objections, paragraph 189, ID8742, p. 91).

2792 Krka's reply to the Statement of Objections, paragraphs 188, 181, ID8742, p. 89-91.

2793 Joined Judgment of 24 May 2012, *MasterCard, Inc. v European Commission*, T-111/08, ECR, EU:T:2012:260, paragraphs 227-229.

2794 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 43.

(2107) Krka failed to explain how healthcare savings in seven Member States would offset the possible consumer harm from Krka's withdrawal from competition in the remaining 18/20 Member States. Consumer demand – by patients and health insurance systems – is almost exclusively national in scope, and there is very little, if any overlap, between consumer groups in different Member States.[2795] Moreover, even if potential consumer harm and benefits are compared on the level of the EU, Krka provides no evidence to support its statement that the estimated consumer benefit of EUR 5-9 million in the seven markets "*overweighs the elimination of the three main countries of the EU18/20*". At the time of the settlement, the combined annual turnover of Servier in France and UK alone was in the range of around EUR 200 million.[2796] With the price decreases when generic entry eventually occurred ranging from 27% in France to around 90% in the UK,[2797] annual savings from generic entry for these two markets alone would be far in excess of EUR 50 million. An early entry with Krka's perindopril could have significantly contributed to such savings in these two markets, or in other markets for which Krka withdrew from competition.

(2108) The restrictions accepted by Krka for the 18/20 Member States were not indispensable to achieve the claimed efficiency gains in the seven Member States. To avoid market sharing, Krka and Servier could have negotiated a less restrictive settlement for the Member States most immediately affected by litigation (notably the UK and the Netherlands) where the restrictions would only be based on the merits of the litigation and not leveraged by an inducement unrelated to the litigation. Alternatively, the settlement could grant Krka earlier entry or a licence for the entire EU territory, or limit the restrictions from the settlement agreement to the Member States covered by the licence agreement.

5.7.6 Alleged efficiency gain from Niche's continued commercial existence

(2109) Niche claims that, absent the Niche/Unichem Settlement Agreement, it would have gone out of business, but the proceeds from the settlement payment allowed Niche to continue as a going concern and invest into current and new projects, culminating in actual or imminent launch of six generic products (none of them contains perindopril) since the settlement. Niche thus submits that the settlement agreement can be justified under Article 101(3) because it directly led to (i) considerable product improvement, (ii) Niche's ability to launch new and important

2795 See, for example, *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 43. The parties suggest that the Commission should have carried out a balancing assessment between the restrictive effects of the agreement in the 18/20 restricted markets and the pro-competitive effects in the seven CEE markets where the licence secures the opening of the market to a competitor. The case law does not support this view, as explained in Advocate General Mengozzi's opinion in Judgment in MasterCard and Others v Commission, C-382/12 P, EU:C:2014:42, paragraphs 158-159: "*In fact, if it were possible to take into consideration the advantages resulting from an agreement for one category of consumers of certain services in order to counterbalance the negative effects on another category of consumers of other services on a different market, that would amount to allowing the former category of consumers to be favoured to the detriment of the latter category. However, distributive logic of that type seem to me, in principle, to have no connection with the practical scope of competition law. […] Competition law is intended to protect the structure of the market, and thus competition, in the interest of competitors and, ultimately, consumers […] in general. Conversely, it is not intended to favour one category of consumers to the detriment of a different category*".

2796 See, for example, paragraphs (2291) and (2331), based on data for 2007H1.

2797 See paragraphs (2290) and (2330).

pharmaceutical products and (iii) more competitive prices for these products. Consumers thus received "*a greater choice of supplier for the aforementioned products at more competitive prices*".[2798] The Commission considers this to be an indirect efficiency claim, in that the restrictive agreement allowed Niche to increase its profits and thus to (i) subsist and (ii) invest into new product development.[2799] It however remains unclear whether Niche's continued existence and R&D investment was causally linked to receiving the payment or to the fact that Niche withdrew from litigation with Servier ("*Niche would have continued to spend money on litigation with Servier until it could no longer afford to do so and go out of business. Niche had absolutely no other option but to enter into the Settlement Agreement in order to remain in the business and compete* ").[2800]

(2110) Concerning the claim that the settlement payment was an efficiency allowing the economic survival of Niche, the Commission points to the Guidelines on the application of Article 81(3) of the Treaty:[2801] "*Reduced competition may also lead to lower sales and marketing expenditures. Such cost reductions are a direct consequence of a reduction in output and value. The cost reductions in question do not produce any pro-competitive effects on the market. In particular, they do not lead to the creation of value through an integration of assets and activities. They merely allow the undertakings concerned to increase their profits and are therefore irrelevant from the point of view of Article 81(3)"*. Receiving "*20 years planned gross profit*"[2802] to be "*bought out*"[2803] by your direct competitor may constitute a subjective efficiency gain for Niche. However, this "*windfall*" was directly related to Niche's agreement to reduce its output and "*postpone the development/launch*".[2804] If additional liquidity allowed Niche to survive, the payment was in direct connection to the restriction of competition, and there cannot be deemed to produce any pro-competitive effects. Moreover, Niche received EUR [0–5]* million for the due diligence exercise from Servier which, given the size of the company and its

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2798 Niche's reply to the Statement of Objections, ID8524, p. 58-59. Niche further argues that the cases Reims II and CECED provide useful precedents for the purpose of analysing the Niche/Unichem Settlement Agreement under Article 101(3) of the Treaty (reply to the Statement of Objections, p. 58). The Commission disagrees. The REIMS II agreement (1999/695/EC: Commission Decision of 15 September 1999, Official Journal L 275 , 26/10/1999, p. 17 – 31) improved cross border mail deliveries by determining the charges that were paid by postal operators for the delivery of mail posted in another country. The Commission considered that the terminal due levels were indispensable in order to achieve the increases in quality of service as well as the increase correlation between terminal dues and the parties' costs for the delivery of incoming cross-border mail. Niche fails to show how an agreement the immediate effect of which was to keep a potential competitor outside the market in exchange for a payment might have a comparable pro-competitive effect. In particular, neither Servier nor Niche demonstrated that there is no less restrictive alternative to favour market entry by generic products.
The CECED agreement (2000/475/EC: Commission Decision of 24 January 1999, Official Journal L 187, 26/07/2000, p. 47–54), by which manufacturers of washing machine agreed to no longer manufacture or import less energy-efficient machines, was exempted under Article 101(3) on the ground that it contributed to economic or technical progress and conferred benefits to consumers. Niche fails to explain the precedent value of this case for the Niche/Unichem Settlement Agreement.

2799 *Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 54.

2800 Niche's reply to the Statement of Objections, ID8524, p. 59.

2801 *Guidelines on the application of Article 81(3) of the Treaty*, Official Journal C 101, 27/04/2004, p. 97 – 118, point 49.

2802 See paragraph (600).

2803 See paragraph (544).

2804 See paragraph (602).

financial exposure, appears to have provided sufficient liquidity for continued operation as a going concern, including further development of perindopril.[2805]

(2111) If it were, as claimed, indeed the litigation costs that ran Niche to the brink of insolvency, Niche does not explain why it was indispensable to enter the Niche/Unichem Settlement Agreement. These costs could be avoided by a settlement agreement without the reverse payment, for example by offering to Servier an undertaking to refrain from selling, manufacturing, importing etc. its perindopril product, as a basis for a consent order to terminate litigation, or by concluding a settlement allowing early entry.[2806]

5.7.7 Alleged efficiency gain consisting in Teva's claim that reverse payment patent settlement agreements secures the incentives to challenge patents and favour generic entry

(2112) Teva argues that, should the Teva Settlement Agreement not be construed as a vertical supply agreement as claimed by Teva, but as a reverse payment settlement agreement, such settlements should be generally exempted as they favour generic entry: *"the significant sunk investments required to develop and launch a new generic product and the major barriers to entry and uncertainties that generic companies confront are critical factors in the decision to develop new products. […] Conversely, prohibiting so-called reverse-payment settlements would restrict the range of settlement options available to generic companies, thus reducing their ability to resolve the patent litigation. This would, in turn, increase the costs and risks of bringing a generic drug on the market"*.[2807]

(2113) Teva raised four points in its reply to the Statement of Objections.

(2114) First, the development and launch of a new generic product requires significant sunk investments and these costs will not be recovered if the generic manufacturer cannot achieve successful market entry because of patent litigation. The threat of costly litigation and the risk of granting of interim injunctions and, possibly, damages, have a strong dissuasive effect on the entry of generic products on the market. Moreover, the European regulatory framework affords no generic entrant any period of exclusivity which would incite to investments in patent challenge activity. Reverse patent settlement reduce the uncertainties attached to patent litigation and reduce the costs and risks of bringing a generic drug on the market. In this context, reverse payment settlements are an alternative to the costly and risky patent challenge entry path. A legal prohibition on reverse payment settlements that includes no restrictions that exceed the scope of the patent would reduce the incentive of generic companies to challenge patents, increase barriers to entry, and lead to efficiency losses.

(2115) Second, in relation to consumer benefits, Teva submits that reverse payments settlements encourage generic patent challenges and facilitate early generic entry. These agreements benefit consumers, who will be able to procure pharmaceutical products at cheaper prices and earlier in time.[2808] Specifically, the fierce competition that occurs upon generic entry ensures that consumers receive a fair share of the

2805 See paragraph (535).

2806 Niche also claims that no competition was eliminated as it was entitled to develop and commercialise non-infringing perindopril (reply to the Statement of Objections, ID8524, p. 60). This point is addressed in paragraph (1311) above.

2807 Teva's reply to the Statement of Objections, paragraphs 730, 732 and 755, ID8495, p. 145, 148.

2808 Teva's reply to the Statement of Objections, paragraph 763, ID8495, p. 150.

benefits generated by reverse payment patent settlements. Teva submits that generic companies are more inclined to pursue a strategy of launching their product prior to patent expiry, when the option of reverse payment patent settlements can be envisaged. The possibility of a reverse payment patent settlement can tilt the generic's decision towards early entry, especially in the UK where securing a first mover advantage is a particularly crucial element in the entry strategy of generic competitors.[2809] Teva thus emphasises the social benefits of settlements agreements as opposed to costly effects of litigation.

(2116) Third, Teva argues that from the generic industry's perspective, the possibility of reverse payment patent settlements is "indispensable" to ensuring incentives to develop new generic products and promote early launches. According to Teva, "*important economic factors, such as information asymmetries between the generic and the originator, variation in risk aversion, differences in expectations, or differences in the value of time, show that reverse payments are often indispensable to reach a settlement*".[2810]

(2117) Fourth, reverse patent settlements do not afford the possibility of eliminating competition when, as in the present case, the settlement is within the scope of the patent. The fact that the agreement did not afford the possibility of eliminating competition was confirmed *ex post* with the entry of Apotex. At last, the possible foreclosure effect resulting from the combination of several settlement agreements cannot be the responsibility of Teva.[2811]

(2118) Teva's position that "even if construed as a patent settlement", the agreement would still benefit from an exemption under Article 101(3) of the Treaty[2812] should be entirely dismissed for the following reasons, in addition to the Commission's arguments presented in section 5.1.5.

(2119) Concerning Teva's first point, the Commission does not suggest that reverse payment settlements should be "condemned"[2813] and only refers to the specifics of each case dealt with in the present Decision. The Commission can understand that given the significant sunk costs generic companies have a strong interest in having patent issues settled quickly. The Commission explained above that patent settlement may benefit both the parties to the dispute and, more generally, society, by allowing for a more efficient allocation of resources than if all litigation were to be pursued to judgment. However, patent issues cannot be settled at any price and patent rights are not immune from the application of competition law. In the Teva case, the agreement did not provide for an early entry for Teva, as Teva did not have any enforceable right to obtain supplies from Servier, and it could not sell its own perindopril or that manufactured by third parties even if their perindopril did not infringe Servier's patents. Moreover, the amendment to the Teva settlement agreement makes it plain that Teva will not enter the market while Servier's patents were still in force.[2814] Teva itself realised that the agreement would result in a "*delay to us [Teva] in entering the*

2809 Teva's reply to the Statement of Objections, paragraph 769, ID8495, p. 151.
2810 Teva's reply to the Statement of Objections, paragraph 789, ID8495, p. 154.
2811 Teva's reply to the Statement of Objections, paragraphs 792 and subsequent, ID8495, p. 155-156.
2812 Teva's reply to the Statement of Objections, section 4.2, ID8495, p. 142 and subsequent.
2813 See paragraph (1118).
2814 See paragraphs (1561) and (1565).

market".[2815] The prohibition of a settlement which blocks any potential market entry cannot be seen as an "efficiency loss".

(2120) The Commission considers that Teva's second point on consumer benefit almost entirely relies on general statements which are unrelated to the case. In any event, the argument that Teva perceived the settlement agreement as a supply arrangement allowing early market entry has already been dealt with above.[2816] It suffices to recall that from the date of conclusion of the settlement agreement, Teva's incentives to engage in any development of an alternative product were null[2817] and no early entry option was foreseen by the agreement.[2818] Teva has not proven that the Teva Settlement Agreement resulted in an earlier generic entry launch than would otherwise have occurred, and saved Teva potential litigation costs. Teva has not characterised any saving to consumers' benefit.

(2121) Thirdly, in order to show that reverse patent settlements are indispensable in general, Teva refers to general economic concepts and general statements such as "*reverse payments are often indispensable*".[2819] Teva does not make a convincing case why the agreement entered into by Teva was, under the circumstances of this case, indispensable and does not provide evidence in this respect. As already explained, the agreement contained restrictions which were not indispensable to attain the alleged objectives of Teva.[2820]

(2122) As Teva failed to show that the agreement met the aforementioned three cumulative conditions for exemption under Article 101(3) of the Treaty, it is not necessary to assess the remaining condition whether the agreement eliminated all competition.

5.8 Duration of the infringements of Article 101 of the Treaty

5.8.1 Niche/Unichem Settlement Agreement

(2123) Based on the conclusion in section 5.2.3 that the Niche/Unichem Settlement Agreement restricted competition by its very object, the infringement of Article 101 of the Treaty by Servier and Niche/Unichem for the EU markets is established for the period starting from the conclusion of the Niche/Unichem Settlement Agreement on 8 February 2005[2821] until the termination of Clause 3 of the agreement on 15 September 2008.[2822] The start date for the infringement is based on the date of conclusion of the agreement because the restrictions on Niche/Unichem's competitive behaviour were immediately effective as of that date. The end date of the infringement is 15 September 2008[2823] because Niche/Unichem's ability to engage in

2815 See paragraph (1560).
2816 See paragraph (1558).
2817 See paragraph (1559).
2818 See paragraph (1560).
2819 Teva's reply to the Statement of Objections, paragraph 789, ID8495, p. 154.
2820 See paragraph (2095).
2821 For Bulgaria and Romania, the infringement started on 1 January 2007, the date of the accession of these countries to the EU. For Latvia and Malta, the infringement started on 1 July 2005 and 1 March 2007, respectively, the dates of the accession of these countries to the European Patent Convention. As for Italy, the SPC for the compound patent only expired there on 13 February 2009. Therefore, the Commission assumes that Italy was not affected by the infringement in question.
2822 While the rest of the agreement, including certain other restrictions, remained in force after that date, the Commission chose an end date which was more favourable to the parties.
2823 The infringement was terminated earlier in the UK (6 July 2007) and the Netherlands (12 December 2007).

competitive behaviour was restricted until at least that date by Clause 3 of the agreement.[2824]

5.8.2 Matrix Settlement Agreement

(2124) Based on the conclusion in section 5.3.3 that the Matrix Settlement Agreement restricted competition by its very object, the infringement of Article 101 of the Treaty by Servier and Matrix for the EU markets is established for the period starting from the conclusion of the Matrix Settlement Agreement on 8 February 2005[2825] until the termination of Clause 1 of the agreement on 15 September 2008.[2826] The start date for the infringement is based on the date of conclusion of the agreement because the restrictions on Matrix's competitive behaviour were immediately effective as of that date. The end date of the infringement is 15 September 2008[2827] because Matrix's ability to engage in competitive behaviour was restricted until at least that date by Clause 1 of the agreement.[2828]

5.8.3 Teva Settlement Agreement

(2125) Based on the conclusion in section 5.4.3 that the Teva Settlement Agreement restricted competition by its very object, the infringement of Article 101 of the Treaty by Servier and Teva for the UK market is established for the period starting from the conclusion of the Teva Settlement Agreement on 13 June 2006 until 6 July 2007, the date of the annulment of the '947 patent by the High Court, after which Teva entered the UK market.[2829] The start date for the infringement is based on the date of conclusion of the agreement because the restrictions on Teva's competitive behaviour were immediately effective as of that date. The end date of the infringement is 6 July 2007 when the High Court annulled Servier's '947 patent.

5.8.4 Krka Agreements

(2126) Based on the conclusion in section 5.5.4 that the Krka Agreements restricted competition by their very object, the single and continuous infringement of Article 101 of the Treaty by Servier and Krka is established for the period starting from the conclusion of the Krka Settlement Agreement on 27 October 2006 until 6 May 2009 the date of the revocation of the '947 patent by the EPO, as of which date the agreement is considered no longer applicable.[2830] The infringement was

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2824 See also paragraph (1309).

2825 For Bulgaria and Romania, the infringement started on 1 January 2007, the date of the accession of these countries to the EU. For Latvia and Malta, the infringement started on 1 July 2005 and 1 March 2007, respectively, the dates of the accession of these countries to the European Patent Convention. As for Italy, the SPC for the compound patent only expired there on 13 February 2009. Therefore, the Commission assumes that Italy was not affected by the infringement in question.

2826 While the rest of the agreement, including certain other restrictions, remained in force after that date, the Commission chose an end date which was more favourable to the parties.

2827 The infringement was terminated earlier in the UK (6 July 2007) and the Netherlands (12 December 2007).

2828 See paragraph (1448).

2829 While the Teva Settlement Agreement (including all the restrictions on Teva) remained in force after the annulment of the '947 patent by the High Court, the Commission chose an end date which reflected the actual implementation of the agreement and which was more favourable to the parties.

2830 See Clause II) of the Settlement Agreement. ID0119, p. 26. Servier labels this approach as illogic, as the infringement duration would be longer in case the patent was valid than in the case that it would be rapidly invalidated (Servier's reply to the Statement of Objections, paragraph 1139, ID10114, p. 375-376). The Commission notes that the Krka Settlement Agreement prevented Krka's patent challenge to Servier, and it is common that an infringement is found for the entire duration of the restrictive

terminated earlier in the UK, on 6 July 2007, the date of the annulment of the '947 patent for the UK, and in the Netherlands, on 12 December 2007, the date of entry at risk by Apotex.[2831]

5.8.5 Lupin Settlement Agreement

(2127) Based on the conclusion in section 5.6.3 that the Lupin Settlement Agreement restricted competition by its very object, the infringement of Article 101 of the Treaty by Servier and Lupin for the EU markets is established for the period starting from the conclusion of the Lupin Settlement Agreement on 30 January 2007 until 6 May 2009, the date of the annulment of the '947 patent by the EPO.[2832] Five exceptions are noted: Malta, Italy, France, the UK and the Netherlands. In Malta, the infringement started on 1 March 2007, the date of the accession of the country to the European Patent Convention. The infringement also started later in Italy, on 13 February 2009 when the SPC for the compound patent only expired there.[2833] The infringement was terminated earlier in France, on 16 September 2008, the date of the first independent generic entry,[2834] in the UK, on 6 July 2007, the date of the annulment of the '947 patent for the UK, and in the Netherlands, on 12 December 2007, the date of entry at risk by Apotex.

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agreement. This said, the Commission needs to take into account elements showing that the restrictions were no longer effective (for example if the patent was no longer enforced and effective generic entry ensued). The Commission would also take into account that a settling party ceased to be a competitor, for example because it could no longer expect to overcome a patent barrier.

2831 For Bulgaria and Romania, the infringement started on 1 January 2007, the date of the accession of these countries to the EU. For Malta, the infringement started on 1 March 2007, the date of the accession of the country to the European Patent Convention. As for Italy, the SPC for the compound patent only expired there on 13 February 2009. Therefore, the Commission assumes that in Italy, the infringement started as of that date.

2832 While the Lupin Settlement Agreement remained in force after that date in certain Member States where the national equivalents of the '947 patent were still valid (see ID2365, p. 29), the Commission chose an earlier end date which was more favourable to the parties.

2833 Generic companies in Italy were able to prepare their entry to the market in Italy well before that date. Generic development times in the case of perindopril were on average two to three years. Servier in its reply to the Statement of Objections (paragraph 1438, ID10114, p. 439) stated that "**It is quite common that generic companies develop their product, obtain an MA but enter the market only upon the expiry of the patent. In any case, no market entry could have taken place before 13 February 2009*". The restrictions of clause 4 of the Lupin Settlement Agreement were likely to reduce Lupin's incentives to seek a marketing authorisation. However, in view of the earlier termination in the UK and the existence of accelerated mutual recognition procedures under which the Member States agree to recognise the validity of the marketing authorisation issued by another Member State, the starting date is conservatively set on 13 February 2009.

2834 Following clause 4.1 (c) of the agreement, see paragraph (1039).

6 FINAL PRODUCT MARKET

(2128) Perindopril[2835] is a maintenance medicine used in the treatment of hypertension, which is recognised as the most common chronic health condition in the human population. Middle-aged patients are expected to follow hypertensive treatment for prolonged periods of time.

(2129) Perindopril was a commercially successful product attracting interest from potential generic entrants. Perindopril had an established position in the selection process for first-time use patients and a growing patient base consisting of continued-use patients. In the course of its exclusivity over perindopril, Servier managed to increase its worldwide sales to over EUR 800 million in its peak year.[2836] At the same time, Servier's average operating margins over the production and distribution of perindopril were at the level of [90–100]* % and higher.[2837]

Table 10: Servier's worldwide sales of products containing perindopril

Result for the budget year	Units	Turnover (in EUR)	% of Servier's total turnover
2003/2004	[50–75]* million	[500–600]* million	[30–40]* %
2004/2005	[50–75]* million	[600–700]* million	[30–40]* %
2005/2006	[75–100]* million	[700–800]* million	[30–40]* %
2006/2007	[75–100]* million	[800–900]* million	[30–40]* %
2007/2008	[75–100]* million	[800–900]* million	[20–30]* %

Notes: The figures also include the sales generated by combination products, circa [5–10]* % of the total sales.

Source: ID0349, p. 581, 648, 745, 830 and 931.

(2130) Section 6.1 presents the demand and supply structure typically observed with respect to prescription medicines. Section 6.2 describes perindopril with respect to its technical (mode of action, main indications, prescription characteristics and basic chemical structure) and qualitative features (relative to other medicines, its characteristics and place in the relevant medical guidelines). Section 6.3 sets out the analytical universe applied in the subsequent sections. Section 6.4 provides an overview of the key characteristics of the relevant regulatory systems, the price and volume developments relating to perindopril and other selected products, and other information required for understanding the mechanisms determining the observed price and volume developments. Based on the factual description set out in sections 6.1 to 6.4, section 6.5 finds that Servier was dominant on the relevant market for perindopril in four Member States under analysis.

[2835] In section 6, all the references to 'perindopril' concern the final product, which in other parts of this document is also referred to as perindopril formulations in order to distinguish it from perindopril's API.

[2836] The majority of sales were generated on the EU markets, see *Annex B: Perindopril sales - geographic distribution*.

[2837] The figure is based on Servier's data for the top 13 EU markets, see also section 6.4.5.3.

6.1 Supply and demand structure

(2131) The pharmaceutical sector has a great variety of stakeholders, significant involvement of the state and a high degree of regulation. This subsection briefly explains the structure of supply and demand sides on the market for prescription medicines as well as the general life cycle of new medicines.

(2132) On the supply side, originator companies are active in research, development (including approval procedures), manufacturing, marketing and supply of innovative medicines. Their products are usually protected by patents for a certain period laid down by law (the *"term of the patent"*), allowing companies to recoup the significant upfront R&D costs and/or finance on-going R&D. The regulatory system ensures that originator companies can sell their products at high prices, thus providing them with incentives to continue innovating. The prices during the term of the patent are typically substantially above variable costs.

(2133) Generic medicines are those that have the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the originator (or 'reference') medicinal product and have been shown to be bioequivalent with it, by conducting bioavailability studies.[2838] Once data exclusivity periods expire, generic medicines can obtain Marketing Authorization ('MA') through an abridged procedure in which the generic company does not need to provide the results of pharmacological, pre-clinical and clinical trials and only needs to demonstrate bioequivalence with the reference product. The medicines authorities rely on the results of such pre-clinical tests and clinical trials submitted by the originator as part of its MA application in order to approve the generic product. Generic products are sold at significantly lower prices (up to 90% lower) than originator products. Generic entry generally leads to a shift of volumes from the originator to the generic company, unless, for example, the originator company manages to move the market to a second generation product.

(2134) Both generic and originator companies may buy APIs from specialised companies (upstream activity) unless they produce APIs themselves (see section 7 for further details on the API technology market).

(2135) On the demand side, the pharmaceutical sector is unusual in that, for prescription medicines, the ultimate consumer (the patient) is not the decision maker. As a general rule, the patient lacks the required medical expertise to determine the appropriate treatment. Decisions are generally made by the prescribing doctors. In certain Member States and typically limited to generic products, the pharmacist also plays a role. In most Member States, costs can be covered and/or reimbursed largely, or even wholly, by national health (insurance) schemes.

(2136) Another peculiarity of the pharmaceutical sector is that prices are, in many Member States, often the result of a regulated decision-making process, involving negotiations between the authorities representing buyers and the sellers (pharmaceutical companies). Where this is not the case, i.e. in countries with so-called 'free pricing', prices are typically dependent on the agreed/fixed reimbursement levels. As a result of reimbursement, doctors, pharmacists and

[2838] For this purpose different salts of API are considered to be the same API, unless they differ significantly with regard to safety and/or efficacy (see Article 10(2) (b) of Directive 2001/83/EC).

patients are not usually very price sensitive, although various mechanisms to control prescription medicine budgets do exist.

(2137) There are three distinct phases in the life cycle of an originator medicine: (1) R&D phase up to market launch; (2) the period between launch and expiry of the compound patent over the molecule, including any SPCs, and data exclusivity; and (3) the period after the expiry of the compound patent and data exclusivity, when generic products can obtain MA through the abbreviated procedure and enter the market.

(2138) During the first phase, companies identify potential new medicines, patent these new compounds and active substances and take them through intensive pre-clinical and clinical trials to confirm the safety and efficacy of the medicine. Companies also develop the industrial production processes and generally seek to protect these with additional patents.

(2139) The time between filing an application for the first compound patent and the launch of the product varies significantly, depending on the obstacles encountered.

(2140) During the second phase, originator companies, once they have obtained a marketing authorisation and pricing and reimbursement status, market the medicines they have developed. Medicines sold on prescription cannot be advertised to the general public in the EEA. Nonetheless, originator companies can advertise prescription medicines to practitioners through the supply of information and visits by medical sales representatives. The purpose of these activities, which are tightly regulated, is to promote their products and differentiate them from those of their competitors. In this regard the information supplied to practitioners must be accurate, up-to-date, verifiable, sufficiently precise and complete to enable practitioners to form their own opinion of the therapeutic value of the medicine.[2839] Originator companies often carry out clinical trials, even after they have obtained MA for their products, with a view to demonstrating the relative efficacy and limited side effects of their products. Such studies may also be conducted with a view to obtaining additional indications for their products. They might also consider refinement of their products or the launch of second generation products.

(2141) Pricing and reimbursement conditions are usually established *ex ante*, i.e. without any knowledge of actual substitution patterns between the product in question and other products and therefore without reference to the competitive mechanism. Any *ex post* significant deterioration of those conditions may limit the incentives to develop new products.[2840]

(2142) During the third phase, following the expiry of the patent and data exclusivity period, generic medicines enter the market. Although the compound patent is the first and strongest protection for the product, as it may make it impossible to reproduce the

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2839 See Articles 92-93 of Directive 2001/83/EC, as amended.

2840 The economic literature refers to the time inconsistency problem, where the policy choices which would be made at later dates if the authorities were starting afresh are inconsistent with commitments made at earlier dates. The policy of promoting R&D provides a good example of the time inconsistency problem. After the R&D investment is made, the authorities may be lured by a temporary gain of setting a low price for the newly-invented product. However, by doing so, the authorities will undermine their credibility and will lose their ability of attracting more R&D investments in the future. For definition of the time inconsistency problem, see: John Black, *A Dictionary of Economics, Oxford University Press*, 2002, page 467.

compound without infringing the patent, products are often still protected by other patents (e.g. process, formulation patents). Generic companies will try to find non-infringing ways to launch their product, usually as early as possible after the compound patent expires. They might also try to invalidate the relevant patent(s) as a way of removing barriers to entry. As aforementioned, when generic entry occurs, price tends to drop significantly (up to 80%-90%) and volume shifts to generics. This leads to the elimination of the high margin that the originator enjoyed during the period before generic entry. Regulatory systems usually have measures stimulating direct price competition between the originator product and generic products or anticipating statutory price cuts on generic entry.

6.2 Description of perindopril

(2143) The subsections below provide basic information on the product characteristics of perindopril in terms of its mode of action (section 6.2.1), main indications (section 6.2.2), contraindications and side effects (section 6.2.3), place and duration of treatment (section 6.2.4), different available salts (section 6.2.5), general production process and delivery form (section 6.2.6), different product brands (section 6.2.7), medical classification (section 6.2.8), medical guidelines (section 6.2.9) and basis for Servier's differentiation strategy (section 6.2.10).[2841]

6.2.1 Mode of action

(2144) Perindopril is a biologically active chemical substance designed to work by inhibiting the action of a body compound called *angiotensin converting enzyme* (ACE). Normally this enzyme converts *angiotensin I* into *angiotensin II*, as part of the human body's natural control of blood pressure. *Angiotensin II* is the so-called vasoconstrictor, i.e. it causes blood vessels to narrow, which consequently increases the pressure within the blood vessels. Since perindopril blocks the action of ACE, it reduces the *angiotensin II* conversion. This means that the blood vessels are allowed to relax and widen. The overall effect of this is a reduction in blood pressure (BP) and hence perindopril can be used in cases of hypertension.[2842] Due to its specific mode of action, perindopril is called an ACE inhibitor (ACEI).

(2145) The first ACE inhibitor, called captopril, has been on the market since the beginning of the 1980s and has been available generically since the 1990s.[2843] The group's composition in terms of all medicines belonging therein will be explained below.[2844]

2841 An important source of information for the below sections and in particular for the section 6.2.10 is Servier's internal orientation plans, where Servier outlines its policy for a next financial year. This type of document, while prospective in its aim, relies on the past experience. As a general rule, the document bearing in its title the year Y/Y+1 (e.g. 2009/2010) is drafted in September of the year Y-1 (e.g. 2008) and largely draws on the facts observed in the preceding period (ID2687, p. 1). This time shift implies that documents bearing in the title the year after the relevant period will actually contain contemporaneous information from the investigated period.

2842 ID0108, p. 115 - 116.

2843 Information based on the IMS data. For this and all subsequent references to the IMS data, it must be noted that data and other information obtained from IMS Health, a provider of pharmaceutical data services, that is cited or used in this Decision (including empirical analyses performed by the Commission) were obtained by the Commission through information requests issued pursuant to Article 18 of Council Regulation 1/2003. IMS Health has not acted as an advisor, expert or consultant on behalf of the Commission in connection with this proceeding. IMS Health is acknowledged by Servier, among others, as a leading reference data provider in the pharmaceutical sector (ID1151, p. 3).

2844 See section 6.2.8.

6.2.2 Perindopril's indications

(2146) Perindopril was first registered in Europe between 1988 and 1989 for the treatment of hypertension. A new therapeutic indication for treating cardiac insufficiency, also known simply as heart failure was approved a few years later, e.g. in 1992 in France. In 2006, the French authorities issued a marketing authorisation for the treatment of coronary heart disease, which is the third and, currently, last indication for the use of perindopril.[2845]

6.2.3 Contraindications and side effects related to perindopril

(2147) Perindopril's main contraindications are: (i) hypersensitivity to perindopril, to any of the components used in the tablets or to any other ACE inhibitor, (ii) history of angioedema associated with previous ACE inhibitor therapy, (iii) hereditary or idiopathic angioedema, and (iv) second and third trimesters of pregnancy. There are also special warnings and precautions for its use. For example, perindopril, as well as other ACE inhibitors, may cause hypotension i.e. too low blood pressure, especially at the start of the treatment.[2846]

(2148) Common undesirable side effects of perindopril i.e. those observed in more than 1/100 but fewer than 1/10 patients are: nervous system disorders (headache, dizziness, vertigo, paraesthesia), eye disorders (vision disturbance), ear and labyrinth disorders (tinnitus), cardio-vascular disorders (hypotension and effects related to hypotension), respiratory, thoracic and mediastinal disorders (cough, dyspnoea), gastro-intestinal disorders (nausea, vomiting, abdominal pain, dysgeusia, dyspepsia, diarrhoea, constipation), skin and subcutaneous tissue disorders (rash, pruritus), musculoskeletal, connective tissue and bone disorders (muscle cramps) and general disorders (asthenia).[2847]

(2149) More precise information can be found in the medical literature, where it is stated that *"[p]erindopril is generally well tolerated, with an adverse effect profile similar to that of other ACE inhibitors. In a post-marketing surveillance study (n=47 351) of perindopril 2 to 8mg once daily for 1 year, adverse events were spontaneously reported by 16.3% of patients. The most common adverse events were cough, GI [gastrointestinal] upset/dyspepsia and asthenia[weakness]"*.[2848] Servier internally praised its product for being recognised for its *"high level of tolerance and compliance"*.[2849]

2845 ID1151, p. 9, ID0119, p. 273. In internal strategy papers analysing the product's qualitative positioning, e.g. "Coversyl Orientation Plan 2005/2006", Servier refers to three main diagnoses/indications for which its perindopril, Coversyl, was prescribed: hypertension (HT), ischemic heart disease (IHD), heart failure (HF) (source: ID0349, p. 579) In addition, there are several countries where perindopril gained an indication for stroke (source: ID0349, p. 585).
Servier explained that the market for plain perindopril was analysed on the basis of three indications: "*Hypertension (HT) + Heart failure (HF) + Coronary disease (CD)". The WHO in its International Statistical Classification of Diseases and Related Health Problems assigned the following codes to them: HT – I10, HF – I50 and I51, and CD – I20 to I25 (source: http://www.who.int/classification/icd/en/).

2846 ID0108, p. 109 - 112.

2847 ID0108, p. 114.

2848 See: Hurst, M; Jarvis, B, *Perindopril; An Updated Review of Its Use in Hypertension*, Drugs 2001: 61 (6), p. 888.

2849 ID0349, p. 851.

(2150) It should be stressed that undesirable side effects can play a very important role in the success or failure of the antihypertensive treatment. The 2007 European Society of Hypertension and European Society of Cardiology Guidelines[2850] call for particular attention to *"be given to adverse events, even when of a purely subjective nature, because adverse events are the most important cause of non-compliance. Adverse events during antihypertensive treatment are not entirely avoidable because they may have, in part, a psychological nature and indeed are also reported during administration of placebo. Great effort should be devoted, however, to limitation of drug-related side effects and preservation of the quality of life either by switching treatment from the responsible drug to another agent or by avoiding unnecessary increases of the dose of the drug employed"*.[2851]

6.2.4 Place and duration of treatment

(2151) Perindopril is mainly prescribed outside hospital in ambulatory care. At the aggregated level of the first-time and continued-use prescriptions, hospital prescriptions are in a clear minority.[2852] However, there is some evidence suggesting that among the hospital prescriptions there is a larger proportion of first-time prescriptions than among the non-hospital prescriptions.[2853] This being said, the bulk of first prescriptions are written outside hospital.

(2152) Based on Servier's promotional materials, both general practitioners (GPs) and cardiologists prescribed perindopril for their patients. GPs were said to treat ordinary hypertensive patients, while cardiologists dealt with more complicated cases involving patients suffering from hypertension and related coronary diseases.[2854]

(2153) The available guidelines[2855] suggest that most patients treated with hypertension medicines continue to use them for the rest of their lives. The UK's National Institute for Health and Clinical Excellence (NICE) recommends patients carry on with treatment if it is bringing blood pressure down, even if the target blood pressure is not achieved. Doctors may agree to patients reducing or stopping taking the medication altogether only if the risk of heart attack or stroke is not high and the patients' blood pressure is under control. This is usually subject to significant lifestyle changes. However, according to the 2007 European Society of Cardiology (ESC) and European Society of Hypertension (ESH) Guidelines, lifestyle measures are not proven to prevent cardiovascular complications in hypertensive patients, and long-term compliance with their implementation is notoriously low. For middle-aged hypertensive patients, treatment with hypertension medicines is likely to last 20 to 30 years. Hypertension is recognised as the most common chronic condition in human beings.[2856]

(2154) In the Commission's survey of prescribers, most of the respondents expected the continued-use patients of perindopril to continue with perindopril treatment for more

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2850 *ESC and ESH Guidelines*, European Heart Journal (2007) 28, p. 1462-1536.

2851 *ESC and ESH Guidelines*, European Heart Journal (2007) 28, p. 1493 - 1494.

2852 For detailed figures, see section 6.3.2.

2853 See *Annex D: Survey of prescribers*.

2854 ID0349, p. 400 - 401.

2855 For instance: *ESC and ESH Guidelines*, European Heart Journal (2007) 28, 1462-1536, *Information about NICE clinical guideline 34*, NHS National Institute for Health and Clinical Excellence, June 2006.

2856 ID0349, p. 812.

than five years.[2857] This is consistent with Servier's own expectations with respect to the length of the treatment period of hypertensive patients. In the 2005/2006 Coversyl Orientation Plan, Servier underlined the rationale for targeting the patients at the beginning of cardiovascular continuum: *"[p]atients who will gain most are young patients, with no or few cardiovascular risks. In hypertension, 70% of patients still have no complications. They should benefit from COVERSYL as first-line treatment and for a very long time"*.[2858] The CEGEDIM (Centre de Gestion, de Documentation, d'Informatique et de Marketing – Centre of Management Documentation, IT and Marketing) data submitted by Servier after the Oral Hearing allows for estimating the average length of the perindopril treatment at seven to eight years,[2859] which is fully consistent with the above-mentioned results of the Commission's survey of prescribers.[2860]

6.2.5 Perindopril salts

(2155) The perindopril API takes the form of salt. There are two main salts of perindopril registered and marketed: *tert-butylamine* (also known under the name of *erbumine*,[2861] the latter name is used in the present Decision) and *arginine*. The *erbumine* salt was first marketed in 1988. There were initially two dosages – 2 mg and 4 mg. An additional dosage of 8 mg was registered at a later stage. The *arginine* salt was introduced as a part of Servier's strategy against generic entry.[2862] The *arginine* salt has a different molecular weight and therefore the corresponding dosages are 2.5 mg, 5 mg and 10 mg. The first marketing authorisation for the *arginine* salt was obtained in 2004,[2863] but it was only commercialised much later when generic entry of perindopril *erbumine* occurred (or was imminent) in the respective territories.

2857 See section 6.4.5.7 and *Annex D: Survey of prescribers*.

2858 ID0349, p. 608.

2859 The CEGEDIM data (ID9977) allows for the quantification of the dynamics of switching process in terms of switches away from the perindopril treatment. The exact quantification is possible with respect to the initial period of five years. The Commission has estimated the remaining treatment time by extrapolating the average erosion ratio observed in the last 24 months of the initial period. The erosion process is assumed to continue at the same rate until the last patient from the analysed cohort stops the treatment. On the basis of this assumption, it can be shown that the patient who continued the perindopril treatment after six months from the first prescription was expected to be prescribed perindopril on average for seven years, while the patient who continued the perindopril treatment after twelve months from the first prescription was expected to be prescribed perindopril on average for eight years. For the underlying switching dynamics see section 6.4.5.5.

2860 In its reply to the Commission's Letter of Facts, Servier argues that the Commission changes its position by indicating that the perindopril treatment was expected to be on average seven to eight years. According to Servier, the Commission's assessment in the Statement of Objection relied on the assumption of a life-long treatment (Servier's reply to the Letter of Facts, paragraphs 107-109, ID10324, p. 35-36). The Statement of Objections established the following facts: hypertension usually requires a life-long treatment, according to the Commission's survey the clear majority of respondents expected their established patients to continue the perindopril treatment for more than five years, Servier's internal documents indicate that a big part of the perindopril patients should benefit from the Servier treatment for a very long time (SO, paragraphs 1118-1119). Those facts were not contested and are repeated in the present Decision (paragraphs (2153)-(2154)). The Commission clearly distinguishes between the expectations as to the general duration of treatment with hypertension medicines and the duration of the perindopril treatment. The estimation of the average length of the perindopril treatment to last seven to eight years falls squarely within the facts relied on in the Statement of Objections.

2861 ID0053, p. 89.

2862 See section 4.1.2.7.

2863 ID1151, p. 9, ID9974, p. 21, ID9974, p. 783.

(2156) In this context, it is important to highlight that the development of perindopril *arginine* was pursued with the objective to find *"*the immediate replacement (annuls and replaces) while retaining all the therapeutic indications"*.[2864]

(2157) From Sanofi-Aventis'[2865] submission, it is apparent that a third salt of perindopril is now available, a sodium salt. However, there is no information to establish that any final product based on this salt entered the market in any Member State before 31 March 2010.[2866]

6.2.6 General production process and delivery form

(2158) As a general rule for medicines based on chemical molecules like perindopril, an API is obtained by way of chemical synthesis. In order to produce a product with the desired pharmacological properties, the entire process may involve many operations during which chemical molecules undergo numerous transformations. The process description contained in patents will usually provide information on the precise conditions in which the transformations are supposed to take place. Depending on the number of steps foreseen in the course of the chemical synthesis, as well as the chemical characteristics of a synthesised substance, the synthesis process may take from some hours to a few days. The final result must meet the conditions specified in the product's monograph.[2867]

(2159) Perindopril is sold in the form of tablets. The API is mixed with non-active ingredients and compressed into tablets. As explained, perindopril tablets are available in three basic dosages, i.e. the perindopril tablets contain different amounts of the API. According to Servier's *"product ideology"*, such a three-step range of dosages serves both doctors and patients.[2868] In its *"Coversyl Orientation Plan 2005/2006"*, Servier explained that *"Coversyl has a dose range that makes it the simplest to prescribe in both indications: [i] in hypertension, one 4mg tablet daily is the effective starting dose and also the usual maintenance dose, the maximum effective dose being only 8mg, [ii] in heart failure, treatment is safely initiated with 2mg daily, one 4mg tablet daily is the usual maintenance dose"*.[2869]

(2160) In general, it is recommended that perindopril is taken once daily in the morning before a meal. It is effective over 24 hours. The dose should be individualised according to the patient profile and blood pressure response.[2870] This is necessarily a part of the selection process in the initial trial period.

(2161) There are also two types of fixed-dose combinations of perindopril with other APIs. The first type of combination includes perindopril and indapamide. It is available in two dosages. The ratios represent perindopril to indapamide respectively (i) 2 mg: 0.625 mg, and (ii) 4 mg: 1.25 mg.[2871] The second is the more recent combination of perindopril and amlodipine. It is available in four different dosages. The ratios represent perindopril to amlodipine respectively (i) 5 mg: 5 mg, (ii) 5 mg: 10 mg,

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2864 ID9974, p. 554.

2865 Sanofi-Aventis is active in the generic business via its subsidiary Winthrop.

2866 ID1967, p. 14.

2867 ID0375, p. 1 – 7; see also section 4.1.2.2 for information concerning the publication of the pan-European monograph for perindopril erbumine.

2868 ID0349, p. 545.

2869 ID0349, p. 545.

2870 ID0108, p. 107, ID0349, p. 789.

2871 ID1151, p. 14.

(iii) 10 mg: 5 mg and (iv) 10 mg: 10 mg.[2872] The dosages of this second combination are based on the *arginine* salt, hence the higher number of milligrams indicated for perindopril.[2873]

6.2.7 Product brands

(2162) A given molecule can have only one international non-proprietary name (INN). In the present case, it is perindopril. However, pharmaceutical producers can register more than one brand name for the same medicine.

(2163) Broadly speaking, Servier used the brand names "Coversyl" and "Prestarium" in the Western European and CEE Member States, respectively, for plain perindopril.[2874]

(2164) Generic companies usually sell their products unbranded using the INN. The CEE markets are an exception in this respect. The lack of a strong substitution mechanism[2875] seems to induce generic companies to introduce their own brands and often to promote them actively through their networks of sales representatives.[2876] For example, Polpharma, a Polish generic producer, informed the Commission of as many as six generic brands of perindopril now present in Poland. They are: Prenessa (by Krka), Apo-Perindox (by Apotex), Vidotin (by Gedeon Richter), Lextril (by Glenmark), Perindoran (by Ranbaxy) and Stopress (by Polpharma).[2877]

6.2.8 Perindopril within the medical classification

(2165) In the Anatomical Therapeutic Chemical (ATC) classification system, medicines are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Both the World Health Organization (WHO)[2878] and the European Pharmaceutical Market Research Association (EphMRA)[2879] maintain systems that classify medicines according to their therapeutic indications.

(2166) The main purpose of the WHO classification is for international drug utilisation research and for adverse drug reaction monitoring. The EphMRA classification has the primary objective of satisfying the marketing needs of the pharmaceutical companies. The two classifications have been to a large extent harmonized with the aim of reaching, whenever possible, an agreement on all mono substances in a given class as listed in the WHO ATC Index (2009), mainly at the third level of classification (the ATC3 level).[2880]

2872 ID1143.

2873 See section 6.3.1 for the sales of plain and combination versions of perindopril.

2874 ID1143; Servier also registered several brand names for its combination products, e.g.: Preterax, Bipreterax (perindopril and indapamide), Coveram (perindopril and amlodipine).

2875 For example. see section 6.4.4.2.

2876 For example, it can be deducted from the information provided to the Commission by Polpharma that the total number of sales representatives promoting perindopril on behalf of the generic companies present on the Polish market in the second half of 2009 was higher than the relevant number for Servier. (ID7956, p. 33).

2877 ID7956, p. 9.

2878 For more information, see at: http://www.whocc.no/atc/structure_and_principles/

2879 For more information, see: *EphMRA/PBIRG Classification Committee; Who we are; What we do 2013*, available at: http://www.ephmra.org/user_uploads/who-atc%202013%20final.pdf

2880 See: *Comparison of the WHO ATC classification & EphMRA/PBIRG anatomical classification; Version January 2013*, document available at: http://www.ephmra.org/user_uploads/who-atc%202013%20final.pdf

(2167) For perindopril at the ATC3 level, the WHO classification overlaps with that of the EphMRA. In both classifications, plain ACE inhibitors are distinct groups at the third layer of coding. The group called "plain ACE inhibitors" bears the code C09A in the WHO classification and C9A in the EphMRA classification.[2881] In addition, in the WHO classification, there is a full overlap between the ATC3 and the ATC4 level, since the code C09A has only one subgroup, namely C09AA.[2882] Altogether there are sixteen plain ACE inhibitors listed under the same ATC3 level code of the WHO classification (see Table 11).

Table 11: Full list of ACE inhibitors

C09AA ACE inhibitors, plain		**C09BA ACE inhibitors and diuretics**	
C09AA01	captopril	C09BA01	captopril and diuretics
C09AA02	enalapril	C09BA02	enalapril and diuretics
C09AA03	lisinopril	C09BA03	lisinopril and diuretics
C09AA04	perindopril	C09BA04	perindopril and diuretics
C09AA05	ramipril	C09BA05	ramipril and diuretics
C09AA06	quinapril	C09BA06	quinapril and diuretics
C09AA07	benazepril	C09BA07	benazepril and diuretics
C09AA08	cilazapril	C09BA08	cilazapril and diuretics
C09AA09	fosinopril	C09BA09	fosinopril and diuretics
C09AA10	trandolapril	C09BA12	delapril and diuretics
C09AA11	spirapril	C09BA13	moexipril and diuretics
C09AA12	delapril	C09BA15	zofenopril and diuretics
C09AA13	moexipril	**C09BB ACE inhibitors and calcium channel blockers**	
C09AA14	temocapril	C09BB02	enalapril and lercanidipine
C09AA15	zofenopril	C09BB03	lisinopril and amlodipine
C09AA16	imidapril	C09BB04	perindopril and amlodipine
		C09BB05	ramipril and felodipine
		C09BB10	trandolapril and verapamil
		C09BB12	delapril and manidipine

Information source: http://www.whocc.no.

(2168) Apart from ACE inhibitors, there are four other main types of antihypertensive medicines: (i) beta-blockers, (ii) diuretics, (iii) calcium channel blockers (CCBs), and (iv) angiotensin-II receptor blockers (ARBs – hereinafter 'sartans').[2883] All of them constitute separate classes at either ATC2 or ATC3 levels of the WHO and the EphMRA classification.

(2169) Table 12 sets out the general classification of the main types of antihypertensive medicines and provides basic information on modes of action and the expected results for the patients in treatment. The four ATC2 classes comprise over 100 single-molecule medicines, not including numerous combinations.[2884]

2881 Ibid.

2882 Information source: http://www.whocc.no/atc_ddd_index/?code=C09AA04

2883 *2003 Guidelines for Management of Hypertension*, Journal of Hypertension 2003, Vol. 21 No 6, p. 1034.

2884 Information established based on the review of the complete classification: http://www.whocc.no/.

Table 12: ATC2-3 classification of main antihypertensive classes (by WHO) and basic information on modes of action

C03 DIURETICS		C07 BETA BLOCKING AGENTS	
Basic description: Diuretics work by causing the kidneys to increase the amount of salts such as potassium and sodium that are filtered out of the blood and into the urine. When these salts are filtered out of the blood by the kidneys, water is also drawn alongside. Removing water from the blood decreases the volume of fluid circulating through the blood vessels. This subsequently decreases the pressure within the blood vessels.		Basic description: Beta-blockers work by blocking beta receptors that are found in various parts of the body, including the heart. As a result, they reduce the energy used by the heart to pump blood around the body and reduce the heart's need for oxygen.	
ATC3 level:		**ATC3 level:**	
C03A	LOW-CEILING DIURETICS, THIAZIDES	C07A	BETA BLOCKING AGENTS
C03B	LOW-CEILING DIURETICS, EXCL. THIAZIDES	C07B	BETA BLOCKING AGENTS AND THIAZIDES
C03C	HIGH-CEILING DIURETICS	C07C	BETA BLOCKING AGENTS AND OTHER DIURETICS
C03D	POTASSIUM-SPARING AGENTS	C07D	BETA BLOCKING AGENTS, THIAZIDES AND OTHER DIURETICS
C03E	DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION	C07E	BETA BLOCKING AGENTS AND VASODILATORS
C03X	OTHER DIURETICS	C07F	BETA BLOCKING AGENTS AND OTHER ANTIHYPERTENSIVES
C08 CALCIUM CHANNEL BLOCKERS		**C09 AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM**	
Basic description: CCBs slow down the movement of calcium through the muscle cells that are found in the walls of blood vessels. They do this by blocking 'calcium channels' in these muscle cells. Calcium is needed by muscle cells in order for them to contract, so by depriving them of calcium, CCBs cause the muscle cells to relax. The relaxing and widening of the small arteries in the body decreases the resistance that the heart has to push against in order to pump the blood around the body.		Basic description of ARBs (sartans) (C09C): ARBs block the receptors that angiotensin II acts on, and so prevent its actions. The main result of this is that the peripheral blood vessels are allowed to widen, which means that there is more space and less resistance in these blood vessels. Basic description of ACE inhibitors (C09A): ACE inhibitors work by inhibiting the action of the *angiotensin converting enzyme* (ACE). Normally this enzyme converts *angiotensin I* into *angiotensin II*, as part of the human body's natural control of blood pressure. *Angiotensin II* is the so-called vasoconstrictor. As ACE inhibitors block the action of ACE, they reduce the *angiotensin II* conversion, blood vessels can widen and thus blood pressure is reduced.	
ATC3 level:		**ATC3 level:**	
C08C	SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS	C09A	ACE INHIBITORS, PLAIN
C08D	SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS	C09B	ACE INHIBITORS, COMBINATIONS
C08E	NON-SELECTIVE CALCIUM CHANNEL BLOCKERS	C09C	ANGIOTENSIN II ANTAGONISTS, PLAIN
C08G	CALCIUM CHANNEL BLOCKERS AND DIURETICS	C09D	ANGIOTENSIN II ANTAGONISTS, COMBINATIONS
		C09X	OTHER AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

Information source: http://www.whocc.no/ and http://www.netdoctor.co.uk.

(2170) The foregoing classes also cover a number of combinations. In order to systematise the most important combinations, it is worth referring to six different combinations

of antihypertensive medications recommended in the 2007 ESH and ESC Guidelines, those are:

- hydrochlorothiazide (hctz)[2885] + ACE inhibitor (classified under C09BA – ACE inhibitors and diuretics),
- hydrochlorothiazide (hctz) + ARB sartan (classified under C09DA - angiotensin II antagonists and diuretics),
- CCB + ACE inhibitor (classified under C09BB – ACE inhibitors and calcium channel blockers),
- CCB + ARB (classified under C09DB – angiotensin II antagonists and calcium channel blockers),
- CCB + hydrochlorothiazide (classified under C08GA – calcium channel blockers and diuretics) and
- beta-blocker + CCB (classified under C07F – beta blocking agents and other antihypertensives).[2886]

The ATC classification relates to the existing fixed combinations which does not exclude that practitioners prescribe other multi-agent treatments where each component medicine is separately administered.

(2171) For the sake of completeness, it must be noted that in its response to the Commission's RFI of 6 August 2009, Servier states that in its analysis of the market for plain perindopril, the company used the C9 and C8 (in particular amlodipine) classes in the EphMRA system.[2887]

6.2.9 Medical guidelines

(2172) A broader view regarding the relations, in terms of medical use, between various cardiovascular medications necessarily needs to include the relevant medical guidelines. The purpose of these guidelines is educational, aiming to offer balanced information to practitioners to help them make decisions in everyday practice. They are also intended for public health authorities, to raise awareness and improve management of hypertension and coronary heart diseases. They are based on all the available sources of scientific evidence, including large clinical trials and their meta-analysis. Before and during the period concerned (2000-2009), there were a number of medical guidelines published. They are described in this section, including the guidelines issued by the WHO and International Society of Hypertension (ISH) in 1999, by the ESH and the ESC in 2003 and 2007, by the British Hypertension Society (BHS) in 1999 and 2004 and by the NICE from the UK in 2004 and 2006.

2885 Hydrochlorothiazide (hctz) is a type of medicine called a thiazide diuretic. Thiazide diuretics act in the kidneys, where they increase the production of urine. Information source: http://www.netdoctor.co.uk/heart-and-blood/medicines/dyazide.html.

2886 ID0349, p. 897. However, *"[a]mong combinations recommended for antihypertensive treatment, a combination of an ACE inhibitor with a CCB is considered as to have the largest evidence base"* (ID0349, p. 916). According to the 2006 UK prescription guidelines in hypertension, the complementarities between individual classes of hypertension medicines should be considered for second-line and third-line treatments (ID0349, p. 918). The earlier version of the ESH and ESC Guidelines, the 2003 edition, listed also two other combinations, namely: diuretic and beta-blocker, and alpha-blocker and beta-blocker, *2003 Guidelines for Management of Hypertension*, Journal of Hypertension 2003, Vol. 21 No 6.

2887 ID1151, p. 4.

(2173) Nonetheless, before summarising the guidelines, it is worth noting that doctors are routinely faced with individual cases which have their own particularities for which the advice set out in the guidelines may not be directly applicable. For example, in the "*2008/2009 Preterax Orientation Plan"*, Servier relied on survey results where it was claimed that the guidelines were not among the main reasons for practitioners to prescribe Servier's combination of perindopril and indapamide. In the same survey, the practitioners interviewed claimed to take the following factors into account: BP-lowering efficacy (36%), tolerability (20%), end organ protection (17%) and ease of use (13%).[2888]

(2174) Even though the guidelines may, due to their general character, not have been examined on an on-going basis by doctors with respect to choices for individual patients, they nonetheless offer a balanced summary of the medical knowledge that was available during the investigated period.[2889] Notably this includes important issues such as the expected treatment outcomes, the likelihood of switching to another agent (product) in and after the initial trial period and of combining a number of agents within a single therapy.

6.2.9.1 World Health Organisation – International Society of Hypertension Guidelines for the Management of Hypertension

(2175) The 1999 WHO-ISH guidelines[2890] were written to guide specialists responsible for the care of hypertensive patients. The guidelines were not intended to offer rigid rules that would constrain practitioners in their judgment about the management of individual patients, who were said to differ in their personal, medical, social, ethnic and cultural characteristics. In this regard, they are written for a global audience, from communities that vary widely in the nature of their health systems and the availability of resources.

(2176) The guidelines focus on the management of patients with 'mild' hypertension on the basis that there is often uncertainty among clinicians on how to manage this condition, although they also deal with the management of more severe forms of hypertension. They relate high blood pressure levels to several cardiovascular diseases such as stroke, coronary heart disease and heart failure. As a means to lower blood pressure, they refer to a number of treatments available for patients: *"The six main drug classes used, worldwide, for blood pressure lowering treatment are: diuretics, beta-blockers, calcium antagonists, ACE inhibitors, angiotensin II antagonists and alpha-adrenergic blockers"*. The guidelines provide the basic principles of prescribing medicines: *"[i] the use of low doses of drugs to initiate therapy […], [ii] the use of appropriate drug combinations to maximise hypotensive efficacy while minimising side effects […], [iii] changing to a different drug class altogether if there is very little response or poor tolerability to the first drug used, [iv] the use of long-acting drugs providing 24-hour efficacy on a once daily basis"*.

2888 ID0349, p. 1242. The guidelines themselves acknowledge that practitioners need to apply their general medical knowledge and clinical judgment when applying recommendations made in the guidelines, which may not be appropriate in all circumstances. The response of individual patients must also be considered (see NICE Clinical Guideline 18, p.6) as well as the indications, contra-indications and precautions listed in the Summary of Product Characteristics (SmPC) or in a particular local resource (e.g. in the UK, the British National Formulary 'BNF').

2889 Different guidelines also acknowledge the fact that previous guidelines were not adequately implemented or that despite previous guidelines, the management of hypertension and coronary heart diseases remained sub-optimal (see, e.g., 2003 ESH guideline, p.1044, 2004 BSH guideline, p. 3).

2890 Journal of Hypertension (1999), Vol. 17: 151 - 185.

(2177) The guidelines state that *"all available drug classes are suitable for the initiation and maintenance of antihypertensive therapy, but the choice of drugs will be influenced by many factors"*. The guidelines provide a selection grid specifying indications and contraindications for each class of medicines (see Table 13 below).

Table 13: Indications and contraindications for different classes of hypertensive medicines according to the 1999 WHO-ISH guidelines

Class of medicine	Compelling indications	Possible indications	Compelling contraindications	Possible contraindications
Diuretics	Heart failure Elderly patients Systolic hypertension	Diabetes	Gout	Dyslipidaemia Sexually active males
Beta-Blockers	Angina After myocardial infarct Tachyarrhythmias	Heart failure Pregnancy Diabetes	Asthma and chronic obstructive pulmonary disease Heart block	Dyslipidaemia Athletes and physically active patients Peripheral vascular disease
ACE Inhibitors	Heart failure Left ventricular dysfunction After myocardial infarct Diabetic nephropathy		Pregnancy Hyperkalaemia	Bilateral renal artery stenosis
Calcium Antagonists		Peripheral vascular disease	Heart block	Congestive heart failure
Alpha-Blockers	Prostatic hypertrophy	Glucose intolerance Dyslipidaemia		Orthostatic hypotension
Angiotensin II Antagonists	ACE Inhibitor cough	Heart failure	Pregnancy Bilateral renal artery stenosis Hyperkalaemia	

Source: Journal of Hypertension (1999), Vol. 17: 151-185, Table 4.

(2178) It is worth noting that ARBs (sartans) were encouraged for patients suffering from the ACE inhibitor-related cough. Such a side effect for ACE inhibitors could only be known after a patient was treated for an initial period with one of the ACE inhibitors, therefore the 1999 WHO-ISH guidelines viewed ARBs as a possible second line treatment when ACE inhibitors were not well tolerated.[2891]

(2179) The 1999 WHO-ISH also pointed out the fact that *"combination therapy of several of the available drug classes has been shown to produce blood pressure reductions that are greater than those produced by any group of individual agents used alone"*. The guidelines cited the study indicating that *"combination therapy was necessary in 70% of patients"* and listed, among effective combinations, a diuretic and an ACE inhibitor (or a sartan), and a calcium antagonist and an ACE inhibitor.

[2891] See also paragraph (2149).

6.2.9.2 Pan-European guidelines for management of hypertension

(2180) From a European perspective, the most comprehensive overview is provided by the 2007 ESH and ESC Guidelines.[2892] This document was intended to disseminate state-of-the-art information on the use of antihypertensive medicines. It begins by recognising that the 1999 WHO guideline was written for a global audience, whereas Europe is a much more homogeneous community with populations enjoying greater longevity but suffering a higher incidence of chronic cardiovascular diseases. Thus, the guidelines respond to WHO suggestions for more specific regional guidelines directed towards the management of patients in specific regions. The 2007 edition was published four years after the first ever pan-European guidelines for management of hypertension.[2893] Whenever the two versions diverge in an important way from the point of view of the description provided in this section, such a divergence is reflected either in the main text or by means of a footnote. Both guidelines will be jointly referred to as the European guidelines, unless there is a need for more precise identification. In its own strategy papers, such as *"Promotional Campaign Plans"* and *"Orientation Plans"* for Coversyl, Servier frequently refers to the European guidelines as endorsing the use of its product.[2894] Those references were made despite the fact that the guidelines' focus is on the entire class of antihypertensive medicines.

(2181) The 2007 ESH and ESC Guidelines make it clear that the selection of a hypertension medicine needs to be based on the individual patient (this point is of considerable importance in the assessment of the relevant market). At the most general level, the Guidelines state that:

"1) the main benefits of antihypertensive treatment are due to lowering of blood pressure per se, and are largely independent of the drugs employed, and 2) thiazide diuretics (as well as chlorthalidone and indapamide), b-blockers, calcium antagonists, ACE inhibitors and angiotensin receptor antagonists can adequately lower blood pressure and significantly and importantly reduce cardiovascular outcomes. Therefore all these drugs are suitable for the initiation and maintenance of antihypertensive treatment either as monotherapy or in some combinations with each other. Each of the recommended classes may have specific properties, advantages and limitations, which are discussed in [the Guidelines] so that doctors may make the most appropriate choice in individual patients.

[…]

[T]here is now conclusive evidence from trials that combination treatment is needed to control blood pressure in the majority of patients. Thus, if two or more drugs are taken for the lifetime of the patients it is of marginal relevance which is the one used alone for the first few weeks of therapy. However, drug classes (and even compounds within a given class) differ in type and frequency of adverse effects they may induce, and different individuals may be differently prone to develop a given adverse effect. Furthermore, drugs may have different effects on risk factors, organ damage and cause-specific events and show specific protective influences in special groups of patients. This makes selection of a given agent alone or in association with other drugs mandatory or advisable according to the circumstances. As a general scenario

2892 *ESC and ESH Guidelines*, European Heart Journal (2007) 28, 1462-1536.

2893 *2003 Guidelines for Management of Hypertension*, Journal of Hypertension (2003), Vol. 21 No 6.

2894 ID0349, e.g. p. 332, 338, 570, 814 and 816.

the choice or the avoidance of drugs should take into account the following: 1) the previous favourable or unfavourable experience of the individual patient with a given class of compounds […]; 2) the effect of drugs on cardiovascular risk factors in relation to the cardiovascular risk profile of the individual patient; 3) the presence of subclinical organ damage, clinical cardiovascular disease, renal disease or diabetes […]; 4) the presence of other disorders […]; 5) the possibility of interactions with drugs used for other conditions […]; 6) the cost of drugs […]. Cost considerations, however, should never predominate over efficacy, tolerability, and protection of the individual patient".[2895]

(2182) General knowledge of the various classes of antihypertensive medicines guides the choice of practitioners who need to tailor the therapy to the requirements of individual patients. Both the 2003 and the 2007 ESH and ESC Guidelines provide a list of indications and contra-indications for specific medicine classes, including ACE inhibitors. Table 14 below compares the two sets of guidelines indications for ACE inhibitors. These indications are often shared with other classes of antihypertensive medicines, in particular with ARBs (sartans) that, according to the 2007 edition, share most of the indications listed for ACE inhibitors except carotid atherosclerosis,[2896] left ventricle dysfunction[2897] and non-diabetic nephropathy. ACE inhibitors are the only advised class of antihypertensive medicines for the latter two conditions.[2898] As regards contra-indications, ACE inhibitors are contraindicated in cases of pregnancy, angioneurotic oedema, hyperkalaemia or bilateral renal artery stenosis.

2895 *ESC and ESH Guidelines*, European Heart Journal (2007) 28, p. 1492-1493.

2896 The prevalence of carotid atherosclerosis is 25.4% in men and 26.4% in women. See: Stroke: 1992; 23, p. 1705 - 1711.

2897 The prevalence of left ventricular systolic dysfunction is 5.5% in men and 2.2% in women. See: Mosterd, A; Hoes, M. C., and others, *Prevalence of heart failure and left ventricular dysfunction in the general population*, European Heart Journal (1999) 20 (6): 447 – 455, p. 450.

2898 This is contrary to Servier's claim of the full overlap between ACE inhibitors and sartans in terms of their therapeutic indications (see Servier's reply to the Statement of Objections, paragraph 1475, ID10114, p. 450-451). Certain differences in conditions favouring the use of ACE inhibitors and sartans were also indicated in the *2003 ESH and ESC Guidelines* (see Table 7 of the guidelines), e.g. ACE-inhibitors were advised for patients with congestive heart failure, left ventricular dysfunction, post-myocardial infarction, non-diabetic nephropathy and type 1 diabetic nephropathy, while sartans for type 2 diabetic nephropathy, diabetic microalbuminuria, left ventricular hypertrophy and ACE-inhibitor cough. Both classes were indicated for proteinuria.

Table 14: Indications for the use of ACE inhibitors according to the ESH and ESC Guidelines

Version 2003	Version 2007
Congestive heart failure	Heart failure
Left ventricle dysfunction	Left ventricle dysfunction
Post-myocardial infarction	Post-myocardial infarction
Non-diabetic nephropathy	Diabetic nephropathy
Type 1 diabetic nephropathy	Non-diabetic nephropathy
Proteinuria	Left ventricle hypertrophy
	Carotid atherosclerosis
	Proteinuria / Microalbuminuria
	Atrial fibrillation
	Metabolic syndrome

Source: 2003 Guidelines for Management of Hypertension, Journal of Hypertension (2003), Vol. 21 No 6, p.1035; ESC and ESH Guidelines, European Heart Journal (2007) 28, p. 1494.

(2183) The 2007 ESH and ESC Guidelines also acknowledge that the suitability of all cited classes of hypertensive medicines for first-time "users" is not because they are all expected to cause blood pressure reduction but rather because it remains largely unknown which therapy is suitable for an individual patient. It is explained that during the trial period:

"Treatment can start with a single drug […]. Switching to an agent from a different class is mandatory in case the first agent had no blood pressure lowering or induced important side effects. This 'sequential monotherapy' approach may allow to find the drug to which any individual patient best responds […]. However, although the so-called 'responder rate' […] to any agent in monotherapy is approximately 50%, the ability of any agent used alone to achieve target blood pressure values […] does not exceed 20–30% […]. Furthermore the procedure is laborious and frustrating for both doctors and patients, leading to low compliance and unduly delaying urgent control of blood pressure in high risk hypertensives".[2899]

(2184) The above quote shows that during the trial period, the first-time use patients may have a number of choices but, once the choice is made, further trials will tend to stop because they are considered as laborious and frustrating for both doctors and patients.

(2185) Although it is clearly stated that hypertension treatment can start with a single medicine, the 2007 ESH and ESC Guidelines also state that *"regardless of the drug employed, monotherapy allows to achieve BP target in only a limited number of hypertensive patients"* and that the *"use of more than one agent is necessary to achieve target BP in the majority of patients"*.[2900]

(2186) The 2007 ESH and ESC Guidelines list the following advantages of combination therapies: *"1) by using a combination both the first and the second drug can be given in the low dose range which is more likely to be free of side effects compared to full dose monotherapy; 2) the frustration of repetitively and vainly searching for effective*

[2899] *ESC* and *ESH Guidelines*, European Heart Journal (2007) 28, p. 1495 (emphasis added); The 2003 ESH and ESC Guidelines provided for a slightly higher percentage of cases where mono-therapy was successful, i.e. 25-40% (*2003 Guidelines for Management of Hypertension*, Journal of Hypertension (2003), Vol. 21 No 6, p. 1032).

[2900] *ESC and ESH* Guidelines, European Heart Journal (2007) 28, p. 1495.

monotherapies in patients with very high blood pressure values or organ damage may be avoided; 3) fixed low dose combinations are available, allowing the two agents to be administered in a single tablet, the treatment simplification optimizing compliance; and 4) starting treatment with a two-drug combination may allow blood pressure targets to be reached earlier than with monotherapy".[2901]

(2187) Overall, the 2007 ESH and ESC Guidelines are neither prescriptive nor coercive in their advice. It is clear that it is ultimately for doctors to make the most appropriate choice of therapy for a given patient taking into account that patient's individual conditions. The hypertension medicines considered by the guidelines may have different effects on individual at the general level because of their specific properties, advantages and limitations. The guidelines also discern between different groups of hypertensive patients, where individual classes of medicines can be regarded as superior to others. That being said, it should also be noted that there are usually two or more classes which are favoured in the presence of a given condition. The guidelines promote the prescription of combination treatments. There is only a limited chance that the target blood pressure is achieved with a single agent and thus a combination treatment is needed to control hypertension for the majority of patients.

(2188) The European guidelines were endorsed by national societies of cardiology, including those in France,[2902] the Netherlands[2903] and Poland[2904] as well as by the International Society of Hypertension.

6.2.9.3 Guidelines issued by British Hypertension Society and National Institute for Health and Clinical Excellence

(2189) Based on the frequency of citations in Servier's group strategy documents, such as *"Promotional Campaign Plans"* and *"Orientation Plans"* for Coversyl, it appears that the British Hypertension Society (BHS) guidelines for hypertension management and the UK clinical guidelines published by NICE were regarded as important documents influencing medical practice.

(2190) BHS issued two guidelines in 1999[2905] and 2004[2906] and was involved in NICE clinical guideline 34 (see below) in 2006.

(2191) With respect to the choice of antihypertensive therapy, the 1999 guidelines advised that:

"[f]or each class of antihypertensive drug there are compelling indications based on sound randomised controlled trial data for use in specific patient groups, and also compelling contraindications. There are also indications and contraindications that are less clear-cut, and which are given different weight by different doctors (possible indications/contraindications). […] When none of the special considerations apply,

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2901 *ESC and ESH Guidelines*, European Heart Journal (2007) 28, p. 1495; The 2003 ESH and ESC Guidelines, despite very similar language, seem to put more emphasis on the fact that there are advantages and disadvantages related to the use of either mono-therapy or combination therapy approach (*2003 Guidelines for Management of Hypertension*, Journal of Hypertension (2003), Vol. 21 No 6, p. 1033).

2902 See: http://www.sfcardio.fr/recommandations/europeennes/recoList?b_start:int=15&-C.

2903 See: http://www.nvvc.nl/richtlijnen/bestaande-richtlijnen.

2904 See: http://www.ptkardio.pl/Standardy_postepowania-278.

2905 BMJ 1999; Vol. 319, p. 630-5.

2906 BMJ 2004; Vol. 328, p. 634-40.

the least expensive drug, with the most supportive trial evidence – a low dose of a thiazide diuretic – should be preferred".[2907]

(2192) The 1999 guidelines, in the similar way to the WHO guidelines from the same year, mostly viewed ARBs (sartans) as an alternative to ACE inhibitors in the case of cough provoked by the latter.[2908]

(2193) In 2004, the BHS updated its guideline in order to take into account new evidence, including on the safety and effectiveness of different classes of blood pressure-lowering medicines, including ACE inhibitors, CCB and sartans. The 2004 guidelines begin by recognising a substantial under-diagnosis, under-treatment and poor rates of blood pressure control in the UK, despite previous guidelines. It refers to the use of monotherapy by most doctors as one of the reasons for poor blood pressure control in people with treated hypertension, despite clinical trials showing that two or more medicines may be needed to achieve target blood pressure levels. In order to address what it considered as a serious shortfall in treatment, the BHS advising the so-called AB/CD algorithm which underscores the need for at least two blood pressure lowering medicines for most people with hypertension. According to that algorithm, hypertension was:

"best treated initially with one of two categories of antihypertensive drug – those that inhibit the renin-angiotensin system (angiotensin converting enzyme inhibitors or angiotensin receptor blockers (A) or [beta] blockers (B)), and those that do not (calcium channel blockers (C) or diuretics (D)). People who are younger than 55 and white tend to have higher renin concentrations than people aged 55 or older or the black population (of African descent). A or B drugs are therefore generally more effective as initial blood pressure lowering treatment in younger white patients than C or D drugs. However, C or D drugs are more effective first line agents for older white people or black people of any age".[2909]

(2194) In the 2000s, NICE published two recommendations concerning hypertension: *Clinical Guideline 18: Hypertension full guideline in 2004* and *Clinical Guideline 34: Hypertension: management of hypertension in adults in primary care (partial update of NICE clinical guideline 18)* in 2006.

(2195) The NICE guidelines were intended for the primary care team, including general practitioners, while more complicated cases were to be referred to secondary care.[2910] Clinical Guideline 18 foresaw a certain algorithm for initiating the treatment of hypertensive patients. According to that algorithm: *"[d]rug therapy should normally begin with a low dose thiazide-type diuretic. If necessary, second line add a beta-blocker unless a patient is at raised risk of new-onset diabetes, in which case add an ACE-inhibitor. Third line, add a dihydropyridine calcium-channel blocker. […] If further blood pressure lowering is warranted, consider adding an ACE-inhibitor or betablocker (if not yet used), another antihypertensive drug, or referring to a specialist".*[2911]

2907 BMJ 1999, Vol. 319, p .632.

2908 BMJ 1999, Vol. 319, p .632.

2909 BMJ, Vol. 328, p. 638.

2910 NICE Clinical Guideline 18, p. 4. Available at: http://guidance.nice.org.uk/index.jsp?action=download&o=48384.

2911 NICE Clinical Guideline 18, p. 103 - 104.

(2196) There was discrepancy between the guidelines issued by BHS and NICE in 2004 with respect to the initial treatment. BHS relied on the AB/CD algorithm, while NICE suggested that the therapy *"should normally begin with"* a diuretic. This discrepancy was ended in 2006 with Clinical Guideline 34 (endorsed by both institutions), which changed the algorithm by recommending that *"[i]n hypertensive patients aged 55 or older or black patients of any age, the first choice for initial therapy should be either a calcium channel blocker or a thiazide-type diuretic […]; [i]n hypertensive patients younger than 55, the first choice for initial therapy should be an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin-II receptor antagonist if an ACE inhibitor is not tolerated)"*.[2912] As regards ACE inhibitors and sartans, the guideline recommended the initiation on ACE inhibitors first because of cost reasons, and to use sartans when ACE inhibitors are not well tolerated because of cough.

(2197) The algorithm introduced by Clinical Guideline 34 was welcomed by Servier which stated in an internal document that *"ACEi and CCB have now rightly come to the forefront of hypertensive management. It is no exaggeration to say that the revised NICE guideline revolutionize the management of hypertension, and that the unified approach, endorsed by NICE/NHS/BHS will end the confusion that for so many years had obscured optimal hypertension management"*.[2913] In the context of both European and UK guidelines, Servier expressed its satisfaction by underlining that *"[t]he 2006 UK revised guidelines were favorable to Coversyl, as were the ESH/ESC 2007 guidelines, which only recommend therapeutic combinations of ACE inhibitors, CCBs, and diuretics. This makes the ACE inhibitor/CCB combination particularly convenient in terms of adherence to guidelines, since the next step in patients requiring triple therapy is logical"*[2914] and that *"Coversyl benefits from international guidelines endorsement (ESC-ESH 2007, BHS-NICE 2006, JNC-7), recognition by opinion leaders and cardiologists, and SERVIER's image"*.[2915]

(2198) The UK guidelines provide another example of the importance attributed to the initial selection process in the trial period by means of which patients are supposed to find a successful treatment for continued use. In addition, BHS and NICE pointed to the need for combination treatments.

6.2.9.4 Conclusion

(2199) Overall the medical guidelines consistently underlined the existence of indications and contra-indications for various classes of antihypertensive agents. Certain guidelines offered an algorithm for initiating the treatment, but an ultimate therapeutic choice was in the hands of an individual prescriber who was to select the treatment that would best suit the patient's profile. The use of combination treatments was also strongly advocated in view of the general insufficiency of mono-therapies to control blood pressure to the required degree.

6.2.10 Basis for Servier's differentiation strategy

(2200) Before presenting the contemporaneous evidence from the investigated period, it should be noted that in one of its submissions to the Commission, Servier insists that:

[2912] NICE Clinical Guideline 34, p. 8.
[2913] ID0349, p. 735.
[2914] ID0349, p. 918.
[2915] ID0349, p. 927.

*"*All competing antihypertensives considered as reference […] have in common the same main indication, hypertension, as first-line treatment and therefore they are in direct competition with each other. They also all have the same main characteristic of being prescribed once daily (1tablet/day) whatever the dosage used. Neither physician nor patient have reported any noticeable difference in terms of effect of the antihypertensives; all lower blood pressure equally".*[2916]

(2201) While the above statement is true in the sense that all antihypertensive medicines are aimed at decreasing blood pressure, it is also true that *"[the] selection of a given agent alone or in association with other drugs [is] mandatory or advisable according to the circumstances".*[2917] In other words, practitioners cannot be indifferent as to which antihypertensive medicine is given to their patients. As will be shown in this section based on Servier's internal documents and several medical studies, there are a number of qualitative features that may be used by the producer of an antihypertensive medicine in an attempt to differentiate its product from potentially alternative treatments and that may be taken into account by prescribers. It is natural to expect that the choice of treatment is also based on the strength of existing scientific evidence and that other things being equal prescribers prefer medicines with well proven effects over alternatives backed by less solid evidence.[2918]

(2202) The qualitative positioning of different medicines relies mainly on the outcomes of numerous scientific trials and studies in the course of which the relevant therapies are evaluated. These trials and studies are usually prepared by reputed scientists but sponsored by the interested companies from the sector. In its internal strategy documents, Servier relies on a number of trials and studies that were considered as relevant for the marketing of perindopril. Table 15 below summarises information about when the results of several important studies that were relied on by Servier (e.g. Figure 2) were released and so from which moment in time they became relevant for the marketing and promotional efforts of Servier as well as for the therapeutic choices of the informed practitioners. The list is not exhaustive as it only contains major trials and studies. There were also other publications regarding the efficacy or safety of perindopril whose results could be favourably exploited by Servier.[2919]

2916 ID1151, p. 5.
2917 *ESC and ESH Guidelines*, European Heart Journal (2007) 28, p. 1492.
2918 E.g. NICE Clinical Guideline 34, p. 29.
2919 E.g. ID0349, p. 540 - 549.

Table 15: Major trials and studies referred to in Servier's internal strategy documents

Trial's/study's name	Year of results publication	Involving the use of perindopril (Yes/No)	Source
PROGRESS	2001	Yes	Lancet 2001; 358, p. 1033-1041
EUROPA	2003	Yes	Lancet 2003; 362, p. 782-788
ASCOT-BPLA	2005	Yes	Lancet 2005; 366, p. 895-905
PREAMI	2006	Yes	Arch Intern Med 2006; 166, p. 659-666
CAFE	2006	Yes	Circulation; 2006;113, p. 1213–1225
ADVANCE	2007	Yes	Lancet 2007; 370: 829-840
ONTARGET	2008	No	N Engl J Med 2008: 358, p. 1547-1559
TRANSCEND	2008	No	Lancet. 2008;372, p. 1174–1183
HYVET	2008 (pilot 2005)	Yes	N Engl J Med 2008 358 (18) , p. 1887-98 (pilot: J Hypertens 2003; 21, p. 2409-2417)

Note: Servier was the sole sponsor of the EUROPA and PREAMI studies and co-supported the PROGRESS, ASCOT-BPLA and HYVET studies. Pfizer (co-) supported the ASCOT-BPLA and CAFÉ studies. Boehringer Ingelheim supported the ONTARGET and TRANSCEND studies. From the above list only the ADVANCE study does not explicitly acknowledge any support from the pharmaceutical industry.

Source: As indicated in the table and the above notes.

(2203) The following subsections will present the summaries of (i) scientific findings relating to perindopril that were available in the early 2000s; (ii) results from major trials and studies involving the use of perindopril published in the 2000s; (iii) Servier's internal perceptions of perindopril's potential for differentiation vis-à-vis other antihypertensive agents; Servier's observations on (iv) market perceptions as to the effective differentiation of perindopril vis-à-vis other antihypertensive agents, (v) opportunities from other companies' attempts to differentiate their hypertensive agents within the same product continuum, (vi) opportunities to explore the existing complementarities and (vii) Servier's position vis-à-vis its potential competitors in terms of the supporting scientific evidence.

6.2.10.1 Summary of scientific studies relating to perindopril available in the early 2000s

(2204) This subsection is based on two articles taking stock of the existing knowledge about perindopril in the early 2000s. Both articles were published in 2001. They rely on over one hundred reports from various studies relating to perindopril and other treatments published, with a few exceptions, in the 1990s.

(2205) The first article, *"Perindopril; An Updated Review of Its Use in Hypertension"*, concluded that:

"[p]erindopril is a well tolerated ACE inhibitor that, in the treatment of patients with mild to moderate essential hypertension, is significantly better (in terms of clinical response rates) than captopril and as effective as other ACE inhibitors. Perindopril appears to reverse some of the vascular and haemodynamic abnormalities associated with hypertension, including arterial stiffness and LVH [left ventricular hypertrophy]. Results from ongoing studies will help confirm whether perindopril also reduces associated cardiovascular morbidity and mortality and will help clarify

its position in the area; currently, perindopril is an effective and well tolerated treatment for patients with mild to moderate essential hypertension".[2920]

(2206) The second article, *"Dosage Considerations with Perindopril for Systemic Hypertension"*, underlined that:

"[perindopril's] ability to lower BP [blood pressure] is comparable to or better than that of other antihypertensive agents, both of its own class and other classes, and its trough-peak ratio is consistently between 75% and 100%, translating into 24 hours of true efficacy per dose. First-dose hypotension caused by an initial acute BP depression occurs less frequently with perindopril than with other ACE inhibitors, an advantage in volume-contracted patients and those whose BP is angiotensin II dependent, such as patients with congestive heart failure. A missed-dose study showed that most of the antihypertensive effect of perindopril remains for 24 to 48 hours after dosing, a characteristic that confers protection to patients who miss a dose. Perindopril improves the distensibility and compliance of large and small arteries, which are compromised in hypertension, and can effect vascular remodeling by a mechanism independent of BP lowering. The clinical implications of these effects are being investigated in large trials".[2921]

(2207) The conclusions of the above articles show that at the time of their publication there was already an important body of scientific evidence suggesting that perindopril should be regarded as a leading ACE inhibitor. Perindopril was equally good or better than other available therapies in terms of its ability to reduce hypertension. In addition, its therapeutic value was recognised as going beyond lowering blood pressure. Perindopril's evidence base was to be further extended with several large trials that are described in next section.

6.2.10.2 Summary of results from major trials and studies involving the use of perindopril published in the 2000s

(2208) Table 15 gives an overview of the major studies referred to in Servier's internal strategy documents. Apart from ONTARGET and TRANSCEND, all the other studies listed in the table involved perindopril either as a principal agent or an addition in the combination therapy. The studies are described below in chronological order.

(2209) The results of the PROGRESS study were published in 2001. The Perindopril Protection against Recurrent Stroke Study (PROGRESS) was a randomised trial of active therapy versus placebo in 6,105 patients with previous stroke or transient ischaemic attack, lasting four years. In the active therapy group patients receive perindopril (4 mg) with the addition of a diuretic (indapamide) at the discretion of the doctor. The study showed that the applied regimen reduced the risk of stroke among both hypertensive and non-hypertensive individuals. Combination therapy with perindopril and indapamide produced larger blood pressure reductions and larger risk reductions than single drug therapy with perindopril alone. It was concluded that the treatment with these two agents should be considered routinely for

2920 M Hurst, B. Jarvis, *Perindopril; An Updated Review of Its Use in Hypertension*, Drugs 2001: 61 (6): 867 - 896.

2921 Sica, D. A., *Dosage Considerations with Perindopril for Systemic Hypertension*, The American Journal of Cardiology, Vol. 88, Issue 7A, supplement 1, p. 13i-18i (4 October 2001).

patients with a history of stroke or transient ischaemic attack, irrespective of their blood pressure.[2922]

(2210) The results of the EUROPA study were published in 2003. The EUropean trial On Reduction of cardiac events with Perindopril in stable coronary Artery disease (EUROPA) involved 12,218 patients with a mean age of 60 years. The study lasted approximately four years. Its aim was to verify the efficacy of perindopril in reducing cardiovascular risk in a low-risk population with stable coronary heart disease and no apparent heart failure.[2923] It compared active therapy consisting in perindopril (8 mg) versus placebo.[2924] It found that there was a relative risk reduction of 20% for the group treated with perindopril. It was concluded that in this group of patients, perindopril can significantly improve outcomes. About 50 patients need to be treated for a period of 4 years to prevent one major cardiovascular event (cardiovascular mortality, non-fatal myocardial infarction and resuscitated cardiac arrest). The study concluded that perindopril treatment, on top of other preventive medications, should be considered in all patients with coronary heart disease.[2925]

(2211) The results of the ASCOT-BPLA study were published in 2005. It was a comparative study of the prevention of cardiovascular events with an antihypertensive regimen of amlodipine (a CCB) adding perindopril versus atenolol (a beta-blocker) adding bendroflumethiazide (a diuretic). It involved 19,257 patients. The study showed that in hypertensive patients at moderate risk of developing cardiovascular events, the former regimen is better in terms of reducing the incidence of all types of cardiovascular events and all-cause mortality, and in terms of risk of subsequent new-onset diabetes. Since the study aimed at comparing the effects of combination treatments, it is important to explain that the starting point for the perindopril/amlodipine combination was to first use amlodipine monotherapy. Perindopril was added as required to reach blood-pressure targets. By the end of the trial, only 15% of patients following the amlodipine regimen were taking amlodipine monotherapy, which means that the remaining patients required a second antihypertensive treatment to reach their blood-pressure targets.[2926]

(2212) The results of the PREAMI study[2927] were published in 2006. It involved a total of 1,252 patients who were aged 65 or older with a left ventricular ejection fraction of 40% or higher and recent acute myocardial infarction. The participating patients were randomised to receive perindopril or placebo for 12 months. The study found that one-year treatment with 8 mg per day of perindopril reduced progressive left ventricular remodelling that can occur even in the presence of small infarct size. The

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2922 PROGRESS Collaborative Group, *Randomised trial of a perindopril-based blood-pressure-lowering regimen among 6105 individuals with previous stroke or transient ischaemic attack*, The Lancet, Vol. 358, p.1033 – 1041 (29 September 2001).

2923 The prevalence of coronary artery disease in this near normal population was 7.3%, with a significant difference in coronary asymptomatic (3.8%) vs symptomatic patients (17.1%). See: Eur Heart J (2000) 21 (1), p. 45-52.

2924 92% of the patients were also taking platelet inhibitors, 62% beta-blockers and 58% lipid-lowering therapy.

2925 *Efficacy of perindopril in reduction of cardiovascular events among patients with stable coronary artery disease: randomised, double-blind, placebo-controlled, multicentre trial*, The Lancet, Vol. 362, p. 782 – 788 (6 September 2001).

2926 Dahlöf, B.; Sever, S. and others, *Prevention of cardiovascular events with an antihypertensive regimen of amlodipine adding perindopril*, The Lancet, Vol. 366, p. 895 – 906 (10 September 2005); see paragraph (2222) for Servier's interpretation of the results of the ASCOT study.

2927 PREAMI Study, Archives of Internal Medicine, Vol. 166, p. 659 - 666.

perindopril regimen was well tolerated and the study indicated that perindopril should be considered as a standard treatment for elderly patients with acute myocardial infarction and preserved left ventricular function.[2928]

(2213) The results of the CAFÉ study, a sub-study of ASCOT, were also published in 2006. It examined the impact of an antihypertensive regimen of amlodipine adding perindopril versus atenolol adding bendroflumethiazide on derived central aortic pressures and hemodynamics. The study was relevant to the debate about how much of the benefit of blood pressure lowering medicines in clinical trials can be attributed to blood pressure lowering per se or to alternative mechanisms beyond blood pressure. The study involved 2,199 patients. It showed that the regimen of amlodipine adding perindopril was much more effective than the other treatment at lowering central aortic pressures. The study suggested that the effects on central aortic pressure may explain, at least in part, the better clinical outcome for patients allocated to the regimen of amlodipine adding perindopril in ASCOT.[2929]

(2214) The results of the ADVANCE study were published in 2007. The study examined the effects of a fixed combination of perindopril and indapamide on macrovascular and microvascular outcomes in 11,140 patients with type 2 diabetes. The study established that the routine administration of the combination of these two medicines to patients with type 2 diabetes was well tolerated and reduced the risks of major vascular events, including death. The results suggested that over five years, one death due to any cause would be averted among every 79 patients assigned active therapy.[2930]

(2215) The results of the HYVET study were published in 2008. The study aimed at clarifying whether the treatment of patients with hypertension who are aged 80 years or older is beneficial or not. It involved 3,845 patients. The study provided evidence that hypertension treatment based on indapamide sustained release, with perindopril added if necessary to achieve the target blood pressure, was beneficial and was associated with reduced risks of death from stroke, death from any cause, and heart failure.[2931]

(2216) The above studies show that perindopril had a strong scientific evidence base throughout the 2000s with some additional evidence of strengths added over time. Perindopril proved to be efficient in (i) reducing the risk of stroke, (ii) preventing major cardiovascular events in patients with coronary heart disease, (iii) reducing progressive left ventricular remodelling and (iv) being a valuable component in combination treatments, in particular with amlodipine and indapamide, effective in reducing various risks for cardiovascular patients. As it will be shown in next sections, the studies based on large groups of patients, as well as smaller studies, were actively disseminated among the medical practitioners by Servier.

(2217) In its reply to the Statement of Objections, Servier points out that the Commission's review of the scientific studies focuses on the perindopril studies, while there were

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2928 An additional example for this age group of patients is provided by the Canadian study concerning mortality rates in patients 65 years of age or older after an acute myocardial infarction that showed that ramipril was associated with lower mortality than most other ACE inhibitors except perindopril. See: Ann Intern Med. 2004; 141, p. 102-112.

2929 CAFÉ study, Circulation, Vol. 113, p. 1213 – 1225 (2006).

2930 The Lancet, Vol. 370, p. 829 - 840.

2931 The New England Journal of Medicine, Vol 358 No. 18, p. 1887 - 1898.

also other studies carried out on the basis of other antihypertensive agents.[2932] Servier's observation is correct as such, but cannot lead to a conclusion that the Commission's review is incomplete. First, the existence of other studies is reflected in sections 6.2.10.5 to 6.2.10.7 insofar those other studies were relevant with respect to Servier's efforts to differentiate its own product. Second, the Commission's focus on the perindopril studies reflects the nature of the relevant market analysis which starts by definition from the product in question.

(2218) Servier also argues that the Commission misinterprets the perindopril studies.[2933] The Commission notes that Servier's criticism is based on the opinion prepared by Professor Vanoverschelde for the purpose of Servier's reply to the Statement of Objections. The Commission does not dispute this opinion, but wants to point out that Servier interpreted and communicated the content of the same studies to the medical practitioners in a distinctively different way during the investigated period.[2934] Moreover, Servier's communication efforts were effective in influencing the prescribers' perception and in *"paving the way for Coversyl to be even more successful"*.[2935]

6.2.10.3 Servier's internal perceptions of perindopril's potential for differentiation

(2219) The "*2005/2006 Orientation Plan",*[2936] the earliest internal strategy document relating to the marketing of perindopril provided to the Commission, presents Servier's arguments for further differentiation of perindopril from other antihypertensive agents. In this respect, the product ideology developed by Servier contains a significant number of statements directly comparing perindopril with other products, all claiming perindopril's superiority within and outside the ACE inhibitors class. Due to the multitude of such statements, only a selection can be cited below:

"COVERSYL has a trough-to-peak ratio of 87% to 100%, significantly superior to other once-daily ACE inhibitors (Morgan I vs enalapril and Morgan II vs enalapril and captopril).

This clinical advantage of COVERSYL is fully recognized with the best trough-to-peak ratio (TPR) ever validated by the US FDA for an ACE inhibitor (75% to 100%) (USA data sheet). […]

COVERSYL's antihypertensive effect is at least equal or superior to that of other ACE inhibitors and other reference antihypertensive agents with which it has been compared (Thurston, Zanchetti). In addition, COVERSYL shows superior synergy, in combination with a diuretic, to that seen with a reference ACE inhibitor. […]

COVERSYL is a first-choice ACE inhibitor, reducing the risk of first-dose hypotension and so allowing a safer start to treatment of heart failure. - First-dose hypotension is a definite risk in all patients when initiating heart failure therapy, whatever the stage of the disease, and has potentially serious and even lethal consequences (Cleland). […]

COVERSYL has excellent hemodynamic tolerance and thus minimizes the risk of hypotensive episodes, compared with other ACE inhibitors, among patients with

2932 Servier's reply to the Statement of Objections, paragraph 1517, ID10114, p. 465.
2933 Servier's reply to the Statement of Objections, paragraph 1521, ID10114, p. 466.
2934 See sections 6.2.10.3 and 6.2.10.4.
2935 See also paragraphs (2222) and (2225).
2936 For the rules considering the dating of Servier's various internal strategy papers see footnote 2841.

acute myocardial infarction (MI) (Lau) and in post-MI patients after coronary artery bypass graft (CABG) (Manché). […]"[2937]

(2220) In the "*2007/2008 Promotional Campaign Plan"*, i.e. the document summarising Servier's promotional actions targeting prescribing doctors, Servier intended to explain to general practitioners (GPs):

"that there is a correlation between Coversyl's efficacy in decreasing BP (brachial and central) and reduction in cardiovascular events (ASCOT, CAFÉ), and that the most important point is that these properties of Coversyl are not shared by any other antihypertensive".[2938]

(2221) In the "*2009/2010 Orientation Plan"*, reference to trials and studies is also made in the context of the consecutive record of positive qualitative assessment of Coversyl vis-à-vis other therapies available for hypertensive patients. Servier notes that:

"Since 2001, when the PROGRESS results were announced, until 2007, when the ADVANCE results were reported, the Coversyl family products had one positive morbidity-mortality trial result each year.

We now have evidence that each everyday hypertensive patients will benefit from Coversyl: [i] a hypertensive with/without renal failure should benefit from Coversyl 5 to 10 mg, a hypertensive with diabetes should receive Coversyl PLUS; [ii] a coronary artery patient should receive Coversyl 10 mg; [iii] a post-MI [myocardial infarction, i.e. heart attack], a post stroke, or a heart failure patient will benefit from Coversyl 5 mg.

Coversyl is now undoubtedly an indispensable antihypertensive agent, throughout the cardiovascular disease continuum, and no other antihypertensive or ACE inhibitor can compare with Coversyl".[2939]

(2222) In its communication efforts to the medical community, Servier used the favourable outcomes of the trials to further differentiate its product from other antihypertensive medicines. For example, in the "*2009/2010 Orientation Plan"*, it is explained that:

"Coversyl 5 to 10 mg is well prescribed right at the start of the cardiovascular disease continuum in everyday hypertensive patients (36%) thanks to the presentation and extensive promotion of ASCOT. ASCOT became a well-recognized landmark study that is paving the way for Coversyl to be even more successful in the future. ASCOT enlarged Coversyl's business and provided definitive clinical proof of Coversyl's superiority to other ACE inhibitors and other antihypertensive agents, at least in terms of cardiovascular protection in hypertensives with risk factors.

ADVANCE confirmed the superiority of Coversyl-based therapy in diabetics and in particular of Coversyl PLUS. […]

Coversyl is very well recognized as a true and effective 24-hour BP-lowering drug and as an unparalleled antihypertensive agent in improvement in cardiovascular outcomes. Coversyl's unique mode of action is a key differentiating point, but always needs to be reinforced. […]"[2940]

2937 For a wider selection of similar statements, see ID0349, p. 540 - 549. In a similar vain, but from a later period, see ID0349, p. 841 - 843.

2938 ID0349, p. 305.

2939 ID0349, p. 917.

2940 ID0349, p. 919.

(2223) The above quotes demonstrate that Servier continuously exploited in its communication efforts the favourable scientific evidence indicating that perindopril should have been recognised for certain characteristics that made it a preferable product as compared to other antihypertensive agents[2941] despite the shared basic function of lowering blood pressure.

6.2.10.4 Servier's differentiation efforts

(2224) Servier's market intelligence closely monitored stakeholders' reactions to the company's attempts to present perindopril as a superior hypertensive agent.

(2225) It should be recalled that the aforementioned "*2005/2006 Orientation Plan"* listed a number of reasons why Servier believed perindopril had certain superior characteristics to other hypertensive drugs. While this document clearly states that at that time perindopril started to capitalise on the EUROPA study, it also recognised that efforts to further differentiate the products were still needed:

"Physicians perceived COVERSYL as an effective antihypertensive agent. Its cardiovascular protection image has improved since last year but mostly among specialists, thanks to the already active promotion of COVERSYL's efficacy in reducing, mortality in cardiovascular events, as shown in the EUROPA study. However, COVERSYL's specific mode of action and efficacy have still not been sufficiently differentiated from other ACE inhibitors.

KEY FACT: Real improvement in COVERSYL's image, mainly at specialist level and to a lesser extent among GPs, but not enough to be differentiated from, and therefore to be more prescribed than, other RAAS [renin-angiotensin-aldosterone system] inhibitors".[2942]

(2226) The uniqueness and the universality of its product were seen by Servier as key marketing points to which prescribers' attention had to be continuously drawn. In the "*2008/2009 Orientation Plan"* for the Coversyl family, those product features are emphasized in particular:

"We have to continue to explain to our physicians that all the benefits obtained in morbidity-mortality trials with Coversyl can be translated into practice: the best method is to treat hypertensive patients as soon as possible, without waiting for any other adaptation of treatment, or any failure in other treatments to control blood pressure.

Coversyl now has many differentiating points with its competitors. We cannot detail all of them, but we now have the possibility to really differentiate Coversyl from other ACEIs/ARBs, in terms of BP efficacy, central aortic BP efficacy, cardiovascular outcome reduction, and prevention of new-onset diabetes. "[2943]

(2227) The same orientation plan, despite the foregoing statements, shows that Servier was not satisfied with many practitioners considering Coversyl to be equal to ramipril.[2944] Hence Servier's conclusion that *"Coversyl's unique mode of action is the key differentiating point, but always needs to be reinforced. Also, while [we] have more*

2941 Including ACE inhibitors.
2942 ID0349, p. 538.
2943 ID0349, p. 823.
2944 ID0349, p. 852.

and more evidence, differentiation between Coversyl and Ramipril still needs to be emphasized".[2945]

(2228) Servier's ambition was clearly to differentiate its product from the medicines that were relatively the most proximate in terms of their mode of action such as ramipril.

6.2.10.5 Servier's observations on opportunities from other companies' attempts to differentiate their antihypertensive agents

(2229) Servier took an interest in trials concerning other hypertension medicines. For example, in relation to the ONTARGET study, Servier remarks that *"because ARBs are more costly than ACE inhibitors and have more side effects, their primary value is an alternative for patients who cannot tolerate ACE inhibitors because of cough"*.[2946] While, with regard to the TRANSCEND study, it is underlined that *"[t]he clinical effect of ARBs seems less robust than that of ACE inhibitors. <<Therefore angiotensin converting-enzyme inhibitors should remain the preferred renin-active agent to prevent vascular events in patients with or at high risk for cardiovascular disease>>[…]. Among ACE inhibitors, Coversyl has the most complete evidence for benefits along the cardiovascular disease continuum. Coversyl reduced cardiovascular death, MI [myocardial infarction, i.e. heart attack], and cardiac arrest by 20% in EUROPA, despite the patients being on similar drugs to those in TRANSCEND [telmisartan]"*.[2947]

(2230) A similar assessment of the ONTARGET and TRANSCEND studies can be also found in external commentaries. The position of ARBs (sartans) in relation to ACE inhibitors was believed to be unchanged by those studies. It was stated that *"the evidence to favor an ARB over an ACE-I is still limited after ONTARGET and because of the higher costs for ARBs one can rather support the old therapeutic advice that ARBs are equally effective as ACE-Is and therefore therapeutic alternatives for patients with ACE-I intolerance"*.[2948] The two studies were said to *"indicate that an ARB can be used for vascular protection in high risk individuals in the place of an ACEi. However ACEi will probably remain the first choice due to the greater body of supportive evidence"*.[2949]

6.2.10.6 Servier's observations on opportunities to explore complementarities

(2231) Servier also examined the studies recommending the introduction of multi-agent treatments to exploit them to its advantage. For example, in the "*2006/2007 Promotional Campaign Plan"* the results from the ASCOT study were discussed:

"Monotherapy in ASCOT demonstrated insufficient efficacy: only 15% of patients were on amlodipine alone and only 9% were on atenolol alone at the end of the trial. It is the first confirmation that most patients need at least a second antihypertensive treatment.

We also have to remember that 100% of patients receiving Coversyl 4 to 8 mg in ASCOT received Coversyl because they were not controlled with amlodipine (70% of patients treated with amlodipine need Coversyl)! And at the end of the trial, the

2945 ID0349, p. 822.
2946 ID0349, p. 908.
2947 ID0349, p. 909.
2948 Ther Adv Cardiovasc Dis. 2008 Aug;2(4), p. 233-48.
2949 Vasc Health Risk Manag. 2009; 5, p. 21 - 29.

authors wrote that most patients can achieve blood pressure control: this was thanks to Coversyl!"[2950]

(2232) The above-mentioned complementarities were also visible when perindopril alone was found to insufficiently control blood pressure; the therapy could then be supplemented by adding amlodipine. That possibility necessarily reduced the number of patients switching away from perindopril if it was insufficient on its own. This fact is further documented by the results of Servier's survey into doctors' practice reported in the "*2008/2009 Orientation Plan"*:

"If Coversyl 4/5 mg is initiated in hypertension, it happens that patients sometimes need more blood pressure control. Physicians will go to Coversyl PLUS or to Coversyl 10 mg in similar proportions (34%/32%), rather than going to amlodipine (+18%), or another drug (+13%), or switch (3%). In France, 54% of cardiologists and 31% of GPs will go to Coversyl PLUS in a hypertensive without risk factors, this is 23% and 18%, if the patient is hypertensive with risk factors. In this case, a large section of physicians prefer to combine with amlodipine (like in ASCOT)".[2951]

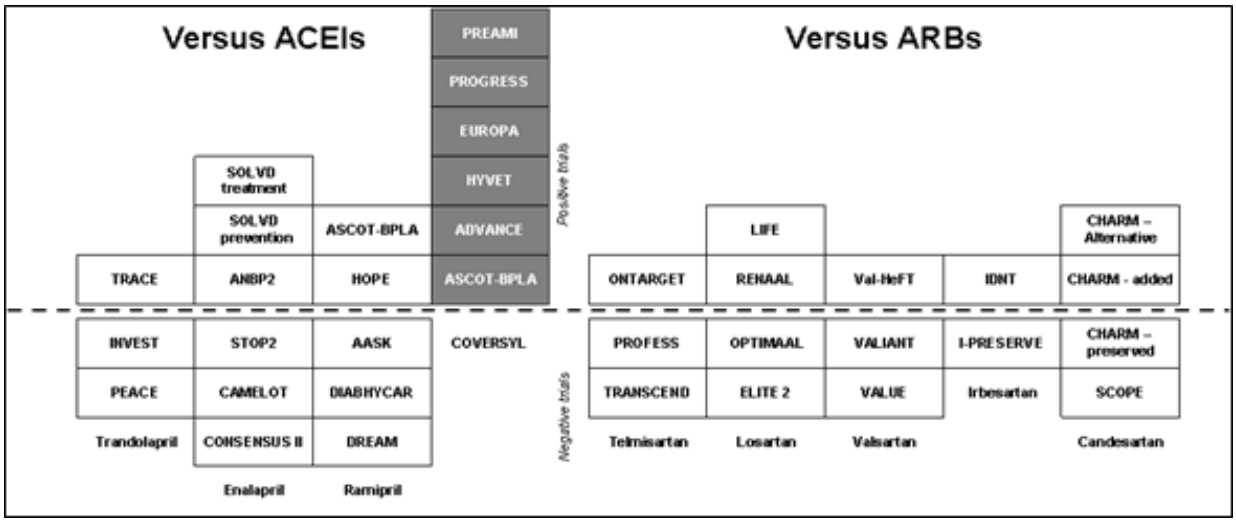
6.2.10.7 Servier's position vis-à-vis its potential competitors in terms of the supporting scientific evidence

(2233) Since the medical guidelines did not provide practitioners with assistance as to the ultimate choice of a molecule within a given class, it was natural for Servier to be interested in building up ample evidence to persuade practitioners that perindopril should be the ACE inhibitors of their choice. In the case where the direct comparisons are not universally practised, it is a wealth and solidity of evidence relating to a given product that can be best exploited.

(2234) Figure 2 below is an extract from the "*2009/2010 Orientation Plan"*. It gives an overview of a number of trials conducted on patients suffering from hypertension, coronary artery disease and heart failure. The presented trials are classified as positive or negative depending on their outcome. *"A trial is considered as positive if the primary end point and/or total mortality and/or cardiovascular mortality is significantly reduced by the evaluated therapy. A trial is considered as negative if the primary end point and/or total mortality and/or cardiovascular mortality is not significantly reduced by the evaluated therapy".*[2952] Among the medicines displayed on the figure, Servier's perindopril, Coversyl, is presented as the only product with a consecutive record of positive trials.

2950 ID0349, p. 203.
2951 ID0349, p. 824.
2952 ID0349, p. 917.

Figure 2: Overview of trials and studies relating to ACE inhibitors and ARBs (sartans) classified as positive or negative depending on their outcome



Source: ID0349, p. 917.

6.2.10.8 Conclusion

(2235) During the investigated period, Servier as well as the producers of other antihypertensive treatments sponsored a number of studies and trials. Based on those studies and trials, the products were differentiated at least in terms of available scientific evidence. The evidence was exploited in marketing efforts aimed at the prescribers and paved *"the way for Coversyl to be even more successful"*.

(2236) In particular, Servier's internal documents confirm that the studies based on large groups of patients as well as smaller studies were an important tool in Servier's marketing efforts. These documents also reflect the fact that perindopril was steadily improving its evidence base used for the purpose of communication with the practitioners throughout the 2000s and thus Servier was in a position to differentiate more and more perindopril from its potential competitors.

6.3 Description of the universe

(2237) Before providing an overview of the facts concerning the sales of perindopril (section 6.4), it is important to explain the analytical universe within which the said overview will be carried out. The main underlying logic of this section is to preliminarily narrow down the presentation of quantitative data to the most likely product candidates that could have potentially constrained the sales of perindopril during the investigated period. This process integrates the factual presentation with elements of assessment that are required to substantiate the choice of the universe.

(2238) The subsections below relate to two themes: (i) a review of perindopril sales across types of perindopril product, distribution channels and indications (sections 6.3.1 to 6.3.3), and (ii) reference points (products) in terms of the commercial policy for perindopril based on the undertakings' perception of the competitive environment (section 6.3.4). Section 6.3.5 concludes by describing the scope of the presentation of the quantitative data and provides the Commission's rationale for selecting a subset of four Member States for further in-depth assessment.

6.3.1 Perindopril sales – plain and combination versions

(2239) In order to make an educated choice regarding the products included in the subsections on price and volume developments, it is necessary to first address the

question whether the inclusion of fixed combination products containing perindopril can reasonably be expected to provide important information as to the competitive situation of perindopril as a single-molecule product. This requires examination of the relative weight of the different products in Servier's portfolio as well as the type of interrelationship existing between perindopril and its fixed combinations.

(2240) As already mentioned above,[2953] Servier introduced two fixed-dose combination products on the market, namely: (i) perindopril and indapamide[2954] (first registered in 1997) and (ii) perindopril and amlodipine[2955] (first registered in 2008[2956]). The former was marketed as *"the antihypertensive designed for diabetic hypertensives"*.[2957] Whereas the latter was intended for *"the everyday hypertensive patients uncontrolled with amlodipine"*[2958] or for *"patients already on amlodipine"*.[2959]

(2241) For the four national markets selected for more detailed analysis during the course of this investigation,[2960] IMS Health (IMS) provides the distribution of sales between the mono and the combination therapies based on perindopril in terms of the turnover generated by each type of therapy. This is summarised in Table 16 (it should be noted that this table only shows co-prescription based on fixed combination products; most co-prescriptions were based on free combinations where the prescribers would simply prescribe two separate medicines to the patient, see section 6.4.5.4).[2961]

2953 See paragraph (2161).

2954 Indapamide is a type of medicine called a diuretic, which works by causing the kidneys to increase the amount of salts such as potassium and sodium that are filtered out of the blood and into the urine. Information source: http://www.netdoctor.co.uk/heart-and-blood/medicines/natrilix-sr.html.

2955 Amlodipine is a type of medicine called a calcium channel blocker, which slows down the movement of calcium through the muscle cells that are found in the walls of blood vessels. It does this by blocking 'calcium channels' in these muscle cells. Calcium is needed by muscle cells in order for them to contract, so by depriving them of calcium, amlodipine causes the muscle cells to relax. Information source: http://www.netdoctor.co.uk/heart-and-blood/medicines/istin.html.

2956 ID1143; The fixed combination of perindopril and amlodipine enjoys the ten-year period of data exclusivity period which runs from the moment the product obtains its market authorisation (ID0117, p. 74).

2957 ID0349, p. 394.

2958 ID0349, p. 4.

2959 ID0349, p. 413.

2960 For the rationale of selecting the UK, France, the Netherlands and Poland see paragraph (2272).

2961 Regarding the split between the turnovers achieved on plain and combination products, the IMS data is generally consistent with the data found in Servier's internal documents (ID0349, p. 583 and 649).

Table 16: Turnovers achieved on plain and combination products containing perindopril

Year	France		UK		Netherlands		Poland	
	P	C	P	C	P	C	P	C
2000	[70–80]* %	[20–30]* %	[90–100]* %	[0–5]* %	[90–100]* %	[0–5]* %	[90–100]* %	[0–5]* %
2001	[70–80]* %	[20–30]* %	[90–100]* %	[0–5]* %	[90–100]* %	[0–5]* %	[90–100]* %	[0–5]* %
2002	[60–70]* %	[30–40]* %	[90–100]* %	[0–5]* %	[90–100]* %	[0–5]* %	[90–100]* %	[0–5]* %
2003	[60–70]* %	[30–40]* %	[90–100]* %	[0–5]* %	[90–100]* %	[5–10]* %	[90–100]* %	[0–5]* %
2004	[60–70]* %	[30–40]* %	[90–100]* %	[0–5]* %	[80–90]* %	[10–20]* %	[90–100]* %	[0–5]* %
2005	[60–70]* %	[30–40]* %	[90–100]* %	[0–5]* %	[80–90]* %	[10–20]* %	[90–100]* %	[0–5]* %
2006	[60–70]* %	[30–40]* %	[90–100]* %	[0–5]* %	[80–90]* %	[10–20]* %	[90–100]* %	[0–5]* %
2007	[60–70]* %	[30–40]* %	[90–100]* %	[5–10]* %	[80–90]* %	[10–20]* %	[90–100]* %	[0–5]* %
2008	[60–70]* %	[30–40]* %	[90–100]* %	[5–10]* %	[70–80]* %	[20–30]* %	[90–100]* %	[0–5]* %
2009	[60–70]* %	[30–40]* %	[80–90]* %	[10–20]* %	[50–60]* %	[40–50]* %	[90–100]* %	[5–10]* %

Note: P – plain, C – fixed combination products.

Source: IMS.

(2242) In the UK and Poland sales of fixed combination products containing perindopril, despite a noticeable rise in the last year, remained at relatively low levels. In France and the Netherlands, their sales attained higher percentages at earlier stages. However in the latter countries the single-molecule product clearly dominated by accounting for over 60% of the total sales.

(2243) In general, a combination medicine is constrained by each of the active ingredients only if the latter are available separately. The competitive relationship between perindopril and the fixed combinations including perindopril was clearly asymmetric. Perindopril (single-molecule product) dominated in terms of sales. The prices of fixed combinations were a function of the prices of component mono-therapies. For example, with respect to the combination of perindopril and amlodipine, Servier wanted to price it either at a certain discount from the aggregated price of relevant mono-therapies or at the sum of relevant generics depending on the availability of generics at the time of the combination's launch.[2962] The combinations' protection against generics seems to have depended, to a large extent, on the protection of perindopril. The competitive relationship between the two products was exclusively at Servier's discretion, where the products were clearly targeted at different patient groups. For example, in its internal presentation of 19 June 2006, Servier referred to *"different patient sourcing for Coversyl and [the] fixed combinations"* of perindopril

[2962] ID0117, p. 75 - 77.

and indapamide.[2963] This suggests that Servier could prevent any unnecessary transfers of sales between its products. It is unlikely that the two products could constrain each other in the same way as would be the case if the same two products were controlled by independent firms.

(2244) For the above stated reasons, the subsequent presentation and assessment will focus on perindopril (single-molecule product) as the "gate-keeper" product for all perindopril-based products. The perindopril-indapamide combination, similar to the perindopril-amlodipine combination (which entered the market at a later stage), should be seen as an indication of strong complementarities between those medicines.[2964] The detailed overview provided in the next sections does not incorporate any references to the fixed combination perindopril products because it is unlikely they would provide critical information regarding the competitive situation of perindopril.

6.3.2 Perindopril sales – retail and hospital channels

(2245) Prescription medicines are dispensed to patients both in hospitals and in the retail (pharmacy) channel. In the case of perindopril, the bulk of prescriptions were written in the retail channel. The retail distribution channel, where medicines are usually delivered through wholesalers or directly to pharmacies and then dispensed to patients, accounted for over 96% of Servier's turnover in France, the UK, the Netherlands and Poland. Table 17 provides an overview of all the producers of perindopril, i.e. Servier as well as its generic competitors.

2963 ID0032, p. 178, see also ID0349, p. 413.

2964 The same logic can be applied to the fixed combinations of other molecules. Each fixed combination is a sum of comprised molecules. For example, the combination of valsartan and hydrochlorothiazide (HCTZ) included by Servier among the top products competing with perindopril (see Table 19) consisted of patent protected valsartan and HCTZ, which was an off-patent diuretic. Because of the patent situation, the originator producers, Novartis and Ipsen, could fully control the sales of both plain valsartan and its combination with HCTZ. In this respect, plain valsartan can be regarded as the "gate-keeper" product for all the valsartan-based products. See also paragraph (2372) and footnote 3273.

Table 17: Percentage of the turnover created by the perindopril sales in the retail and the hospital distribution channels

Year	France		UK		Netherlands		Poland	
	Retail	Hospital	Retail	Hospital	Retail	Hospital	Retail	Hospital
2000	[90–100]* %	[0–5]* %	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%
2001	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%
2002	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%
2003	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%
2004	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%
2005	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%
2006	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%
2007	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%
2008	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%
2009	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%	[90–100]*%	[0–5]*%

Source: IMS.

(2246) The Commission asked Servier to submit data on perindopril sales within and outside hospitals. Servier's internal data show an even higher proportion of the retail distribution channel with virtually all the company turnover generated within that channel across all four countries. Importantly the cross comparison between the quantities and turnovers reported by Servier reveals that the company charged for lower prices when supplying hospitals in France, the UK and Poland in comparison with the retail prices in those Member States. For example, in 2005, French hospitals paid on average EUR 0.13 per 30 tablet pack of perindopril 4 mg, while the same pack in the retail channel cost EUR 19.71 in ex-factory terms.[2965] Similarly in the UK, the prices were respectively GBP 4.42 to GBP 9.52,[2966] while in Poland they were PLN 10.92 to PLN 23.18.[2967]

(2247) It must be concluded that the hospital sales had a very limited impact on the overall prices and volumes. However, in the assessment section,[2968] the Commission will address the substantial price differences observed between the retail and the hospital distribution channels.

[2965] ID3011.
[2966] ID2958.
[2967] ID2685, p. 5.
[2968] See section 6.5.

6.3.3 Perindopril sales across indications

(2248) As explained in section 6.2.2, Servier refers to three main indications for which perindopril was prescribed: hypertension (HT), ischemic heart disease (IHD) and heart failure (HF). In some countries there was also a fourth indication, stroke.

(2249) In each of the four countries presented in Table 18, the most frequent prescription category for the mono and combination therapies based on perindopril was by far hypertension.[2969]

Table 18: Distribution of prescriptions between the three main indications in France, the Netherlands, the UK and Poland, in the period 2004-2009

France				Netherlands			
Year	**HT**	**IHD**	**HF**	**Year**	**HT**	**IHD**	**HF**
2004	81.70%	5.52%	5.64%	**2004**	50.41%	9.83%	8.40%
2005	77.64%	7.61%	5.55%	**2005**	49.60%	9.53%	8.18%
2006	75.59%	9.92%	5.45%	**2006**	49.92%	10.62%	6.61%
2007	73.98%	11.68%	5.19%	**2007**	50.81%	10.64%	6.52%
2008	75.76%	10.96%	5.27%	**2008**	51.85%	10.64%	5.41%
2009	71.63%	11.21%	6.44%	**2009**	52.32%	10.63%	4.73%
United Kingdom				**Poland**			
Year	**HT**	**IHD**	**HF**	**Year**	**HT**	**IHD**	**HF**
2004	50.60%	12.72%	4.85%	**2004**	66.21%	24.82%	1.06%
2005	51.81%	12.59%	3.81%	**2005**	65.74%	25.53%	0.85%
2006	55.12%	11.17%	3.09%	**2006**	67.00%	24.13%	1.67%
2007	58.13%	10.84%	2.57%	**2007**	69.46%	22.58%	0.82%
2008	59.59%	10.33%	2.80%	**2008**	67.80%	24.83%	0.77%
2009	58.52%	9.21%	2.40%	**2009**	70.93%	21.77%	0.76%

Source: IMS.

6.3.4 Reference points in terms of the commercial policy for perindopril

(2250) In the space of differentiated products, individual products will be separated by variable distances, i.e. some are closer while others are more distant. Relative closeness or remoteness may concern multiple dimensions of different importance for the competitive process. In general though, the freedom for a given firm to act in relation to a particular product is usually defined by those other products that are the closest in terms of their proximity along the key competitive dimension. If the other products regarded as the closest alternatives do not exercise sufficient competitive pressure on the product under consideration, it is even less likely that significant competitive constraints are exercised by more distant candidates. In other words, the analysis can be confined to the closest alleged alternatives whilst its results can be expected to be generally conclusive for the entire product space and for concluding on the competitive position of the product under consideration within that space. It is also true for any chain effects that can be expected to be transmitted by the "closest

2969 Servier's internal documents confirm that hypertension was the most important indication for perindopril (ID0349, p.651, 753, 836 and 933).

neighbours" in the product space. In this respect, the argument is that even other products that are "more distant" will be taken into account if they themselves influence the "closest neighbours".[2970]

(2251) This section presents the outcomes of the Commission's investigation regarding Servier's perception of the competitive environment and its alleged competitors, both the originator and the generic companies.

6.3.4.1 Reference points in terms of the commercial policy for perindopril declared by Servier

(2252) The Commission requested Servier to indicate up to five products which the company considered to be the reference points / closest competitors in terms of its marketing and pricing policy for perindopril.[2971] In its reply to the request,[2972] Servier explained that between 2000 and 2008, among numerous hypertension medicines, the main reference point was Norvasc, Pfizer's amlodipine.[2973] In addition, Servier was asked to establish a ranking of the top five competitors. Its reply is shown in Table 19. All the medicines listed by Servier were mainly prescribed for hypertension.[2974] They belong to several ATC-3 classes of medicines: the plain ACE inhibitors class (enalapril, lisinopril and ramipril), the plain angiotensin II antagonists class (losartan, valsartan and irbesartan), the combination angiotensin II antagonists class (valsartan+hctz) and the calcium channel blockers class (amlodipine).

Table 19: Ranking of the top five products competing with perindopril submitted by Servier

Year	Main competitors as perceived by Servier				
	1	2	3	4	5
2000	Amlodipine	Enalapril	Lisinopril	Ramipril	Losartan
2001	Amlodipine	Ramipril	Enalapril	Lisinopril	Losartan
2002	Amlodipine	Ramipril	Enalapril	Lisinopril	Losartan
2003	Amlodipine	Ramipril	Enalapril	Losartan	Valsartan
2004	Amlodipine	Ramipril	Losartan	Enalapril	Valsartan
2005	Amlodipine	Ramipril	Losartan	Irbesartan	Valsartan
2006	Amlodipine	Ramipril	Losartan	Valsartan+hctz	Irbesartan
2007	Amlodipine	Ramipril	Valsartan+hctz	Irbesartan	Losartan
2008	Amlodipine	Valsartan+hctz	Irbesartan	Ramipril	Losartan

Source: ID1151, p.3.

Note: Servier makes a number of remarks on country-specific divergences from the general pattern. However, none of these remarks refers to the two top products, amlodipine and ramipril. With regard to the key national

2970 Conceptually, this approach reflects the method described in the *'Commission Notice on the definition of relevant market for the purposes of Community competition law'* (OJ C 372, 9.12.1997, p. 5-13, paragraphs 16 to 18), where the market analysis starts from the product in question and is extended to additional products in subsequent iterations (starting with the closest potential substitutes) until the relevant market is found. The analysis stops at the moment additional products do not prove to be sufficiently strong constraints. This being said, the selection of candidate products must be consistent with other elements of the overall analysis. In this context, see in particular section 6.5.1.2.2

2971 The Commission's RFI dated 6 August 2009, ID0904.

2972 ID1151.

2973 Servier explained that it was the most successful hypertension product in terms of units sold across a number of national markets.

2974 The information is based on the IMS data from the UK, the Netherlands, France and Poland.

markets for the present investigation, Servier flags minor shifts: in France, lisinopril is to be replaced by irbesartan and in the UK, valsartan+hctz by valsartan.

(2253) Servier claims a higher (than the requested five) number of hypertension medicines were considered by the company as reference points for its marketing and pricing policy for Coversyl.[2975] In its reply to the Statement of Objections, Servier provides a selection of quotes from the documents prepared by Servier and the third parties in which Servier's perindopril is set against a broad range of other antihypertensive medicines.[2976] This does not undermine the logic that attention should be given primarily to the most important candidate competitors,[2977] as long as their importance is confirmed by other elements of the overall analysis.[2978]

6.3.4.2 Reactions by the alleged competitors among the originator companies

(2254) The products listed in the above table were marketed or co-marketed in their respective pre-generic periods by the following originator companies: Pfizer (amlodipine), Sanofi-Aventis (ramipril and irbesartan), Bristol-Myers Squibb (irbesartan), Merck Sharp & Dohme (enalapril, lisinopril and losartan), Astra Zeneca (lisinopril), Novartis (valsartan, valsartan+hctz) and Ipsen (valsartan, valsartan+hctz).

(2255) The Commission asked the above-mentioned originator companies whether they considered Servier's perindopril as a product (i) with which their products competed for a significant proportion of new patients/prescriptions, (ii) from which they could acquire a significant number of additional patients/prescriptions by means of switching from the existing perindopril patients/prescriptions, (iii) that should be regarded as a substitute or a complement to their products.[2979]

(2256) Sanofi-Aventis replied only for France and Poland, as it did not have the data for the Netherlands and the UK (the company ceased active marketing on those markets in 2003). With reference to its ramipril sales in France, Sanofi-Aventis explained that *"switches between ramipril and perindopril [were] very limited"* and that both products were *"building their growth on the newly acquired first-time treated patients"*. Sanofi-Aventis also contended that *"the concerned patient population that may benefit from ramipril treatment, with respect to its therapeutic indications, is significantly larger"*, and that ramipril had a broader range of dosages. Concerning France, Sanofi-Aventis concluded that *"perindopril and ramipril should not be regarded as substitute to each other"*. It is worth noting that Sanofi-Aventis ranks perindopril as ramipril's second closest competitor and that its response does not exclude that certain interactions between ramipril and perindopril as regards first-time use patients were actually taking place. Rather it is on balance of all the factors (including the very limited switching among the continued-use patients) that Sanofi-Aventis draws its conclusion that the two products should not be regarded as substitutes. Sanofi-Aventis was able to provide one internal presentation on the French market from 2003 that mainly focused on the strengths of its own product, Triatec. As a background to its performance, the company referred to the sales

2975 ID1151, p. 2 - 3.

2976 Annex 11-01 to Servier's reply to the Statement of Objections, ID9064.

2977 See also footnote 3251 for the distinction between the notions of primary competitive focus and of a significant competitive constraint.

2978 In particular, see section 6.5.1.2.2.

2979 The Commission's requests for information of 12 October 2010 and 12 November 2010, ID2713, ID2714, ID2719, ID2721, ID2723, ID2725 and ID2997.

dynamics achieved by other branded products based on amlodipine, irbesartan, losartan and perindopril.[2980] Sanofi-Aventis stated that on the Polish market it *"considered perindopril as product from which Sanofi-Aventis' ramipril acquired patients however there is no data available regarding this. The switch was due to both pharma-economic reason (patient price of Sanofi-Aventis' ramipril was significantly decreased after reimbursement in October 2005) and medical reason. Again, there is, however, no data available regarding the number of patients switched due to a particular reason".* From the presentations submitted concerning the Polish market and Sanofi-Aventis' commercial plans for the years 2008-2009, it is apparent that the market situation was analysed in different dimensions from a broad perspective encompassing all classes of cardiovascular products to a narrow one limiting the overview to original and generic ramipril. Concerning perindopril and enalapril, the first and second closest respective rival to ramipril, it was noted that ramipril generally had the most favourable brand perception of the three. With respect to losartan, Sanofi-Aventis claimed that perindopril was not a direct competitor.[2981]

(2257) AstraZeneca did not have information about competition for new patients and switches between its product, lisinopril, and perindopril. However, AstraZeneca's submission indicates that AstraZeneca regarded perindopril as a substitute for its lisinopril until the date of lisinopril patent expiry.[2982] In its internal strategy documents dating from the beginning of the investigated period, AstraZeneca mentioned ramipril and perindopril posing a threat in the UK. In the strategy summary for its lisinopril dated 19 December 2000, AstraZeneca mentioned perindopril among five other ACE inhibitors that were believed to be important competitors. Finally, in the strategy document prepared in 1999 for the French market, AstraZeneca carried out a review of five ACE inhibitors including its lisinopril and Servier's perindopril, where it attempted to identify main drivers for prescriptions of each product. In the same document, AstraZeneca's lisinopril was claimed to be superior to Servier's perindopril in two aspects, namely myocardial infarction indication and price for patient.[2983]

(2258) Merck Sharp & Dohme (MSD) which produces enalapril, lisinopril and losartan, in its reply took a much broader perspective, asserting that *"Servier is one of many companies that compete with MSD in the hypertension area and its perindopril product is one of many hypertension medicines that can be used as an alternative to MSD's hypertension treatments".* MSD did not consider it meaningful to distinguish between sales to new and existing patients for the purpose of a competitive analysis, as it could not be distinguished *"ex ante if a sale is going to be made to a new or existing patient or to differentiate their prices on this basis".* MSD did not provide any internal strategy documents from the period 2000 to 2009 to evidence its statements.[2984]

(2259) Bristol-Myers Squibb (BMS) explained in relation to its product irbesartan that among antihypertensive medicines, two classes have the most significant effect on

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2980 ID2875.

2981 ID2867, p. 8 - 10.

2982 See Table 21, Table 24, Table 27 and Table 30 for the dates when lisinopril's exclusivity expired in the selected Member States.

2983 ID5396, ID5397 and ID5398.

2984 ID3036, p. 2 - 3.

the renin-angiotensin-aldosterone hormonal system. These are: (a) the angiotensin receptor blockers, including irbesartan ("ARBs", with names normally ending in "sartan") and (b) ACE inhibitors. According to the company, *"[g]iven the number of products in the ARB class, BMS has focused its competitive efforts on this class, and as such BMS does not consider that Servier's perindopril competes with irbesartan for a significant proportion of new patients/prescriptions"*. Accordingly, its reply only indicates other ARBs as the closest competitors to irbesartan. With regard to switching, BMS replied that *"[t]he prime reason for switching a patient from an ACE inhibitor to an ARB would be if the patient suffered a persistent cough, which is a common side effect of ACE inhibitors. BMS does not consider that irbesartan would acquire a significant number of additional patients/prescriptions by switching them from perindopril"*. Finally, BMS added that *"[p]erindopril would not be regarded as a substitute or a complement to irbesartan"*.[2985] BMS did not provide any internal strategy documents from the period 2000 to 2009 to evidence its statements.

(2260) Novartis, despite the fact that it *"broadly considered that all classes of anti-hypertension medications […] were in competition with its product, valsartan"*, stated that *"during the period 2000 to 2009, [it] did not consider [perindopril] as a primary competitor to valsartan for the treatment of hypertension."* With regard to both France and the UK (Novartis had no data for the Netherlands and Poland), Novartis explained that *"Servier's perindopril did not compete with valsartan for a significant proportion of new patients/prescriptions"*. For France, Novartis reported a certain number of switches from perindopril to valsartan but it also stated it was *"unable to identify the reason for these switches. However, general reasons for switching could include the lack of efficacy of a particular hypertension product, the lack of efficacy of perindopril, potential side-effects and the difference in cost compared to other treatments."*[2986] For the UK, Novartis asserted that no switches took place during the investigated period.[2987] Novartis did not provide any internal strategy documents from the period 2000 to 2009 to evidence its statements.

(2261) Ipsen explained that *"*[p]erindopril and more broadly all treatments of the class of ACE inhibitors, are not considered by IPSEN as direct competitors of Nisis [Ipsen's valsartan] and Nisisco [Ipsen's valsartan + hctz], neither in terms of new patients, nor in terms of change ("switch") of treatments. In its trade policy IPSEN does not present Nisis and Nisisco as potential substitutes of or supplements to perindopril"*. Ipsen also added that *"*[b]esides, the recent recommendations of the High Health Authority [in France] confirm that ARBs and ACE inhibitors do not occupy the same place in the therapeutic strategy, as ACE inhibitors are recommended as first-line therapy in the treatment of HT, before ARBs"*. [2988]

2985 ID2848, p. 2 - 3.

2986 In its reply to the Statement of Objections, Servier refers to the fact that Novartis estimated the transfers from perindopril to valsartan to be at the level from 5-10% to 10-15% a year (see Servier's reply to the Statement of Objections, paragraph 1478, ID10114, p. 452). However, given that sartans were regarded as more expensive, as confirmed among others by Servier (see Servier's reply to the Statement of Objections, paragraph 1472, ID10114, p. 450), the reported switches were most likely based on medical considerations (see paragraph (2503) for explanation why medical switches are not informative with respect to the pattern of economic substitution).

2987 ID2976, p. 3 - 10.

2988 ID3007.

(2262) Pfizer said that, in its view, *"there is no significant substitution between Calcium Channel blockers such as amlopidine and Servier's perindopril based products. Perindopril is an angiotensin converting enzyme (ACE) inhibitor, and forms part of a separate ATC3 class to amlopidine, which is a calcium channel blocker, already a strong indicator that the products are not close competitors"*. Further, Pfizer noted that *"treatment guidelines, such as i) the British Hypertension Society guidelines for hypertension management (1999) and ii) the NICE Clinical Guideline 18, Hypertension: management of hypertension in adults in primary care (August 2004) concur that the products do not substitute except in rare cases, based on specificities of a particular patient's treatment regime. Each of these guidelines suggests usage of the two different classes of product at different stages of treatment, or as complements rather than substitutes in combination therapies"*. Pfizer also submitted two presentations concerning the company's marketing plans for the Polish market in the years 2002-2003. The focus was on calcium channel blockers, while ACE inhibitors are mentioned as a class in the overview of general trends in the cardiovascular field. In the context of the SWOT analysis, Pfizer considered that *"exceptionally good perception of ACEI among medical community"* was one of the threats to its branded amlodipine.[2989]

(2263) Similarly, the above-mentioned originator companies were asked to provide their reference points in terms of marketing and pricing policy for their products. The replies received can be summarised as follows: the producers of non-ACE inhibitors pointed to the products which belonged to the same class of medicines as their own. The only exception was made by Novartis, who also ranked perindopril among its most important reference points. The producers of ACE inhibitors all included perindopril on their lists, except MSD which did not provide any ranking but instead made a general claim as to the broad character of the market.[2990]

(2264) In conclusion, the producers of non-ACE inhibitors generally did not consider that they were in competition with Servier's perindopril and did not target the existing population of the perindopril patients as a potential source of switches that could increase the sales of their products. It is interesting to note that Pfizer, the original producer of amlodipine, which was selected by Servier as the most important reference point, emphasises complementarities and generally excludes substitution between the products. As regards the producers of other ACE inhibitors, they differ in their perception of the external environment in which various ACE inhibitors were marketed. On the one hand, Sanofi-Aventis, whose ramipril is the most important ACE inhibitor according to Servier, did not regard it as a substitute for perindopril in France. Poland is referred to as a possible market where ramipril could gain some patients at the expense of perindopril. However, Sanofi-Aventis was not able to provide any meaningful figures to show that this issue was significant. On the other hand, AstraZeneca was able to provide some evidence suggesting that the company regarded a number of ACE inhibitors as a threat to its lisinopril. However, whether such a threat was indeed material and could lead to mutually constraining positions whereby lisinopril would constrain perindopril remains an open question.

2989 ID7559, p. 23.

2990 ID2894, ID2867, ID2850, ID3036, ID2977, ID2812. As to AstraZeneca, this information is based on the Commission's assessment of the submitted documents (ID5396, ID5397 and ID5398).

6.3.4.3 Reference points in terms of the commercial policy for perindopril declared by the generic producers of perindopril

(2265) In order to achieve a complete overview, the generic companies that were known to be active in the development and/or marketing of perindopril were asked about reference competitors (in terms of marketing and pricing policies for perindopril) in the period 2000 to 2008. In their replies to the Commission's requests for information dated 5 August 2009[2991] a clear majority of the responding generic companies indicate that other producers of perindopril were perceived as the only reference point for their own activities relating to the drug.[2992]

Table 20: List of reference products considered by the generic companies in relation to their own activities in perindopril

Generic company	Reference product(s)	Source
Actavis	Only perindopril	ID1042, p. 7
Apotex	Only perindopril	ID1547, p. 4
Arrow	Only perindopril	ID1571, p. 10
Gedeon Richter	Only perindopril	ID6628, p. 5
Generics UK (Mylan)	Only perindopril	ID1496, p. 10
Glenmark	Only perindopril	ID1045, p. 5-6
Krka	Mainly perindopril (1)	ID1307, p. 31-32
Polpharma	Only perindopril	ID7956, p. 9
Ratiopharm	Only perindopril	ID1481, p. 6
Sandoz (Novartis)	Mainly perindopril (2)	ID1466, p. 40-43
Sanofi-Aventis	Only perindopril	ID6379, p. 10-13
Stada	Only perindopril	ID1034, p. 3-4

Source: As indicated in the table.

Note: (1) Krka's reply refers to the Czech Republic, Hungary and Poland. On each market, the perindopril products of Servier and Egis are mentioned as the most important competitors. The second places are usually occupied by the products based on ramipril.

(2) Sandoz's reply refers to Belgium, the Czech Republic, Germany, Ireland, Italy, Hungary, the Netherlands, the United Kingdom, Romania and France. Sandoz only mentions a non-perindopril product (i.e. the product based on ramipril) in relation to the Czech market. Those are, however, considered only after the perindopril products of Servier, Egis and Krka.[2993]

2991 For example ID0929.

2992 Servier argues that the fact that Lupin was engaged in arbitrage between the production of various ACE inhibitors indicates the existence of competition among ACE inhibitors (see Servier's reply to the Statement of Objections, paragraph 1492, ID10114, p. 458). The Commission rejects Servier's argument. The allocation of production capacity between various products is generally not informative with respect to the competitive constraints faced by a given product. A producer that is able to switch its capacity from the production of other products to the product at stake will be usually considered as a potential competitor, but this does not mean that those other products are demand substitutes to the product at stake. As to the supply substitution, to be effective it requires smooth transition between the products in question both in terms of time and costs. See also footnote 3411.

2993 As an additional commentary to the table, it is interesting to note that Sandoz explains that its own analysis of markets varies across Europe by adopting two distinctively different approaches. The said distinction is made between Western Europe on the one hand, and Central and Eastern Europe on the other. *"In Western Europe, perindopril, like any other product, has been analysed by Sandoz on a*

(2266) The perspective of the generic companies, with their principal focus on perindopril, is not surprising given that they targeted Servier's existing patient base consisting of the continued-use patients. If there was a switch from original to generic perindopril, there was no need for a patient to undergo a new trial period.

6.3.4.4 Conclusion

(2267) Overall the perception of reference points in terms of the commercial policy differed depending on the position of a given undertaking. Servier described its universe in broad terms as encompassing virtually all antihypertensive treatments. Other originators generally declared that their main interactions were centred within the class of medicines to which their product belonged. The generic companies took the narrowest perspective by almost exclusively focusing on perindopril.

6.3.5 Summary – the analytical universe

(2268) For the reasons explained in section 6.3.1, the overview and assessment will focus on perindopril, Servier's mono-therapy.[2994]

(2269) It is clear that perindopril was predominantly dispensed in the retail (pharmacy) channel. The limited sales taking place in the hospital channel could not affect the overall price and volume trends in any appreciable manner. Therefore the subsequent overview of market facts can concentrate on the sales achieved in the retail channel without any serious risk of omitting valuable information. The finding of substantial price differences made in section 6.3.2 between the two channels will be further interpreted in the assessment section (section 6.5).

(2270) Hypertension is perindopril's main indication in terms of the existing prescription statistics (see Table 18) and is the focus of this analysis. Potentially competing products were also predominantly prescribed for hypertension.

(2271) Finally, since perindopril belongs to the broad group of medicines used in the treatment of health problems from the cardiovascular continuum, it is necessary that a choice is made of those other products that were most likely to influence the sales of perindopril. Based on Servier's own submission,[2995] it is possible to preliminarily restrict the presentation of the quantitative data to the following medicines: amlodipine, enalapril, lisinopril, ramipril, losartan, valsartan, valsartan+hydrochlorothiazide (hctz) and irbesartan. In the Commission's opinion, the selection process by Servier, even if imposed by the Commission through its request for establishing a list of top five "competitors" (see section 6.3.4.1), allows for regarding the above-mentioned molecules as the most likely candidates to have exercised competitive constraints on the sales of perindopril in the inter-molecule

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molecule and dosage form/strength level. […] Therapeutic groups or indications mainly influence total market growth assumptions and are of secondary importance in Western Europe. In Central and Eastern Europe, Sandoz's analysis typically focuses on therapeutic classes. Therefore, in the case of perindopril, Sandoz looks at the ACE inhibitor class" (ID1480, p. 5 - 6). While a similar practice with respect to the Central and Eastern European (CEE) markets is adopted by Krka, which also lists non-perindopril products in its reply, this practice does not seem to be shared by all the other companies interested in the Central and Eastern European markets. Those other companies are Actavis, Apotex, Gedeon Richter, Glenmark, Polpharma and Sanofi-Aventis. Each of them in its reply refers to at least one national market from the CEE region. The replies indicate that the six companies take into account solely other manufacturers of perindopril.

2994 In this document all references to perindopril are meant to refer to mono-therapy (plain) perindopril unless an explicit reference is made to the combination products of perindopril and other molecules.

2995 See Table 19.

setting. The selected medicines also provide a representative universe for the quantitative analysis of the relevant market because they are leading products that belong to different classes of hypertension medicines: the plain ACE inhibitors class (enalapril, lisinopril and ramipril), the plain angiotensin II antagonists class (losartan, valsartan and irbesartan), the combination angiotensin II antagonists class (valsartan+hctz) and the calcium channel blockers class (amlodipine). The general correctness of this selection, in particular the inclusion of the leading ACE inhibitors,[2996] is further confirmed by the Commission's analysis carried out in section 6.5.1.2.2.

(2272) As to the choice of Member States for further in-depth investigation, the Commission notes that France and the UK were the most important Member States for Servier in terms of the annual revenues generated in the period prior to generic entry (see *Annex B: Perindopril sales - geographic distribution*). This fact in itself favours including at least these two markets. Naturally these are also the markets where the consumer benefit from generic entry could be expected to be the greatest, at least in absolute terms. Due to the considerable amount of time required for description and in-depth analysis of each additional market, it was considered appropriate to limit the in-depth analysis to two more Member States. The choice of including the Netherlands and Poland is not determined by the relative importance in terms of the annual revenues generated for Servier but rather by their specific importance in understanding Servier's practices. The Netherlands is an important market from the perspective of generic entry, where in fact the first generic entrant, Apotex, decided to enter "at risk" and managed to clarify the situation by taking recourse to court litigation.[2997] The Netherlands is also an example of the country with the cross-border reference pricing system.[2998] The Polish market represents a distinctively different type of market where generic competition was based on building and maintaining generic brands. The branded character of the market may have an important impact on the market dynamics. This is also a typical characteristic of the Central and East European (CEE) markets of which Poland was the most important for Servier (actually number four across the EU). In addition, Poland was also subject to early entry,[2999] which provides a higher number of observations for the assessment of intra-molecule competition. This choice of Member States has been already implicitly included in earlier sections of the present document, for example when reporting on the turnovers achieved on plain and combination products containing perindopril (see Table 16).

6.4 Overview of the facts concerning the sales of perindopril

(2273) This section provides an overview of the facts concerning the sales of perindopril. It consists of four country-specific sub-sections (sections 6.4.1 – 6.4.4) followed by sub-section 6.4.5 complementing the country-specific information with other aspects concerning the sales of perindopril.

(2274) Each of the country-specific sub-sections (sections 6.4.1 – 6.4.4) first describes the regulatory aspects (such as official prices and reimbursement conditions) relevant for the sales of original and generic perindopril. The key characteristics of each national

2996 The three ACE inhibitors in question along with perindopril constituted almost all sales of ACE inhibitors in the four selected Member States during the investigated period. Source: IMS.

2997 See paragraph (194).

2998 See section 6.4.2.1.

2999 On the nature and context of this particular entry see section 4.3.3.

system are explained to the extent necessary to understand what type of factors were taken into account in deciding about the conditions of sales for original and generic perindopril during the investigated period (2000-2009).[3000] The regulatory aspects are followed by the overviews of the price and volume developments concerning perindopril and other pre-selected products.[3001] In addition, for each of the selected national markets, the sales of perindopril are separated into the sales of the original and the generic versions of perindopril.

(2275) The purpose of sub-section 6.4.5 is to provide a more comprehensive context to the price and volume developments observed during the investigated period.

6.4.1 The United Kingdom

(2276) This section describes the regulatory aspects such as official prices and reimbursement conditions relevant for the sales of original and generic perindopril in the United Kingdom (sections 6.4.1.1 and 6.4.1.2). The description of the regulatory aspects is followed by the country-specific overview of the relevant price and volume developments (sections 6.4.1.3 and 6.4.1.4).

6.4.1.1 Regulatory aspects concerning Servier as an originator of perindopril in the United Kingdom

(2277) The UK system was in principle a free price system, where originator companies entering with new prescription medicines had freedom of pricing. The originator companies had to inform the authorities when they introduced a new product. The product's price was registered on the National Health Service's (NHS) price list, according to which pharmacists were reimbursed by the state for dispensing the originators' products in primary care. The UK system fully reimbursed the vast majority of new prescription medicines,[3002] including perindopril.[3003] Although originator companies were free to set the prices for each of their products, the overall price level was influenced by the Pharmaceutical Price Regulation Scheme (PPRS), by which the originator companies were bound to limit their prices in line with the allowed profitability level of their operations.[3004]

(2278) Servier's perindopril erbumine, Coversyl, was launched at an NHS list price of GBP 9.45 for 2 mg and GBP 13.65 for 4 mg in 1990. The 8 mg version was introduced at a NHS list price of GBP 14.63 in 2002. In each case, the prices refer to the standard 30 tablet pack. Subsequent price changes were not product specific but were introduced in the framework of industry-wide re-negotiations of the PPRS.

3000 The descriptions reflect the structures of regulatory systems as described by the national authorities in their replies to the Commission's requests of information of 7 April 2010 completed with the information provided by Servier and from the publicly available sources, in particular the ÖBIG study: *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, available at: http://ec.europa.eu/competition/mergers/studies_reports/oebig.pdf.

3001 As illustrated in Table 19, Servier includes eight reference products for its perindopril pricing and marketing policy. As already mentioned, among these products there are three plain ACE inhibitors: enalapril, lisinopril and ramipril, three plain angiotensin II antagonists: losartan, valsartan and irbesartan, one combination angiotensin II antagonist: valsartan + hctz, and one calcium channel blocker: amlodipine. The overviews focus on the essential price and volume developments, in particular with respect to those products that were subject to generic entry in the course of the investigated period. The overviews are supplemented with *Annex A: Price developments*.

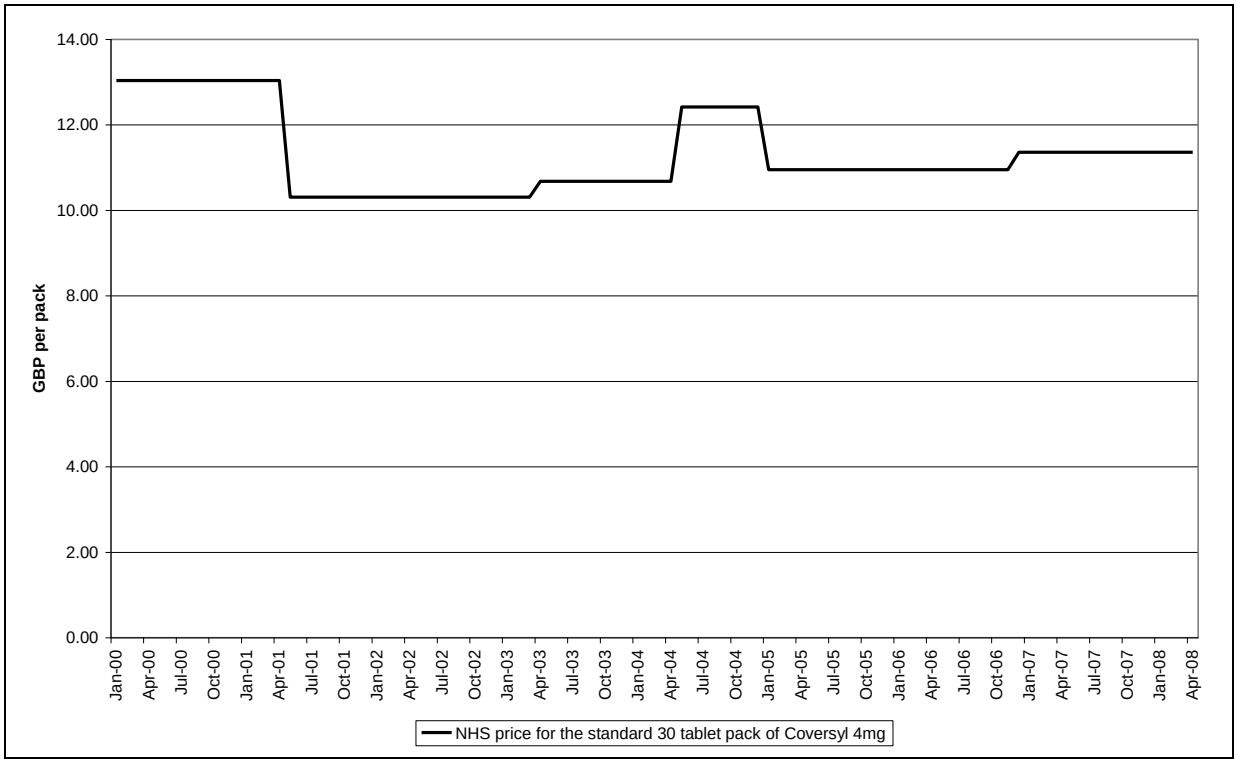
3002 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 721.

3003 ID2217, p. 4.

3004 ID2217, p. 1 - 4.

Figure 3 below shows the NHS price of the standard 30 tablet pack of Coversyl 4 mg. As illustrated, the official NHS price remained broadly stable during the investigated period and relatively close to the launch price.[3005]

Figure 3: The official NHS (retail) list price for the standard 30 tablet pack of Coversyl 4 mg



Source: ID2913.

Note: Servier reported that its wholesale price was on average 10% below the official NHS retail list price.

(2279) In July 2007, generic perindopril entered the UK market. Perindopril erbumine was therefore no longer a "new" product. In April 2008, Servier discontinued selling its perindopril *erbumine* and replaced it with perindopril *arginine*. The UK authorities did not treat the latter as a new product and thus Servier did not have freedom of pricing. Servier applied for prices for the *arginine* product at parity with the originator prices of the previous *erbumine* product. The UK authorities agreed to these prices.[3006] However, at that time the market was already switched to generic perindopril *erbumine* and Servier did not manage to acquire any significant sales for its *arginine* product.[3007]

(2280) Primary Care Trusts (PCTs) could also influence the conditions of sales for branded perindopril. PCTs were the statutory NHS bodies responsible for commissioning most health services.[3008] There were originally 303 PCTs. After 2005, their number was reduced to 152 PCTs.[3009] Servier internally reported that *"in April 2005, the reimbursement prices of lisinopril and ramipril were reduced enormously (by 70-80%) […]. The effect of these price reductions [has] encouraged some PCTs to […] actively encourage GPs to use these cheaper generics than branded drugs, such as*

3005 For ex-factory prices of perindopril and other selected molecules in the UK, see paragraph (2287).
3006 ID2217, p. 4.
3007 See section 6.4.1.4.
3008 ID0036, p. 311 - 312.
3009 See: http://www.nhsconfed.org/Publications/Documents/The_legacy_of_PCTs.pdf.

Coversyl".[3010] In its replies to the Statement of Objections and the Letter of Facts, Servier referred to several instances in which the PCTs attempted to shift at least a part of the demand for perindopril to the cheaper generics of other ACE inhibitors.[3011] For example, in September 2005, Plymouth Teaching PCT advised its prescribers to *"consider the difference in price when initiating prescribing of ACE inhibitors"*.[3012] Some PCTs also encouraged GPs to use other cheaper ACE inhibitors for the continued-use patients. In those cases, the switches were usually subject to safety measures such as additional controls, GPs' consent, etc.[3013] The available examples show that from a certain moment in view of important changes in relative prices perindopril started to be regarded as an expensive product and some PCTs attempted to restrict the demand for perindopril in quantity terms. However, from the perspective of the overall demand for perindopril, the efforts of the PCTs do not appear to have significantly impacted perindopril's sales, neither in terms of volume nor price.[3014] Several factors can explain such an outcome: (a) the local and uncoordinated character of the PCT measures, (b) no collective follow up by a larger number of the PCTs, (c) the PCT measures were aimed at GPs, but could not influence the prescriptions made in the specialised care, and (d) the PCTs could only exercise indirect influence since the ultimate prescription decision was left in the prescribers' hands. Other than the PCTs recommendations which tried to steer the demand away from perindopril, there is no evidence showing a regulatory intervention into the pricing of perindopril.

6.4.1.2 Regulatory aspects concerning the generic suppliers of perindopril in the United Kingdom

(2281) The generics market was a competitive one where producers were free to set prices according to their own business models. However, the medicines prescribed generically, i.e. with their international non-proprietary names (INN), were reimbursed according to the Drug Tariff, which determined how much a dispensing contractor, e.g. a pharmacy, would be paid for the medicines dispensed to patients. Part VIII of the Drug Tariff contained three different categories A, C and M for medicines which were prescribed generically.[3015] Medicines in category C were those for which a generic was not readily available. Medicines in category A and category M had available generics but the reimbursement rules for those two categories varied with respect to the method used for updating the reimbursement level and the frequency of those updates.[3016] Both categories aimed at stimulating competition among the generic suppliers. Category M was introduced in April 2005 and led to even lower generic prices.[3017]

3010 ID0036, p. 312.

3011 Servier's reply to the Statement of Objections, paragraphs 1534 to 1537, ID10114, p. 469-472 and Servier's reply to the Letter of Facts, paragraphs 132 and 188-207, ID10324, p. 42 and 57-63.

3012 ID0032, p. 97.

3013 See for example Servier's reply to the Letter of Facts, ID10292, p. 64-65 and 231.

3014 See section 6.5.1.2.3.3 for the natural event analysis, including the effects of generic entries in lisinopril and ramipril on the sales of perindopril.

3015 ID2217, p. 5 - 6.

3016 ID2217, p. 6-7, ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 722 - 723.

3017 ID0036, p. 312, ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 715.

(2282) The UK system generally enabled strong price competition where there were multiple manufacturers of the same medicine. For medicines dispensed under a generic name, pharmacies received the same reimbursement price irrespective of the source from which they acquired the medicine. Therefore, with respect to a specific medicine (e.g. ramipril) pharmacies had a strong incentive to purchase from the cheapest source and retain a discount, thus driving price competition.[3018] Subsequently, the discounts acquired by pharmacies were reflected in recalculations of the Drug Tariff. Overall, the UK system used a reiterative mechanism where in each reiteration generic suppliers had to undercut an ever lower reimbursement price.

(2283) Before November 2007, perindopril erbumine was listed in category C for the medicines that are not readily available as a generic. Its reimbursed price was referenced to the proprietary product, i.e. Servier's Coversyl.[3019] In November 2007, perindopril erbumine was moved to category A for medicines that are available as a generic and subsequently, in October 2008, to category M.[3020]

(2284) In the UK, practitioners were encouraged to prescribe by generic name, i.e. by INN.[3021] For example, some PCTs, i.e. the authorities responsible for provision of health services at local level, encouraged general practitioners to prescribe generically by offering incentives for practices that achieved a target generic prescribing rate.[3022] Since 2002 there was also an obligation of issuing 72% of prescriptions generically.[3023] Notably, doctors could prescribe a medicine "generically" by listing the pre-existing generic name of the product even though generics had not yet entered the market. This was an important feature of the UK system in view of the fact that it did not allow for generic substitution at pharmacy level,[3024] where a medicine had to be dispensed in accordance with the prescription.[3025] In the *2006/2007 Coversyl Orientation Plan*, Servier noted that *"[a]s yet there are no indications that generic perindopril are to be made available in the UK. […] the high degree of generic prescribing is a threat […] Current data suggest that 99.5% of Coversyl scripts are written generically as perindopril"*.[3026] The 99.5% ratio of generic prescriptions implied that at its arrival, generic perindopril could capture virtually the entire market for perindopril.

6.4.1.3 The sales of perindopril and other selected products in the United Kingdom

(2285) All the short-listed products (except the valsartan + hctz combination) were commercialised by the originator producers before the year 2000. Generic entries took place in relation to five molecules, including all four ACE inhibitors and amlodipine. Four out of five generic entries happened between 2002 and 2007. Further details regarding the launch dates of individual originator and generic products are given in Table 21.

3018 ID2217, p. 7 - 8.

3019 See section 6.2.7.

3020 ID2217, p. 7.

3021 ID2217, p. 7.

3022 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 724.

3023 ID2909, p. 7.

3024 For the avoidance of doubt, therapeutic substitution by pharmacists was not allowed in the United Kingdom. ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 728.

3025 ID2217, p. 8.

3026 ID0036, p. 311.

Table 21: Product launch dates in the UK

Product	First launch date	
	Originator	Generic
Perindopril	01/1990	07/2007 (*)
Enalapril	01/1985	12/1999
Lisinopril	06/1988	10/2002
Ramipril	03/1990	01/2004
Amlodipine	01/1990	03/2004
Irbesartan	09/1997	-
Losartan	02/1995	-
Valsartan	10/1996	-
Valsartan + hctz	07/2004	-

Source: IMS.

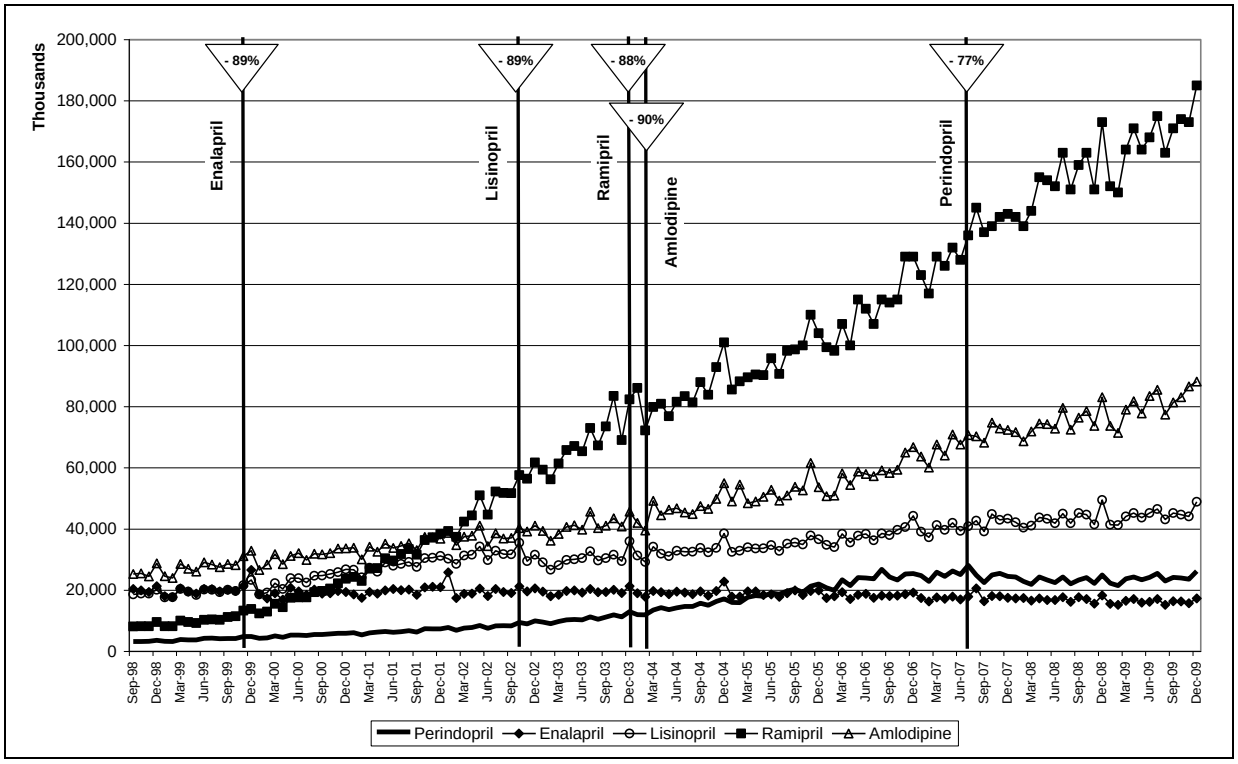
Note: (*) – corrected with the company data, for details see section 6.4.1.4.

(2286) Perindopril's monthly sales were below [1–25]* million DDDs[3027] before 2000. By the time of generic entry in July 2007, its sales had grown steadily to attain over [25–

[3027] DDD stands for a Defined Daily Dose, which is an assumed average maintenance dose per day for a drug used for its main indication in adult patients. A DDD brings all possible sizes of packages and dosages of the product to a standard unit, which in turn allows for aggregation of quantities and calculation of average prices per DDD. WHO fixed a DDD of perindopril erbumine at 4 mg (see: http://www.whocc.no/atc_ddd_index/?code=C09AA04). The equivalent value for a DDD of perindopril arginine is assumed to be 5 mg (see section 6.2.5 for the relation between the two salts of perindopril). As to DDD values for other non-perindopril products, they are also based on the reference values as provided by WHO. The principles for fixing DDDs differ with respect to combination products. With respect to the combination products used for treatment of hypertension, their DDDs are based on the average number of dosing intervals per day (see: http://www.whocc.no/ddd/definition_and_general_considera/#ddds2). The only combination product considered by the below overview is valsartan + hctz, which in all its forms is marketed as a once-daily product (see: http://www.diovan.com/index.jsp), hence one tablet is made equal to one DDD. In its reply to the Letter of Facts, Servier criticises the Commission for the use of prices per DDD (Servier's reply to the Letter of Facts, paragraphs 165-173, ID10324, p. 51-53). In this context, the Commission wants to point out that the prices per DDD are used to bring the price of each product available in different packages and different dosages to a single figure that enables to observe relative changes in prices, e.g. as a result of generic perindopril entry, the average prices of perindopril were found to be lower by 17% to 90%. The consistent use of any other unit, e.g. the average prescribed daily dose, would lead to the same result. In its Statement of Objections and the present Decision, the Commission does not delineate the markets on the basis of the absolute differences in prices, in which case the choice of the correct unit would be critical. Moreover, the Commission's analysis of the price developments on the Polish market, where the absolute prices might have had a greater impact on the prescription and purchase decisions by the doctors and the patients, takes into account that the DDDs do not fully reflect the medical practice (see paragraph (2348), and Figure 26 in Annex A). Finally, the Commission must note that Servier itself relies on the DDD quantities in advancing the arguments for which the nature of the DDD conversion is indeed critical. In particular the comparison of relative sales of leading ACE inhibitors prepared by Servier's economic consultant does not take into account that the conversion of ramipril's sales into DDDs inflates ramipril's sales figures by a factor of two or more and that in this respect ramipril is a clear outlier (see Servier's reply to the Statement of Objections, paragraphs 1446-1447, ID10114, p. 441-443, and its annex 00-01A – CRA's report – paragraphs 33-38 and 122, ID9054, p. 12-20 and 51 and CRA's supplementary report, paragraphs 22-25, ID10318, p. 11-13). For the sake of completeness, the overviews of the sales of perindopril and other selected products

50]* million DDDs per month. From September 1998 onwards, perindopril was selling in lower quantities than enalapril, lisinopril, ramipril and amlodipine. The situation did not substantially change in this respect throughout the investigated period, except for enalapril which was not growing in volume terms and was eventually surpassed by perindopril in 2005. Ramipril attained the highest sales with over 180 million DDDs in December 2009.[3028] Figure 4 below presents further details on the volumes marketed in the United Kingdom with respect to the selected ACE inhibitors and amlodipine. The relevant generic entries are marked with vertical lines. The inverted triangles inform on how the prices of products that turned generic evolved between a month preceding generic entry and December 2009.

Figure 4: Volumes of perindopril, enalapril, lisinopril, ramipril and amlodipine in the UK, in the period September 1998 - December 2009 (in thousand DDDs) and the percentage price changes observed post relevant generic entries



Source: IMS.

(2287) Throughout the period September 1998 to December 2009, perindopril remained more expensive per DDD than enalapril, lisinopril, ramipril and amlodipine. It was sold at prices[3029] in the range of GBP 0.30 to 0.40 per DDD.[3030] Ramipril was the

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in sections 6.4.1.3, 6.4.2.3, 6.4.3.3 and 6.4.4.3 are completed with the information on volumes and prices expressed in terms of tablets and capsules instead of DDDs.

3028 As regards the pre-selected ARBs (irbesartan, losartan, valsartan and valsartan + hctz), for most of the period and in particular in its second half, all those products were sold in smaller quantities than perindopril. None of them achieved the level of 20 million DDDs per month during the period in question.

In terms of the sales of tablets and capsules, the medicines in question ranked as follows (in thousands tablets and capsules), in January 2000: amlodipine (19 893), lisinopril (18 605), enalapril (17 950), ramipril (7 777), perindopril (5 424), losartan (4 637), valsartan (1 625) and irbesartan (1 222); in June 2007: ramipril (52 466), amlodipine (48 950), lisinopril (33 602), perindopril (23 169), enalapril (13 166), losartan (12 709), irbesartan (9 552) and valsartan (7 508). Source: IMS.

3029 Unless otherwise specified, all prices quoted in this document are the ex-factory prices, i.e. the net prices obtained by manufacturers after all discounts but before taxes, in particular value added tax.

cheapest in terms of price per DDD.[3031] For each molecule, generic entries of the same molecule can be clearly identified as turning points in the evolution of their respective prices.

(2288) For the products that went off patent during the reviewed period, each of the respective turnovers reached its peak precisely in the month when the respective originator company's exclusivity was coming to its end. From that moment onwards, the earlier growth trend was discontinued and the value of sales started falling to a substantially lower level as compared with the peak moment. Before generic entry, the monthly sales of perindopril attained the level of approximately GBP 8 million.

6.4.1.4 The sales of original and generic perindopril in the United Kingdom

(2289) Table 22 below provides an overview of the quantities sold by Servier and by the generic companies at half-year intervals during the period 2006 to 2009. After the second generic launch[3032] in July 2007, the generic companies acquired a substantial share of the UK market. The aggregated market share of all generics in volume terms rose from an initial [60-70]% in the second half of 2007 to [90-100]% in the second half of 2009. The 2007 generic entry had a mitigated impact on the overall quantities sold. The comparison of sales from 18 months preceding and following the entry shows a slight increase in six-monthly average sales from [100-150] to [100-150] million DDDs, i.e. an increase of approximately [5-10]%. If, however, an average is calculated for 30 months following the entry, it is [100-150] million DDDs, which is still approximately [1-5]% above the pre-entry level.

3030 Certain price movements within that band were due to a statistical effect of the raising sales of the 8mg dose of perindopril, which in theory represented the cheapest form of perindopril, given the mechanism for DDD transformation. In general, the pre-generic prices of perindopril per each type of packs remained by and large stable, which can be exemplified with the official NHS list prices for perindopril 4 mg quoted in section 6.4.1.1.

3031 As regards the possible comparison with the prices of ARBs (sartans), there is a reverse situation. A DDD of perindopril was less expensive than the cost of daily treatment with the selected ARBs (sartans). Unsurprisingly, the price gap broadened in the wake of generic entry in perindopril. The highest price was paid for the combination of valsartan + hctz that was introduced in the UK in the middle of the investigated period. The combination of valsartan + hctz entered the UK market at a price above GBP 0.60 per DDD.

In terms of an average (for all available doses of a given medicine) price per tablet/capsule, the medicines in question ranked as follows (GBP prices in brackets), in January 2000: irbesartan (0.543), losartan (0.538), valsartan (0.503), amlodipine (0.432), perindopril (0.328), enalapril (0.301), lisinopril (0.287) and ramipril (0.266); in June 2007: losartan (0.625), valsartan (0.562), irbesartan (0.430), perindopril (0.319), amlodipine (0.171), ramipril (0.089), lisinopril (0.072) and enalapril (0.056). Source: IMS.

3032 The first launch by Apotex was stopped by the interim injunction Servier obtained from the High Court after a week of Apotex's market presence. For more details, see section 4.1.2.4.2.2.1.

Table 22: Sales of perindopril in the UK

	Servier (*erbumine*) in million DDDs	Servier (*arginine*) in million DDDs	Generics (*erbumine*) authorised by Servier in million DDDs	Generics (*erbumine*) with independent API sources in million DDDs	Total market in million DDDs	Total market in GBP millions
2006H1	[100-150]	0	0	0	[100-150]	[20-75]
2006H2	[100-150]	0	0	[0-25]	[100-150]	[20-75]
2007H1	[100-150]	0	0	0	[100-150]	[20-75]
2007H2	[25-100]	0	[25-100]	[25-100]	[150-200]	[30-100]
2008H1	[0-10]	[0-10]	[25-100]	[25-100]	[100-150]	[2-15]
2008H2	0	[0-10]	[25-100]	[25-100]	[100-150]	[2-15]
2009H1	0	[0-10]	[25-100]	[25-100]	[100-150]	[2-15]
2009H2	0	[0-10]	[25-100]	[25-100]	[100-150]	[2-15]

Source: The Commission's own calculation based on ID1774, ID1861, ID1865, ID1869, ID1872, ID1875, ID1844, ID1963, ID3347.

Note: Towards the end of the reported period, one of the generics authorised by Servier turned to an independent source of API. This fact is not reflected in the table.

(2290) After full generic entry in July 2007, the UK market experienced a sharp decrease in perindopril prices. The average price per DDD fell from GBP [0.20 - 0.50] in the first half of 2007 to GBP [0.02 - 0.10] in the second half of 2009. This represents an almost ten-fold drop in the average price of perindopril. Table 23 provides further details on the price developments in the UK during the analysed period, including a separate price for each type of supplier.

Table 23: Prices of perindopril in the UK

Prices in GBP per DDDs	Servier (*erbumine* & *arginine* combined)	Generics (only *erbumine*) authorised by Servier	Generics (only *erbumine*) with independent API sources	Weighted average price
2006H1	[0.20-0.50]	n/a	n/a	[0.20-0.50]
2006H2	[0.20-0.50]	n/a	[0.20-0.50]	[0.20-0.50]
2007H1	[0.20-0.50]	n/a	n/a	[0.20-0.50]
2007H2	[0.20-0.50]	[0.10-0.30]	[0.10-0.30]	[0.20-0.50]
2008H1	[0.20-0.50]	[0.02-0.10]	[0.02-0.10]	[0.02-0.10]
2008H2	[0.10-0.50]	[0.02-0.10]	[0.02-0.10]	[0.02-0.10]
2009H1	[0.10-0.50]	[0.02-0.10]	[0.02-0.10]	[0.02-0.10]
2009H2	[0.10-0.50]	[0.02-0.10]	[0.02-0.10]	[0.02-0.10]

Source: The Commission's own calculation based on ID1774, ID1861, ID1865, ID1869, ID1872, ID1875, ID1884, ID1963, ID3347.

Note: Towards the end of the reported period, one of the generics authorised by Servier turned to an independent source of API. This fact is not reflected in the table.

(2291) The changes in volumes and prices have a knock-on effect on the overall turnover achieved by the product. In terms of total market value, the ultimate outcome depends on the direction and the magnitude of these changes. In the UK, the slight increase in volumes in the post-generic entry period coincided with a very substantial

decrease in prices. Hence, the total market value dropped from over GBP [40-150] million in 2006 to less than GBP [4-30] million in 2009.

(2292) In the context of the sharp fall in the value of the UK market, it is interesting to read Servier's internal commentary relating to the direction of market developments:

"The patent of perindopril was revoked in July 2007. Generics entered the market immediately. 99% of the prescriptions are written in INN (C9A) and the pharmacists are just keeping the margin between their selling price and the NHS reimbursed price, hence the generic penetration is very fast. Servier is supplying TEVA and GUK.

Servier UK is significantly behind its budget. Few key reasons:

- The erosion of the perindopril price going down faster than expected, which is not compensated by the relatively good start of the year for Coversyl, combined with a limited performance from our partners […]".[3033]

6.4.2 The Netherlands

(2293) This section describes the regulatory aspects such as official prices and reimbursement conditions relevant for the sales of original and generic perindopril in the Netherlands (sections 6.4.2.1 and 6.4.2.2). The description of the regulatory aspects is followed by the country-specific overview of the relevant price and volume developments (sections 6.4.2.3 and 6.4.2.4).

6.4.2.1 Regulatory aspects concerning Servier as an originator of perindopril in the Netherlands

(2294) In principle, the Dutch system allowed originator companies to set prices freely when selling their medicines to wholesalers. However, in practice, originator companies needed to take into account the maximum wholesale price and the reimbursement level that were set for each prescription medicine. The maximum wholesale price was calculated as the average wholesale price of the same active ingredient, strength and pharmaceutical form in four European countries: Belgium, France, Germany and the UK. This mechanism can be referred to as the cross-border reference pricing system. The maximum wholesale price system was introduced in the Netherlands in 1996.[3034]

(2295) According to the Österreichisches Bundesinstitut für Gesundheitswesen (ÖBIG) study, Dutch patients were not used to co-payments and therefore manufacturers tended to bring their products' prices down to the applicable reimbursement level.[3035] This created the link between product prices and reimbursement limits. Therapeutically interchangeable medicines were grouped together if they were used for the same indications, had the same pharmaceutical form and were used for patients in the same age category. Servier's perindopril, Coversyl, was first placed in a group of interchangeable medicines together with other ACE inhibitors and AT-1 antagonists (sartans). In October/November 2005, ACE inhibitors became a separate group with a separate reimbursement limit.[3036] Apart from the separation from

3033 ID0359, p. 30.

3034 ID2274 and ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 497 - 524.

3035 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p.511.

3036 ID2274, ID3192.

sartans, the reimbursement levels for ACE inhibitors were not actively adapted to the market developments. In general, the Dutch authorities refrained from adjusting the reimbursement levels throughout the period 2000 to 2009. The last adjustments were made in 1999.[3037]

(2296) Out of the two above-mentioned instruments, and as explained below, it was the instrument imposing a lower price (in the present case, the maximum wholesale price) that was effectively decisive for the conditions of sales for prescription medicines.

(2297) Servier's perindopril *erbumine* was allocated a reimbursement limit in October 1998. The initial reimbursement limit per tablet was set at EUR 0.40840 per 2 mg tablet and EUR 0.68067 per 4 mg tablet. The 8 mg version was introduced at a reimbursement limit of EUR 1.36134 per tablet in June 2003. In October/November 2005, the reimbursement limits were lowered to EUR 0.35045, EUR 0.58408 and EUR 1.16816 respectively.[3038] However, as shown in Figure 5, the maximum wholesale price for Coversyl 4 mg, the most frequently prescribed dose of perindopril, remained below the reimbursement limit throughout the investigated period.[3039] Therefore it can be concluded that the maximum wholesale price (based on the cross-border reference pricing system) was decisive for determining the sales conditions of perindopril in the Netherlands. The graph is completed with the official pharmacy price, which is based on the official wholesale price (equal to or lower than the maximum wholesale price)[3040] increased by a fixed fee for the pharmacy service, which is also reimbursable.[3041] The fall in the official pharmacy price visible in March 2008 occurred following Servier's own decision related to the introduction of a preference policy[3042] by Dutch private insurers.[3043]

3037 *Prijsvorming van generieke geneesmiddelen: forse prijsdalingen in het nieuwe zorgstelsel*, CPB Document, No 175, page 17. The document is available at: http://www.cpb.nl/publicatie/prijsvorming-van-generieke-geneesmiddelen-forse-prijsdaling-het-nieuwe-zorgstelsel.

3038 ID2275.

3039 For ex-factory prices of perindopril and other selected molecules in the Netherlands, see paragraph (2306).

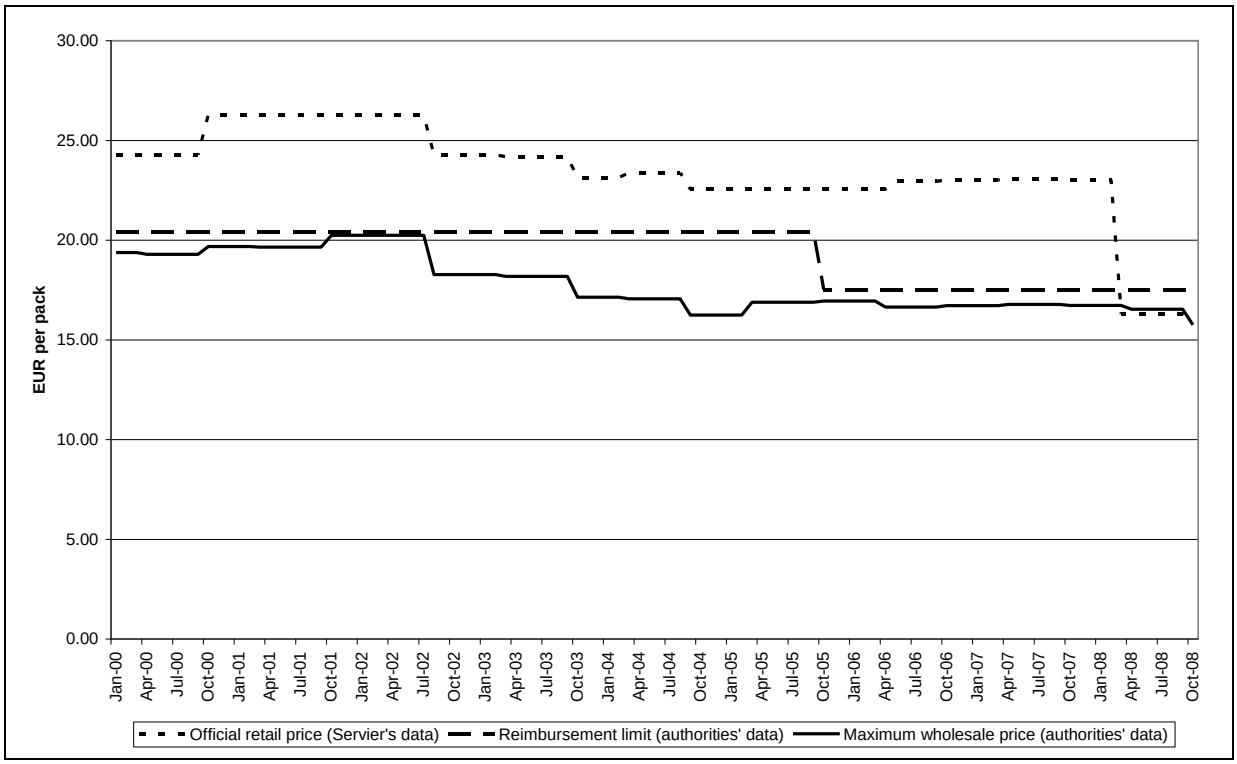
3040 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 505 – 507.

3041 The extent to which each health insurer reimburses this service charge depends on individual terms of insurance, but in principle the service charge will normally be fully reimbursed. The precise level of the service charge also depends on negotiations between a health insurer and pharmacies. Information source: http://www.fk.cvz.nl/voorna/i/inl%20de%20kosten%20voor%20farmaceutische%20zorg.asp, and http://www.nza.nl/publicaties/nieuws/129549/.

3042 Dutch law allows health insurers, which have been privatised, to limit patients' reimbursement of medicines that use the same active ingredient to a single supplier. This has led health insurers to conduct the so-called "preference policy" for a number of generic medicines, selecting the cheapest supplier(s) whose products alone will be reimbursed during a certain period of time. The selection of the suppliers follows the same logic as a tender process, where the bidder with the lowest price is selected. For more on the preference policy: the European Commission's *Report on the pharmaceutical sector inquiry* of 8 July 2009, para. 374-382.

3043 ID2909, p. 5.

Figure 5: The official prices and the reimbursement limit for the standard 30 tablet pack of Coversyl 4 mg in the Netherlands



Source: ID 2275, ID2911, ID3193.

(2298) In February 2008, Servier launched its perindopril *arginine*, which was given the same reimbursement limit as perindopril *erbumine*. This was set at EUR 0.58408 and EUR 1.16816 per 5 mg and 10mg tablets respectively. In April 2008, it was set at EUR 0.35045 per 2.5 mg tablet. Concurrently, Servier's perindopril *arginine* took over the maximum wholesale price of perindopril erbumine: set at EUR 0.35034, EUR 0.55767 and EUR 0.67867 per 2.5 mg, 5 mg and 10 mg tablets respectively.[3044] However, perindopril *arginine* was launched after the arrival of generic perindopril *erbumine* and Servier did not manage to acquire any significant sales for its *arginine* product.[3045]

6.4.2.2 Regulatory aspects concerning the generic suppliers of perindopril in the Netherlands

(2299) The main rules relevant for pricing and reimbursement of generic perindopril were, in principle, similar to the rules explained in the previous section that were applied to Servier's perindopril. For example, generic perindopril *erbumine*, launched by Apotex in December 2007, was subject to the same price limits for maximum wholesale price[3046] and the reimbursement limit as Servier's Coversyl at that time.[3047]

(2300) Initially (i.e. previous to the full development of the "preference policy" in 2008), the main cost containment measures were adopted in the Netherlands by means of agreements between the authorities and the pharmaceutical industry, the so-called covenants. Those agreements related to the wholesale prices of generics and

3044 ID2275, ID2911.

3045 See section 6.4.2.4.

3046 With the exception of the maximum wholesale price for the 2 mg tablet of perindopril erbumine which was in any event higher than the respective reimbursement limit and thus did not affect the actual pricing of Apotex' product.

3047 ID2275.

originators' products with generic alternatives. The initial price cuts agreed in the years 2004-2005 accounted for 40%. The agreements were extended to the years 2006-2007 with additional price cuts.[3048] However, that mechanism could not affect the prices of perindopril because the first generic perindopril only entered at the very end of 2007.

(2301) Since 2004, Dutch health insurance funds were permitted to reimburse only one version of an active ingredient, i.e. the lowest priced generic.[3049] This "preference policy" fully developed in 2008 when it was applied to a wider group of medicines.[3050] Based on this policy, a preferred generic was primarily selected according to its price and became the only medicine with a given API (molecule) that was reimbursed for a certain period of time. Therefore, manufacturers had a strong incentive to compete in their prices in exchange for the guarantee of continued sales.[3051] It is important to note that the "preference policy" could only apply to the medicines that were available generically. The "preference policy" stimulated intra-molecular competition. It could be applied only if there was a generic version of a given molecule available on the market.

(2302) As explained in its response to the Commission's RFI of 11 October 2010, Servier reacted to the "preference policy" by lowering the price of its perindopril from as early as March 2008.[3052] The same timing of price reductions is also visible in the price data provided by the Dutch authorities for other producers of perindopril.[3053]

(2303) In the Netherlands, medical practitioners were encouraged to prescribe generically and to discuss in local groups (forums) the optimal use of pharmaceuticals.[3054] Also pharmacists were encouraged to make optimum use of generics to which they agreed under the covenants of 2004, 2005 and 2006-2007.[3055] If a practitioner did not prescribe by international non-proprietary name (INN), pharmacists could only substitute a branded medicine after obtaining the practitioner's consent. For pharmacists, it was possible to obtain such consent en bloc at the level of a local pharmacotherapeutic forum gathering practitioners and pharmacists from a given area. In addition, the substitution had to be approved by the patient.[3056] As to therapeutic substitution, i.e. replacement with a medicine based on a different active substance, it was not commonly practised during the investigated period.[3057] The

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3048 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 509.

3049 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 515.

3050 European Commission's *Report on the pharmaceutical sector inquiry* of 8 July 2009, para. 375.

3051 ID2274.

3052 ID2909, p. 5.

3053 ID2275.

3054 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 518.

3055 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 519.

3056 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 518-519 and *Handleiding Substitutie*, Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (Royal Dutch Association for the Advancement of Pharmacy), version February 2012, pages 23-24, available at: http://www.knmp.nl/downloads/producten-diensten/farmacotherapie/handleiding-substitutie.

3057 Information found at the website of the Dutch Healthcare Authority: http://www.nza.nl/104107/105763/105918/47373/82356/Adstrat.pdf.

substitution rules can be regarded as of lesser importance from the moment of the broad adoption of the "preference policy", which in fact led to the reimbursement of a single preferred generic.

6.4.2.3 The sales of perindopril and other selected products in the Netherlands

(2304) All the short-listed products were introduced by the originator producers before the year 2000. Generic entries took place in relation to five molecules, including all four ACE inhibitors and amlodipine. Generic entries into enalapril, amlodipine and ramipril took place in the second half of 1999. The first generic lisinopril was marketed in mid-2002. Generic perindopril became available towards the end of 2007. Further details regarding the launch dates of individual originator and generic products are given in Table 24.

Table 24: Product launch dates in the Netherlands

Product	First launch date	
	Originator	Generic
Perindopril	07/1989	12/2007 (*)
Enalapril	01/1985	08/1999
Lisinopril	10/1988	07/2002
Ramipril	05/1990	11/1999
Amlodipine	06/1990	09/1999
Irbesartan	08/1997	-
Losartan	03/1995	-
Valsartan	11/1996	-
Valsartan + hctz	05/1998	-

Source: IMS.

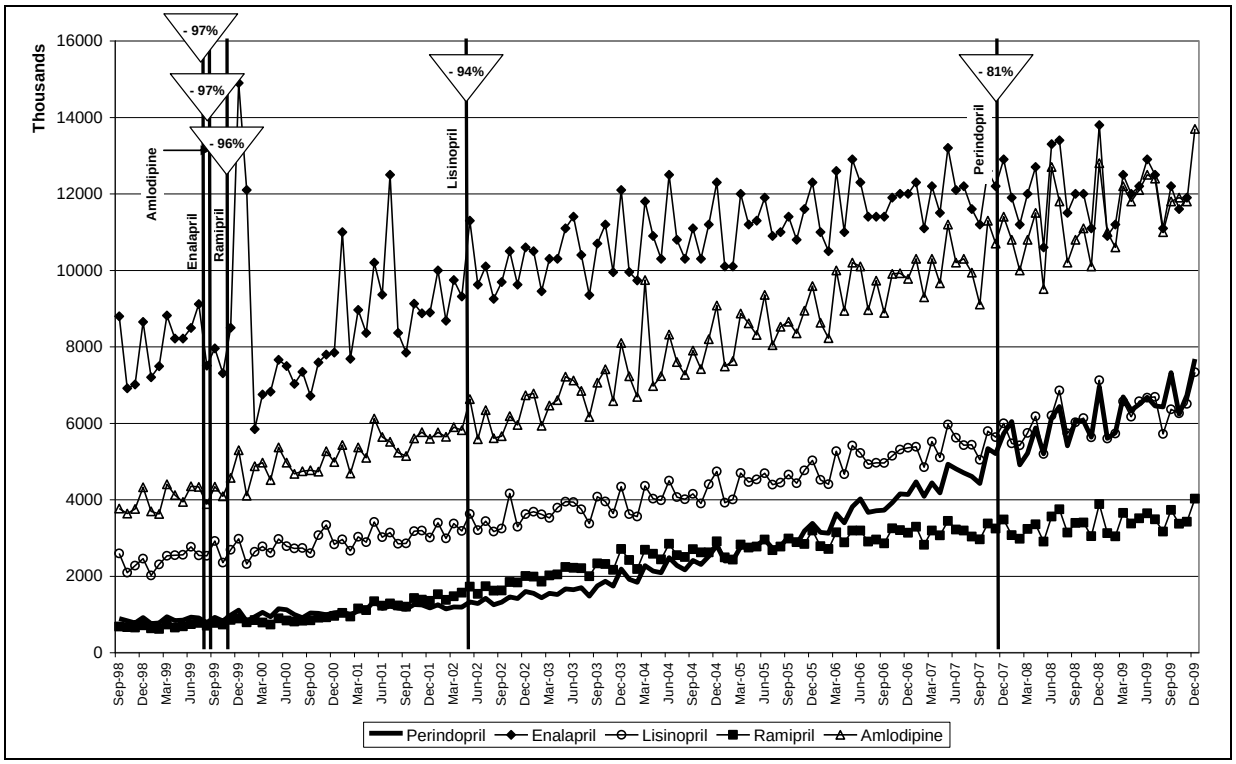
Note: (*) – corrected with the company data, for details see section 6.4.2.4.

(2305) Perindopril started the investigated period with sales below 1 million DDDs a month. By the time of generic entry in December 2007, its sales had grown steadily to attain approximately [1–25]* million DDDs per month. In September 1998, perindopril sold in lower quantities than enalapril, lisinopril and amlodipine, and in similar quantities to ramipril. By December 2009, perindopril had outgrown ramipril and reached volumes comparable to lisinopril. Among the five products, the highest sales volumes were recorded for enalapril and amlodipine. By the end of the investigated period, both were repeatedly reaching the sales of over 14 million DDDs per month. If compared across the entire period September 1998 to December 2009, all five products increased their respective sales in terms of quantities.[3058] Figure 6 shows the

[3058] In the period directly preceding generic entry, perindopril sold in higher quantities than irbesartan, valsartan and valsartan + hctz, but lower than losartan. All the selected ARBs (sartans) increased their volumes during the investigated period. For most of the period, perindopril sold in quantities that were comparable to irbesartan and valsartan, where all the three products were following similar growth patterns in volume terms.
In terms of the sales of tablets and capsules, the medicines in question ranked as follows (in thousands tablets and capsules), in January 2000: enalapril (9 622), amlodipine (2 970), losartan (2 129), lisinopril (1 931), perindopril (874), valsartan (626), irbesartan (533) and ramipril (505); in November 2007: enalapril (8 940), amlodipine (7 814), losartan (5 349), lisinopril (4 378), perindopril (4 339), valsartan (3 041), irbesartan (2 897) and ramipril (1 490). Source: IMS.

trends for the individual molecules. The relevant generic entries are marked with vertical lines. The inverted triangles inform on how the prices of products that turned generic evolved between a month preceding generic entry and December 2009.

Figure 6: Volumes of perindopril, enalapril, lisinopril, ramipril and amlodipine in the Netherlands, in the period September 1998 – December 2009 (in thousand DDDs) and the percentage price changes observed post relevant generic entries



Source: IMS.

(2306) Perindopril was more expensive than the other selected ACE inhibitors and amlodipine. For most of the pre-generic period, perindopril cost over EUR 0.50 per DDD. The price gap became most visible after 2004 when the prices of all the other products, each of which had experienced generic entry for their own molecule, were brought down to EUR 0.20 per DDD and below. The gap, in absolute terms, narrowed after generic entry in perindopril. The prices of the other products were also lowered at the same moment as the generic entry in perindopril.[3059] In their replies to the series of Commission's requests for information, the manufacturers of the other products confirmed that the decrease had a regulatory character (the introduction of a preference policy) and was intended to lower the purchasing costs of medicines available generically.[3060] These price changes were due to the fact that

3059 In relation to the prices of ARBs (sartans), the pre-generic prices of perindopril were similar to the prices of irbesartan and valsartan, but below those of losartan and valsartan + hctz. The latter product was the most expensive from the discussed group with the average price of over EUR 0.70 per DDD as of March 2004. The prices of ARBs (sartans) appear to remain within their historic price corridor also after the generic entry in perindopril.
In terms of an average (for all available doses of a given medicine) price per tablet/capsule, the medicines in question ranked as follows (EUR prices in brackets), in January 2000: irbesartan (0.747), amlodipine (0.671), valsartan (0.661), losartan (0.630), ramipril (0.557), perindopril (0.509), lisinopril (0.466) and enalapril (0.435); in November 2007: losartan (0.757), irbesartan (0.659), valsartan (0.646), perindopril (0.519), ramipril (0.231), amlodipine (0.182), enalapril (0.174) and lisinopril (0.157). Source: IMS.

3060 ID2867 p. 16, ID3036 p. 5, ID5399, ID3272, p.19, ID2909, p. 5.

the Dutch law allowed health insurers, which have been privatised, to limit patients' reimbursement of medicines that use the same active ingredient (molecule) to a single supplier. As explained above, this led health insurers to conduct the so-called "preference policy" for a number of generic medicines, selecting the cheapest supplier(s) whose products alone would be reimbursed during a certain period of time.[3061]

(2307) Perindopril steadily increased its turnover until the arrival of the first generic of perindopril at the end of 2007. From September 1998 to November 2007, perindopril's sales increased from EUR [500,000–600,000]* million to EUR [1–25]* million a month. During the same period, the other three ACE inhibitors as well as amlodipine were, at best, maintaining their levels of turnover. Immediately before turning generic, the value of perindopril's monthly sales outgrew enalapril and amlodipine.[3062]

6.4.2.4 The sales of original and generic perindopril in the Netherlands

(2308) The first generic of perindopril was launched by Apotex's subsidiary, Katwijk Farma, B.V. on 13 December 2007. The generic product was launched at risk, but after Apotex had initiated an annulment action against Servier.[3063] Table 25 illustrates the quantities sold by Servier and by its generic competitors in the period 2006 to 2009. During the first half of 2008, Servier already lost [70-90]% of the perindopril market in volume terms. One year later, Servier's market share was reduced to less than [5-15]%. During the same period, the perindopril market increased in size from [20-30] million DDDs in the second half of 2007 to [30-40] million DDDs at its peak recorded for the first half of 2009. The comparison of sales from 18 months preceding and following the entry shows a considerable increase in six-monthly average sales from [13-23] to [30-40] million DDDs, i.e. an increase of approximately 88%.

3061 See also section 6.4.2.2.

3062 As regards the comparison with ARBs (sartans), the turnover of perindopril in the pre-generic period was on a par with the respective turnovers of irbesartan and valsartan. Among the pre-selected ARBs (sartans), losartan was the most valuable product with the peak monthly sales of EUR 4.4 million in May 2007.

3063 See section 4.1.2.4.2.3.1. for more details.

Table 25: Sales of perindopril in the Netherlands

	Servier (*erbumine*) in million DDDs	Servier (*arginine*) in million DDDs	Generics (*erbumine*) in million DDDs	Total market in million DDDs	Total market in EUR millions
2006H1	[10-20]	0	0	[10-20]	[4-12]
2006H2	[10-20]	0	0	[10-20]	[4-12]
2007H1	[10-20]	0	0	[10-20]	[4-12]
2007H2	[20-30]	0	[0-5]	[20-30]	[8-18]
2008H1	[0-5]	[0-5]	[20-30]	[30-40]	[1.5-8]
2008H2	0	[0-5]	[30-40]	[30-40]	[1.5-8]
2009H1	0	[0-5]	[30-40]	[30-40]	[1.5-8]
2009H2	0	[0-5]	[30-40]	[30-40]	[1.5-8]

Source: The Commission's own calculation based on ID1774, ID1804, ID1844, ID1846, ID1865, ID1869, ID1873, ID1875 and ID3347.

(2309) Generic entry led to a substantial decrease (over five-fold) in prices from the pre-entry level of EUR [0.4-0.6] per DDD charged by Servier to the post-entry average of EUR [0.08-0.12] per DDD achieved in the second half of 2009. Table 26 illustrates the price reductions in more detail.

Table 26: Prices of perindopril in the Netherlands

Prices in EUR per DDD	Servier (*erbumine* & *arginine* combined)	Generics (only *erbumine*)	Weighted average price
2006H1	[0.4-0.6]	n/a	[0.4-0.6]
2006H2	[0.4-0.6]	n/a	[0.4-0.6]
2007H1	[0.4-0.6]	n/a	[0.4-0.6]
2007H2	[0.4-0.6]	[0.05-0.20]	[0.4-0.6]
2008H1	[0.2-0.6]	[0.05-0.20]	[0.05-0.20]
2008H2	[0.2-0.6]	[0.05-0.20]	[0.05-0.20]
2009H1	[0.2-0.6]	[0.05-0.20]	[0.05-0.20]
2009H2	[0.2-0.6]	[0.05-0.20]	[0.05-0.20]

Source: The Commission's own calculation based on ID1774, ID1804, ID1844, ID1846, ID1865, ID1869, ID1873, ID1875 and ID3347.

(2310) Like the UK, the market dynamics regarding volumes and prices led to the value of the Dutch market decreasing significantly following the huge price fall caused by generic entry. From its peak of almost EUR [12-30] million in 2007, the Dutch market decreased in value to EUR [3-16] million in 2009.

6.4.3 France

(2311) This section describes the regulatory aspects such as official prices and reimbursement conditions relevant for the sales of original and generic perindopril in France (sections 6.4.3.1 and 6.4.3.2). The description of the regulatory aspects is followed by the country-specific overview of the relevant price and volume developments (sections 6.4.3.3 and 6.4.3.4).

6.4.3.1 Regulatory aspects concerning Servier as an originator of perindopril in France

(2312) In France, the prices of medicines were negotiated between the originator companies and the authorities represented by the Comité Economique des Produits de Santé (CEPS). CEPS examined a price request made by an originator company on the basis of an opinion delivered by the health authorities on the medical benefit of a new product. A requested price was compared to the prices of other similar medicines. If a new product did not offer enhanced medical benefits, it had to offer savings to the healthcare system in order to be officially listed. CEPS fixed the price at which the producer could sell the product to wholesalers. This procedure applied to all reimbursable medicines. The retail price was increased by the wholesaler and the pharmacy mark-ups, which for reimbursable medicines were regulated by the state and depended on the range of the producer's price.[3064] Apart from setting the price of medicines, the French authorities also fixed a reimbursement level at a percentage of the fixed price.

(2313) In 1988, the French authorities, namely the Transparency Commission ('la Commission de la Transparence'), decided that perindopril offered enhanced medical benefits in terms of its efficacy, tolerance and compliance. This conclusion was drawn on the basis of the comparative studies of perindopril and captopril.[3065]

(2314) Servier's perindopril *erbumine*, Coversyl, was launched at a producer price of EUR 14.28 for 2 mg and EUR 19.71 for 4 mg in 1988. The 8 mg version was introduced at a producer price of EUR 31.71 in 2007. In each case, the prices referred to the standard 30 tablet pack. The initial prices were set with regard to the average price of other ACE inhibitors as well as the specific medical value of perindopril.[3066]

(2315) Perindopril was reimbursed from its first launch. In 1993, its reimbursement rate was set at 65%, which is the standard rate applied to medicines treating serious diseases and was applied to all ACE inhibitors available on the French market.[3067] In practice the percentage co-payments were covered by supplementary health insurance funds, with which the majority of the French population had a contract.[3068] As confirmed by Servier, the periodic reviews carried out by the Transparency Commission did not lead to any changes in the reimbursement rate applicable to the sales of perindopril.[3069] In particular, the reimbursement rate remained unchanged despite the generic entries and related considerable price reductions that affected other ACE inhibitors.

(2316) Figure 7 shows the official wholesale price of the standard 30 tablet pack of Coversyl 4 mg.[3070] The producer's price was affected by state measures only once during the investigated period. In January 2007, the prices of Coversyl 2 mg and 4 mg were

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3064 ID2433, p. 2, ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 219 - 249.

3065 ID5594.

3066 ID2433, ID2909, p. 2, ID2910.

3067 Information verified at: http://www.codage.ext.cnamts.fr/codif/bdm//fiche/index_fic_sp_cip.php?p_code_cip=3400933103279&p_menu=FICHE&p_site=.

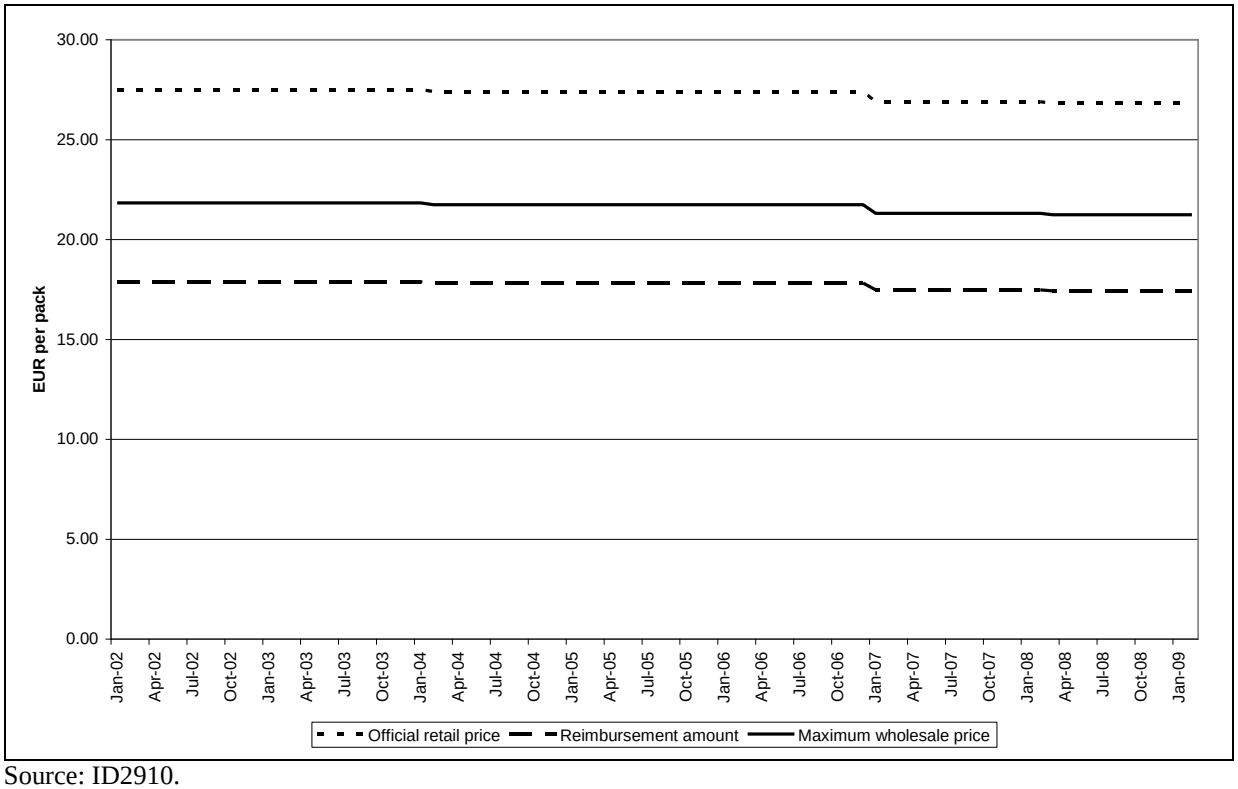
3068 ID2910, ID2433, p. 2-4, ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 236 - 239.

3069 Servier's reply to the Statement of Objections, paragraph 1527, ID10114, p. 467.

3070 For ex-factory prices of perindopril and other selected molecules in France, see paragraph (2325).

lowered by 5% and by 2% respectively as a part of the government's saving plan to reduce the prices of patent protected medicines in classes where there was significant generic presence.[3071] Generic perindopril had not yet been launched (as noted below, it only came onto the market in September 2008). According to Servier's internal documents, the price decrease of Coversyl 4 mg was related to the registration of Coversyl 8 mg at the price that was intended to compensate Servier for lowering the price of the 4 mg version.[3072] Even if this fact was disregarded, the price cuts relating to Coversyl introduced in January 2007 were not comparable to the price reductions concerning the other medicines from the ACE inhibitors class, such as enalapril, lisinopril and ramipril that had turned generic some time before that date. The latter had been reduced by approximately 50% (see Figure 22).

Figure 7: The official prices and the reimbursed amount for the standard 30 tablet pack of Coversyl 4 mg in France



Source: ID2910.

(2317) Generic perindopril came onto the French market in September 2008. At approximately the same time, Servier was advancing its project to launch its perindopril arginine. In March 2009, the French authorities, namely the Agence française de sécurité sanitaire des produits de santé, decided to register perindopril *arginine* as the second reference product in the generic group created for perindopril *erbumine*. Consequently, CEPS chose to align the price of the new salt with the price of Servier's perindopril *erbumine*.[3073] In the same month, Servier replaced its *erbumine* product with its *arginine* version and introduced it at EUR 14.08, EUR 20.04 and EUR 31.71 for a standard 30 tablet pack of 2.5 mg, 5 mg and 10 mg tablets respectively.[3074] Perindopril *arginine* gained considerable sales in France as a

3071 ID2433 and ID2909.
3072 ID0119, p. 277.
3073 ID2433, p. 3.
3074 ID2909, p. 2, ID2910.

result of the limited presence of generic perindopril *erbumine* at the time of its launch.[3075]

6.4.3.2 Regulatory aspects concerning the generic suppliers of perindopril in France

(2318) A generic price was set by applying a discount calculated from the price of a reference product, i.e. the originator's product. The percentage size of a discount has changed over time and is currently at 55% of the reference price. Generic perindopril *erbumine*'s price was set at a discount of 50% in relation to Servier's equivalent product.

(2319) Generic entry also had important implications for the price of a reference product. After commercialisation of the first generic, the authorities decreased the price of a reference product by 15%. In the case of perindopril, the authorities implemented such a decision in October 2009. In fact, that price decrease only concerned Servier's perindopril arginine, which from March 2009 was registered as the second reference product in the generic group of perindopril. At that time this was the only version of perindopril marketed by Servier after the full switch from perindopril *erbumine* to perindopril *arginine*.[3076] It is apparent that CEPS decided to delay the price decrease until the conclusion of the EPO opposition proceedings concerning the '947 patent (in May 2009).

(2320) The French system did not foresee any change in the percentage of the price that was reimbursed to patients at the moment of generic entry. However, the amount of reimbursement necessarily reflected a lower price that was given to a generic product.[3077] Throughout the period under investigation, perindopril remained reimbursed with the standard 65% rate.[3078]

(2321) In France, pharmacies could substitute a prescribed medicine with its generic equivalent as long as a practitioner did not explicitly exclude the generic substitution on the prescription. Pharmacies were incentivised to dispense generics by the possibility of receiving higher commercial discounts on the generic products from the manufacturers.[3079] The French system did not, however, allow for therapeutic substitution, i.e. dispensing a medicine based on a different active substance, by pharmacies.[3080]

(2322) Perindopril *erbumine* and *arginine* were considered fully substitutable. However, the French authorities have admitted that they encountered difficulties in substitution regarding certain group of patients, such as older persons. Those difficulties were related to the confusion following the change to the new dosages of perindopril *arginine*. Following insufficient substitution, in December 2010 the French authorities, CEPS, decided to apply a special tariff to Servier's perindopril *arginine*, the so-called **flat rate of responsibility*. By that decision, the producer's price of the

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3075 See section 6.4.3.4.

3076 ID2433.

3077 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 237 - 240.

3078 Information verified at: http://www.codage.ext.cnamts.fr/codif/bdm//fiche/index_fic_sp_cip.php?p_code_cip=3400933103279&p_menu=FICHE&p_site=.

3079 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 243.

3080 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 247

standard 30 tablet pack of Coversyl 5 mg was reduced from EUR 16.42 to EUR 9.66, i.e. by 41%.[3081]

6.4.3.3 The sales of perindopril and other selected products in France

(2323) All the short-listed products were introduced by the originator producers before the year 2000. Generic entries took place in relation to five molecules, including all four ACE inhibitors and amlodipine. All the generic entries occurred between 2001 and 2008. Further details regarding the launch dates of individual originator and generic products are given in Table 27.

Table 27: Product launch dates in France

Product	First launch date	
	Originator	Generic
Perindopril	12/1988	09/2008 (*)
Enalapril	01/1985	05/2001
Lisinopril	09/1988	10/2004
Ramipril	09/1989	10/2005
Amlodipine	11/1992	07/2007
Irbesartan	01/1998	-
Losartan	06/1995	-
Valsartan	06/1997	-
Valsartan + hctz	03/1998	-

Source: IMS.

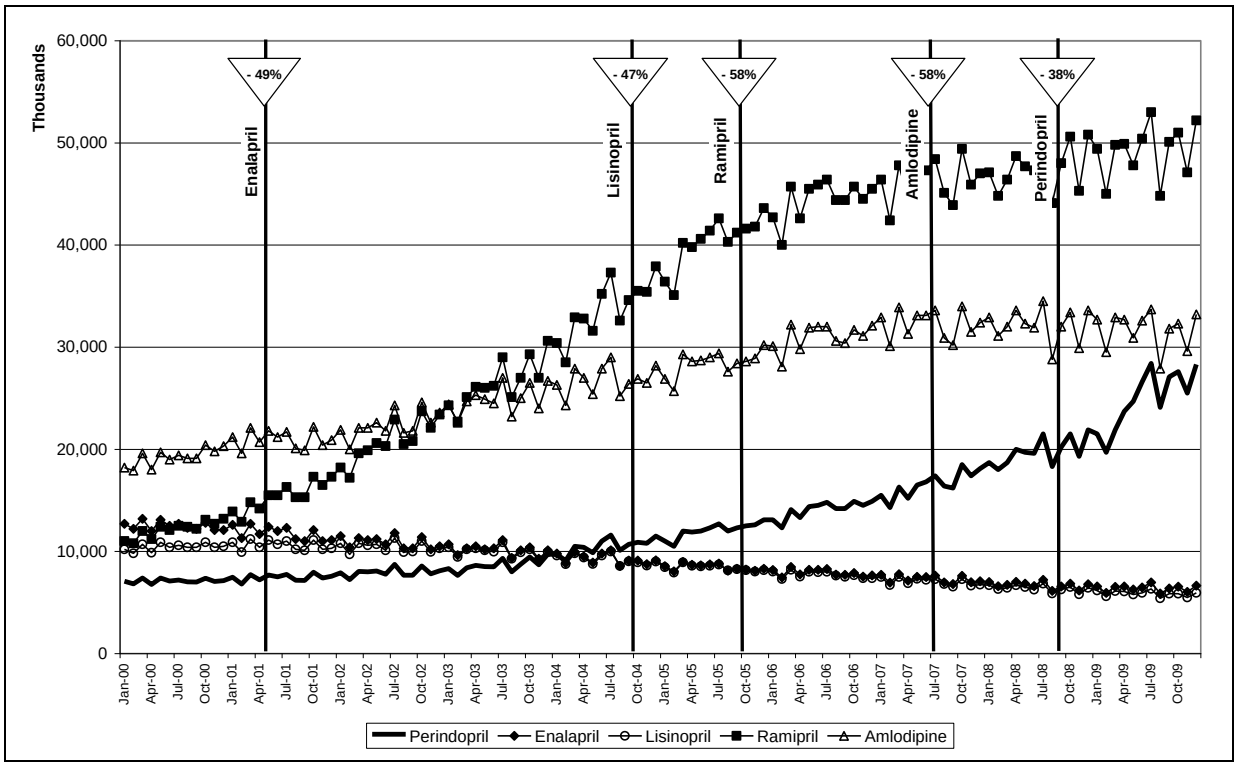
Note: (*) – corrected with the company data, for details see section 6.4.3.4.

(2324) Perindopril started the year 2000 with monthly sales of approximately 7 million DDDs. By the time of generic entry in September 2008, perindopril's sales had grown steadily to over 20 million DDDs per month. The upward trend also continued after generic entry of perindopril and attained almost [25–50]* million DDDs per month in the second half 2009. Before 2003, amlodipine was selling the highest quantities. After 2003, that position was taken by ramipril, the only product to reach monthly sales in the range of 50 million DDDs during the investigated period. Enalapril and lisinopril were steadily decreasing and ended the period with monthly sales of approximately 6-7 million DDDs each.[3082] The trends are shown in Figure 8. The relevant generic entries are marked with vertical lines. The inverted triangles inform on how the prices of products that turned generic evolved between the month preceding generic entry and December 2009.

3081 ID2433 and http://www.codage.ext.cnamts.fr.

3082 With respect to the volumes sold by the producers of the selected ARBs (sartans), perindopril followed a largely similar pattern of sales as irbesartan, valsartan and valsartan + hctz. Losartan was the only product from the group of the selected ARBs (sartans) that remained largely at the same level of sales, in the range of 10 million DDDs per month, during the entire investigated period.
In terms of the sales of tablets and capsules, the medicines in question ranked as follows (in thousands tablets and capsules), in January 2000: amlodipine (18 179), ramipril (8 901), losartan (8 704), perindopril (8 122), enalapril (8 039), lisinopril (6 494), irbesartan (5 977) and valsartan (4 594); in August 2008: amlodipine (22 312), ramipril (21 993), perindopril (18 649), irbesartan (15 066), valsartan (13 303), losartan (7 735), enalapril (3 787) and lisinopril (3 605). Source: IMS.

Figure 8: Volumes of perindopril, enalapril, lisinopril, ramipril and amlodipine in France, in the period 2000-2009 (in thousand DDDs) and the percentage price changes observed post relevant generic entries



Source: IMS.

(2325) In the period before generic perindopril entered the market, perindopril was priced at EUR 0.70 per DDD. By contrast, other ACE inhibitors were sold at prices below EUR 0.40 per DDD from the beginning of the investigated period.[3083]

(2326) Perindopril exhibited a continuous growth trend in its monthly turnover until mid-2008. From EUR [1–25]* million in January 2000, it grew to EUR [1–25]* million in July 2008. Ramipril's and amlodipine's turnovers reached their respective peaks in mid-2005 and in mid-2007. In all the three cases (i.e. perindopril, ramipril and amlodipine), the peaks were achieved directly before the arrival of generics in the respective molecules. Enalapril's and lisinopril's figures were characterised by the progressive decline of turnover during the entire period 2000 to 2009 (but to a lesser extent in the first three years).[3084]

3083 In the pre-generic period, perindopril was also more expensive than the selected ARBs (sartans). However, in this regard, the price differences were considerably smaller. For most of the discussed period, the selected ARBs (sartans) were priced around or above the level of EUR 0.50 per DDD.
In terms of an average (for all available doses of a given medicine) price per tablet/capsule, the medicines in question ranked as follows (EUR prices in brackets), in January 2000: irbesartan (0.688), losartan (0.669), valsartan (0.619), perindopril (0.611), enalapril (0.526), ramipril (0.470), lisinopril (0.456) and amlodipine (0.409); in August 2008: losartan (0.694), perindopril (0.641), valsartan (0.605), irbesartan (0.601), ramipril (0.274), enalapril (0.273), lisinopril (0.253) and amlodipine (0.209). Source: IMS.

3084 The turnover dynamics in the group of the selected ARBs (sartans) were similar to those of perindopril. Except for losartan, ARBs (sartans) increased their respective turnovers through the discussed period. From 2005, the combination of valsartan + hctz was the best performing product from the group of ARBs (sartans), followed by irbesartan and valsartan. Towards the end of the period in question, valsartan + hctz generated monthly turnovers in the range from EUR 10 to 12 million, irbesartan from EUR 9 to 11 million and valsartan from EUR 8 to 9 million.

6.4.3.4 The sales of original and generic perindopril in France

(2327) The first generic entry of perindopril on the French market happened relatively late compared to the UK and the Netherlands. Sandoz was the source of the first entry, which was limited. Sandoz started selling its perindopril on 17 September 2008.[3085] The company said it entered the French market with *"perindopril erbumine inclusion complex […], wherein perindopril erbumine is in an amorphous form and free of any crystalline form of perindopril erbumine"*.[3086] Therefore Servier could not block Sandoz's entry on the basis of the '947 patent. Servier's internal assessment from 4 January 2008 acknowledges that (i) *"*the product […] has a chemical and stereochemical quality comparable to that of the Servier product"*, (ii) *"*the synthesis method used does not seem to use the Servier method"* and (iii) *"*the product has an amorphous structure"*.[3087]

(2328) Sandoz referred to the entry barriers raised by Servier to explain the limited scope of entry.[3088] […]*.[3089] Sandoz also claimed that *"Servier's decision to change the dosage of its new Coversyl and to rebrand Biocoversyl as Coversyl made it difficult for Sandoz to commercialise its perindopril generic. The rebranding in particular, led to confusion on the part of the patients and the pharmacists. Sandoz therefore had to devote a significant amount of time and resources to reassuring the market"*.[3090]

(2329) Prior to generic entry, France was the largest national market for Servier's perindopril in terms of turnover and the second biggest market in terms of units sold, just after the UK. Post-generic entry in the latter, the French market became Servier's largest national market in terms of the quantities too. Generic entry of perindopril on the French market does not seem to have impacted on Servier's absolute sales level. It appears that generic competitors were able only to capture an incremental increase in the overall market sales. That, nonetheless, led to Servier's market share diminishing continuously from the first generic entry. The overall market volumes increased from [90-120] million DDDs in the first half of 2008 to [120-180] million DDDs in the second half of 2009, i.e. an increase of approximately 24%. Table 28 illustrates the market dynamics in terms of sales volumes.

3085 ID1527, p. 3.
3086 ID1480, p. 16.
3087 ID0108, p. 182 – 183.
3088 ID7814, p. 2-3.
3089 See paragraph (213).
3090 ID7814, p. 2-3.

Table 28: Sales of perindopril in France

	Servier (*erbumine*) in million DDDs	Servier(*arginine*) in million DDDs	Generics (*erbumine*) authorised by Servier in million DDDs	Generics (*erbumine*) with independent API sources in million DDDs	Total market in million DDDs	Total market in EUR millions
2007H1	[90-120]	0	0	0	[90-120]	[54-96]
2007H2	[90-120]	0	0	0	[90-120]	[54-96]
2008H1	[90-120]	0	0	0	[90-120]	[54-96]
2008H2	[90-120]	0	0	[10-30]	[120-180]	[72-144]
2009H1	[30-60]	[30-60]	0	[10-30]	[120-180]	[48-108]
2009H2	0	[90-120]	[0-10]	[10-30]	[120-180]	[48-108]

Source: The Commission's own calculation based on ID1774, ID1804, ID1844, ID1851, ID1865 and ID1869.

(2330) The generic presence on the French market resulted in lower prices. The entry of Sandoz, later joined by other generics (Actavis and Ratiopharm), reduced the average price per DDD from EUR [0.6-0.8] in the first half of 2008 to EUR [0.4-0.6] in the second half of 2009, representing a price decrease of more than 27%. According to the data available, the generic products were initially offered at around 40% of the price of the originator product.[3091] Table 29 provides an overview of the price developments on the French market for the period 2007 to 2009. The French authorities delayed the statutory price decrease of Servier's perindopril, which is meant to be triggered by generic entry, until October 2009, i.e. over a year after Sandoz's entry.

Table 29: Prices of perindopril in France

Prices in EUR per DDD	Servier (*erbumine* & *arginine* combined)	Generics (only *erbumine*) authorised by Servier	Generics (only *erbumine*) with independent API sources	Weighted average price
2007H1	[0.6-0.8]	n/a	n/a	[0.6-0.8]
2007H2	[0.6-0.8]	n/a	n/a	[0.6-0.8]
2008H1	[0.6-0.8]	n/a	n/a	[0.6-0.8]
2008H2	[0.6-0.8]	n/a	[0.2-0.5]	[0.6-0.8]
2009H1	[0.6-0.8]	n/a	[0.2-0.5]	[0.4-0.6]
2009H2	[0.4-0.6]	[0.2-0.5]	[0.2-0.5]	[0.4-0.6]

Source: The Commission's own calculation based on ID1774, ID1804, ID1844, ID1851, ID1865, ID1869.

(2331) The changes in respect of volumes and prices were less significant in France, at least in terms of price reductions, compared to the changes in the UK and the Netherlands. An increase in volumes was coupled with a decrease in prices of a similar magnitude. Consequently, the total value of the French market decreased from its 2008 peak of

[3091] See also section 6.4.3.2. The Commission notes the discrepancy between the average price discount reported in this section (based on the company data) and the nominal discount reported by the authorities.

EUR [126-240] million to EUR [96-216] million in 2009, i.e. by about 12% within a year.

6.4.4 Poland

(2332) This section describes the regulatory aspects such as official prices and reimbursement conditions relevant for the sales of original and generic perindopril in Poland (sections 6.4.4.1 and 6.4.4.2). The description of the regulatory aspects is followed by the country-specific overview of the relevant price and volume developments (sections 6.4.4.3 and 6.4.4.4).

6.4.4.1 Regulatory aspects concerning Servier as an originator of perindopril in Poland

(2333) The Polish system included statutory pricing for reimbursable pharmaceuticals at the wholesale level. Pharmaceutical companies had to introduce an application for price determination which was decided by the authorities, primarily the Ministry of Health (*"the MOH"*).[3092] A number of criteria might be taken into account, including cross-border price comparisons and pharma-economic factors.[3093]

(2334) Before 2002, the prices of perindopril in Poland were subject to the annual annexes to the bilateral agreement between the MOH and Servier signed in 1992. The annual annexes only specified the sales price in French francs. The original agreement did not link the sales conditions for perindopril with any other product.[3094] The official maximum wholesale price for Servier's perindopril was first determined by the MOH in March 2002. The price cap at wholesale level was set at PLN 25.73 per 30 tablet pack of 4 mg tablets.[3095] In December 2004, the official maximum wholesale price was determined for the 8 mg dosage of perindopril at PLN 40.72 per 30 tablet pack.[3096]

(2335) The MOH decided on two other measures that influenced the sale of pharmaceuticals in Poland. First, it fixed the level of reimbursement, which could be set at 100%, 70% or 50%. If a medicine was "fully" reimbursed, the patients had to pay a flat fee of PLN 3.20 plus VAT (but importantly patients did not have to pay any fee at all if the lower rates of reimbursement were applied).[3097] Second, the MOH introduced the so-called price limits which served as a ceiling from which the actual reimbursement was calculated. A price limit was determined for a group of medicines that was formed from medicines that had either the same INN or different names but similar therapeutic effects (the same indication, similar clinical efficacy, the same most frequent side effects and the same delivery form).[3098]

(2336) In practice, the price limit was almost always lower than the retail price. This meant that the patient had to pay the full retail price and could only get reimbursed for a portion of this (i.e. either 100% of the price limit minus the flat fee or a percentage of the price limit). The difference between this reimbursement and the retail price was a co-payment. In other words, an actual reimbursement was often much lower than a

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3092 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 535.

3093 Article 7(3) of the Act of 5 July 2001 on prices, OJ 2001.97.1050.

3094 ID2925.

3095 ID2222, p. 1.

3096 Minister of Health's decree of 20 December 2004, OJ 2004.275.2733.

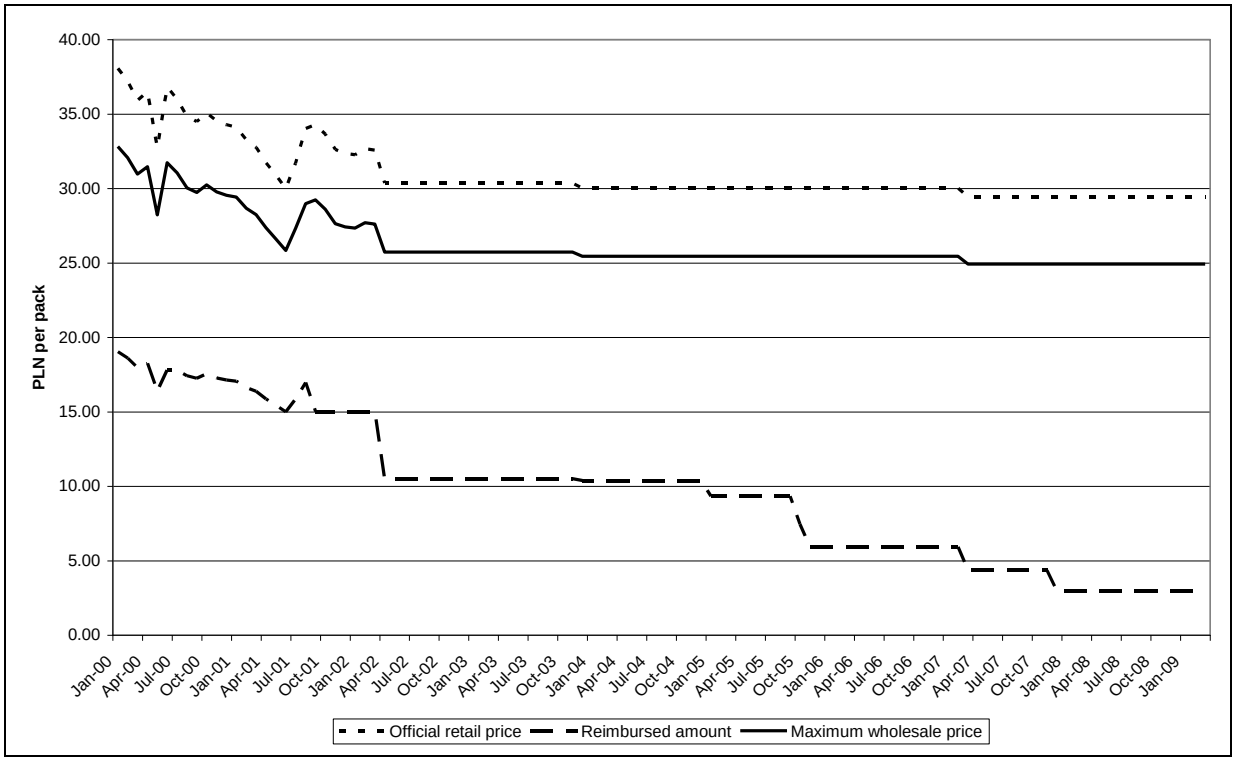
3097 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 540 - 543.

3098 Article 1 of the Minister of Health's decree of 9 December 2004, OJ 2004.266.2646.

price that the patients had to pay at pharmacies. The available evidence shows that Polish patients very often had to pay co-payments.

(2337) In 1993, Servier's perindopril, Prestarium, was added to the reimbursement list with the level of reimbursement set at 70%.[3099] Between 2000 and 2009, the level of reimbursement was first at 50% and, in October 2005, increased to 100%.[3100] The October 2005 change was, however, accompanied by lowering of the relevant price limits for both dosages of perindopril available in Poland, i.e. 4 mg and 8 mg.[3101] Figure 9 shows the evolution of the maximum wholesale price allocated to the standard 30 tablet pack of Prestarium 4 mg.[3102] It also illustrates the actual amount reimbursed to patients as a result of adjustments in the price limit and the reimbursement level, the difference between the retail price and the reimbursed amount constituted the co-payment that patients had to make themselves. The co-payment made by patients was already a substantial fraction of the retail price at the beginning of the investigated period and was further increased as time went on to reach 90% of the price of Prestarium 4 mg in its last months of sales, i.e. from December 2007 to March 2009.

Figure 9: The official prices and the reimbursed amount for the standard 30 tablet pack of Prestarium 4 mg in Poland



Note: the maximum wholesale price was only established in March 2002. The wholesale prices before that date were simply a function of the price agreed (in French francs) in the annexes to the contract between Servier and the Ministry of Health.

Source: ID2912.

3099 ID2222, p. 3.

3100 Minister of Health's decree of 22 September 2005, OJ.2005.192.1608 and Minister of Health's decrees listed in ID2222, p. 3 - 4.

3101 Minister of Health's decree of 22 September 2005, OJ.2005.192.1610.

3102 For ex-factory prices of perindopril and other selected molecules in Poland, see paragraph (2246).

(2338) In April 2006, Servier launched its perindopril *arginine* in Poland (also branded Prestarium).[3103] Generic perindopril erbumine entered the market in June 2006. In February 2007, Servier's perindopril *arginine* was allocated a maximum wholesale price, a price limit for reimbursement and full reimbursement status.[3104] The 30 tablet pack of Prestarium received a maximum wholesale price of PLN 24.93 and PLN 39.90; and a price limit of PLN 7.35 and PLN 14.70 for the 5 mg and 10 mg tablets respectively.[3105] Upon receiving reimbursement status for perindopril arginine, Servier decided to increase its price by the amount equal to the reimbursement. Due to the idiosyncrasies of the Polish system and Servier's anti-generic strategy, Servier's perindopril *arginine* managed to gain considerable sales in Poland.[3106]

6.4.4.2 Regulatory aspects concerning the generic suppliers of perindopril in Poland

(2339) The main rules relevant for pricing and reimbursement of generic perindopril were in principle the same as the rules that were applied to Servier's perindopril (see section 6.4.4.1). There was statutory pricing for reimbursable pharmaceuticals at wholesale level and free pricing for manufacturers that did not request reimbursement status. The same procedures applied to originators and generics.[3107] The reimbursement status had to be requested individually for each brand, package and dose of a given molecule.

(2340) Before 2010, only two generic producers that were actively selling, namely Krka and Gedeon Richter, had requested reimbursement of their own perindopril products. The official maximum wholesale price for Krka's perindopril, Prenessa, was first determined by the Ministry of Health in February 2007. The price cap at wholesale level was set at PLN 17.02 per 30 tablet pack of 4 mg tablets.[3108] In December 2009, Krka also obtained the official maximum wholesale price for its 8 mg dosage of perindopril, which was set at PLN 23.06 per 30 tablet pack. In the same month, Gedeon Richter was allocated the maximum official wholesale price for its 4 mg and 8 mg versions of perindopril which was branded as Vidotin. The respective price-caps were set at PLN 13.18 and PLN 27.10 per 30 tablet pack of 4 mg and 8 mg tablets.[3109]

(2341) Both Krka's and Gedeon Richter's generic perindopril were subject to the same reimbursement conditions as Servier's products in terms of the reimbursement level and the relevant price limits.[3110] Figure 9 in the previous section shows the actual amount reimbursed to patients.

(2342) In Poland, pharmacies were allowed to substitute within one INN group. Practitioners could exclude substitution by an annotation on the prescription. Pharmacies were obliged to inform patients about the possibility of generic substitution and to offer them the cheapest pharmaceutical within the reference price group. The Polish system did not allow for therapeutic substitution, i.e. dispensing a

3103 ID2912.
3104 Minister of Health's decree of 9 February 2007, OJ.2007.31.202.
3105 Minister of Health's decree of 9 February 2007, OJ.2007.32.204 and Minister of Health's decree of 15 February 2007, OJ.2007.33.205.
3106 See section 6.4.4.4.
3107 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 535.
3108 Ministry of Health's decree of 15 February 2007, OJ 2007.33.205.
3109 Ministry of Health's decree of 9 December 2009, OJ 2009.212.1649.
3110 E.g. Ministry of Health's decree of 8 December 2009, OJ 2009.212.1648.

medicine based on a different active substance, by pharmacies.[3111] There were neither specific rewards for pharmacists for dispensing generics nor specific incentives for doctors to prescribe generic pharmaceuticals.[3112]

(2343) Regarding the possible replacement of perindopril *erbumine* with *arginine*, the relevant rules in the Polish legislation excluded substitution of different dosages.[3113] Servier explicitly referred to that fact by indicating in its internal strategy that the switch to 5 mg and 10 mg dosages was intended to block generic substitution.[3114] This meant that pharmacists could not substitute generic perindopril *erbumine* instead of perindopril *arginine*.

6.4.4.3 The sales of perindopril and other selected products in Poland

(2344) The originator producers introduced most of the short-listed products, except ramipril and valsartan + hctz, in the 1990s. Another exception is enalapril which was never launched by its originator producer in Poland and was only introduced as a generic. Generic entries took place in relation to all the short-listed products, except irbesartan. All entries, except enalapril, occurred in the period 2000 to 2009. Further details regarding the launch dates of individual originator and generic products are given in Table 30.

Table 30: Product launch dates in Poland

Product	First launch date	
	Originator	Generic
Perindopril	01/1993	06/2006
Enalapril	-	10/1991
Lisinopril	01/1993	09/2000
Ramipril	09/2000	10/2003
Amlodipine	01/1994	01/2003
Irbesartan	02/1999	-
Losartan	10/1996	05/2000
Valsartan	07/1998	03/2008
Valsartan + hctz	05/2000	09/2009

Source: IMS.

(2345) Perindopril began the investigated period with monthly sales of 6 million DDDs. By the time of generic entry of perindopril in June 2006, this figure had grown steadily to [1–25]* million DDDs. During the same time, enalapril enjoyed the highest sales fluctuating in the broad range of 40 to 60 million DDDs per month, while sales of amlodipine increased from fewer than 3 million DDDs in September 1998 to almost 37 million in May 2006. However, the most dynamic change relates to ramipril. It increased its monthly sales from fewer than 5 million DDDs in mid-2005 to 80

3111 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 551.

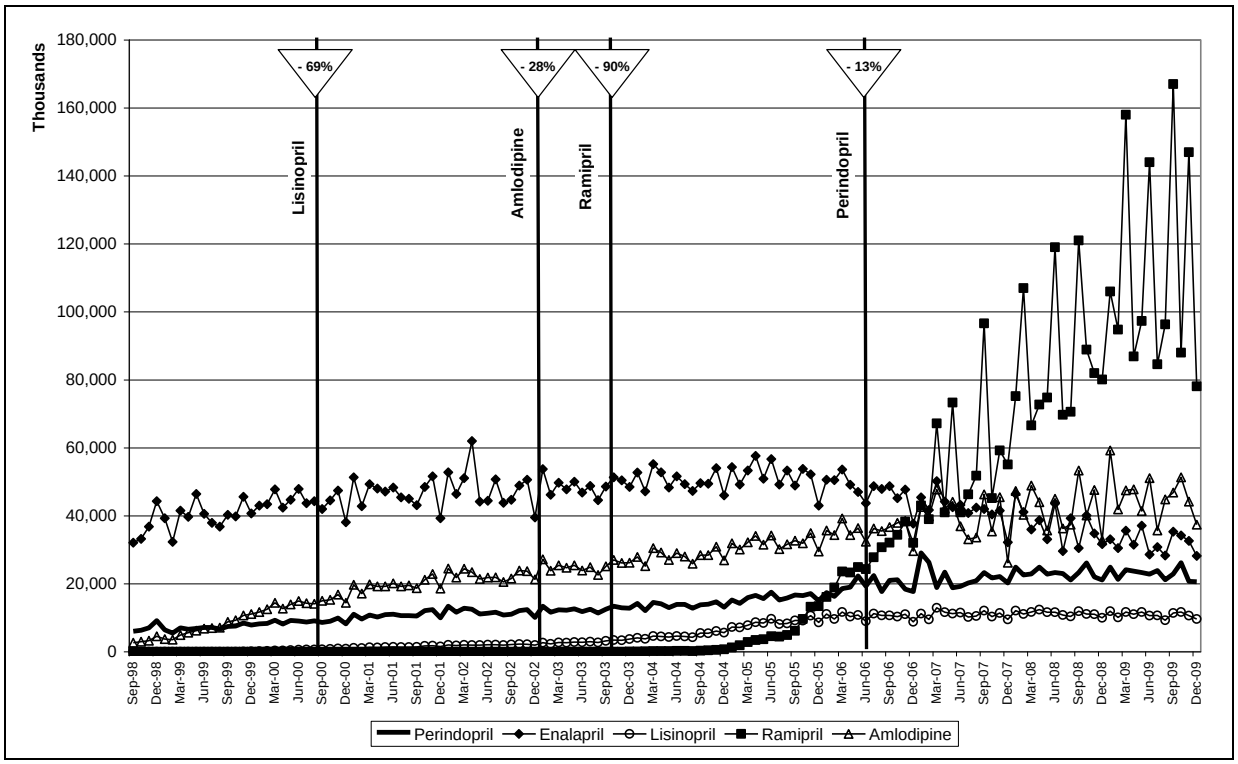
3112 ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 544 - 546.

3113 Article 38, paragraph 4 of the Act of 27 August 2004 on health care services financed from public means, OJ 2008.164.1027.

3114 ID0032, p. 186.

to 160 million DDDs[3115] in 2009.[3116] Sanofi-Aventis, the originator producer of ramipril, cites[3117] two reasons for this: the decrease in price charged to patients due to the grant of the reimbursement status; and ramipril's competitive advantages, including with respect to perindopril.[3118] Figure 10 illustrates the respective trends for the selected ACE inhibitors and amlodipine. The relevant generic entries are marked with vertical lines. The inverted triangles inform on how the prices of products that turned generic evolved between the month preceding generic entry and December 2009.

Figure 10: Volumes of perindopril, enalapril, lisinopril, ramipril and amlodipine in Poland, in the period September 1998 – December 2009 (in thousand DDDs) and the percentage price changes observed post relevant generic entries



Source: IMS.

(2346) From 2004, perindopril was the most expensive daily treatment of all the selected ACE inhibitors and amlodipine in terms of their price per DDD. In the period preceding generic entry, perindopril was sold at approximately PLN 0.72 per DDD,

3115 The IMS data for the sales of ramipril in Poland shows considerable inter-month volatility, hence the broad range of quoted figures. The impact of the DDD conversion on the sales figures of ramipril is explained in footnote 3027.

3116 In Poland, the selected ARBs (sartans) started selling in more substantial quantities relatively late in the course of the investigated period and also did not attain the same volume levels as the products mentioned in the previous paragraph. For example, at the moment of generic entry in perindopril, i.e. in June 2006, the sales of Losartan, the most successful product in terms of quantities among the selected ARBs (sartans), sold fewer than 5 million DDDs a month.

In terms of the sales of tablets and capsules, the medicines in question ranked as follows (in thousands tablets and capsules), in January 2000: enalapril (48 972), amlodipine (9 612), perindopril (8 203), lisinopril (175), losartan (41), valsartan (10) and irbesartan (8); in May 2006: enalapril (47 987), amlodipine (26 525), perindopril (18 802), lisinopril (9 423), ramipril (9 041), losartan (4 546) and valsartan (230).

3117 In its reply to the Commission's RFI of 12 October 2010.

3118 ID2867, p. 16.

while at the same time the cheapest ACE inhibitor, enalapril, was available at approximately PLN 0.14 per DDD.[3119]

(2347) Perindopril's turnover exhibited an upward trend from September 1998 to mid-2006. Before generic entry, perindopril attained monthly sales of over PLN [1–25]* million. During that initial period, only amlodipine achieved similar levels of sales. From 2005, ramipril displayed the highest dynamics of sales, gaining the highest value of sales among all the four ACE inhibitors at the end of 2009.[3120]

(2348) As explained in section 6.4.4.1, the high co-payment by patients is a particular feature of the Polish system compared to the health systems in the UK, the Netherlands and France. As a consequence, demand can generally be expected to exhibit higher price sensitivity in Poland than in the other three countries. Co-payments can be expected to more likely influence the overall market dynamics, especially with respect to a part of the demand created by patients with lower purchasing power. In this context, it is informative to compare the out-of-pocket payments required from Polish patients purchasing different dosages of perindopril and ramipril.[3121] It should be recalled that the latter managed to build up substantial sales within a relatively short period, although it was virtually absent from the market prior to 2005 (see Figure 10). Figure 11 shows the size of the co-payment per tablet of Servier's perindopril and Sanofi-Aventis' branded ramipril, Tritace.[3122] Tritace obtained reimbursement status in October 2005[3123] which, in its case, meant a substantial drop in the co-payment level. Tritace's reimbursement conditions (i.e. the reimbursement level) and the price limit were, in principle, identical to the conditions secured by Servier's perindopril. However, it is important to note that in Poland the reimbursement conditions were established with reference to the official DDDs, the value of which was set at 4 mg for perindopril erbumine (and later 5 mg for perindopril arginine), while at only 2.5 mg for ramipril. The DDD value for ramipril was substantially lower as compared to the effectively prescribed daily dose. In fact, ramipril's higher dosages were also intended for daily administration and patients starting with lower dosages were often put on to higher daily dosages subsequently.[3124] Since on the Polish market the bulk of perindopril sales were achieved with the 4 mg/5 mg dose (equal to one DDD as defined by WHO), while the largest part of ramipril sales came from the 10 mg dose (equal to four DDDs as defined by WHO), the reimbursed amount for the most popular dose was actually four times higher for ramipril than for perindopril. Further, ramipril was more

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3119 ARBs (sartans) were priced at substantially higher levels compared to perindopril, in particular before 2006. Losartan was the cheapest of the selected ARBs (sartans) and was successively lowering its price to attain the price of PLN 1.08 per DDD in June 2006. The process continued and losartan was selling at slightly over PLN 0.60 per DDD in the course of 2009.
In terms of an average (for all available doses of a given medicine) price per tablet/capsule, the medicines in question ranked as follows (PLN prices in brackets), in January 2000: valsartan (4.046), losartan (3.519), irbesartan (3.090), perindopril (0.949), lisinopril (0.915), amlodipine (0.629) and enalapril (0.112); in May 2006: irbesartan (2.771), valsartan (2.637), losartan (1.097), ramipril (0.782), perindopril (0.707), lisinopril (0.475), amlodipine (0.456) and enalapril (0.135). Source: IMS.

3120 Losartan was the only ARB (sartan) from the selected group to reach the sales of over PLN 10 million in individual months towards the end of the investigated period.

3121 For the similar comparison with the other selected products, see *Annex A: Price developments.*

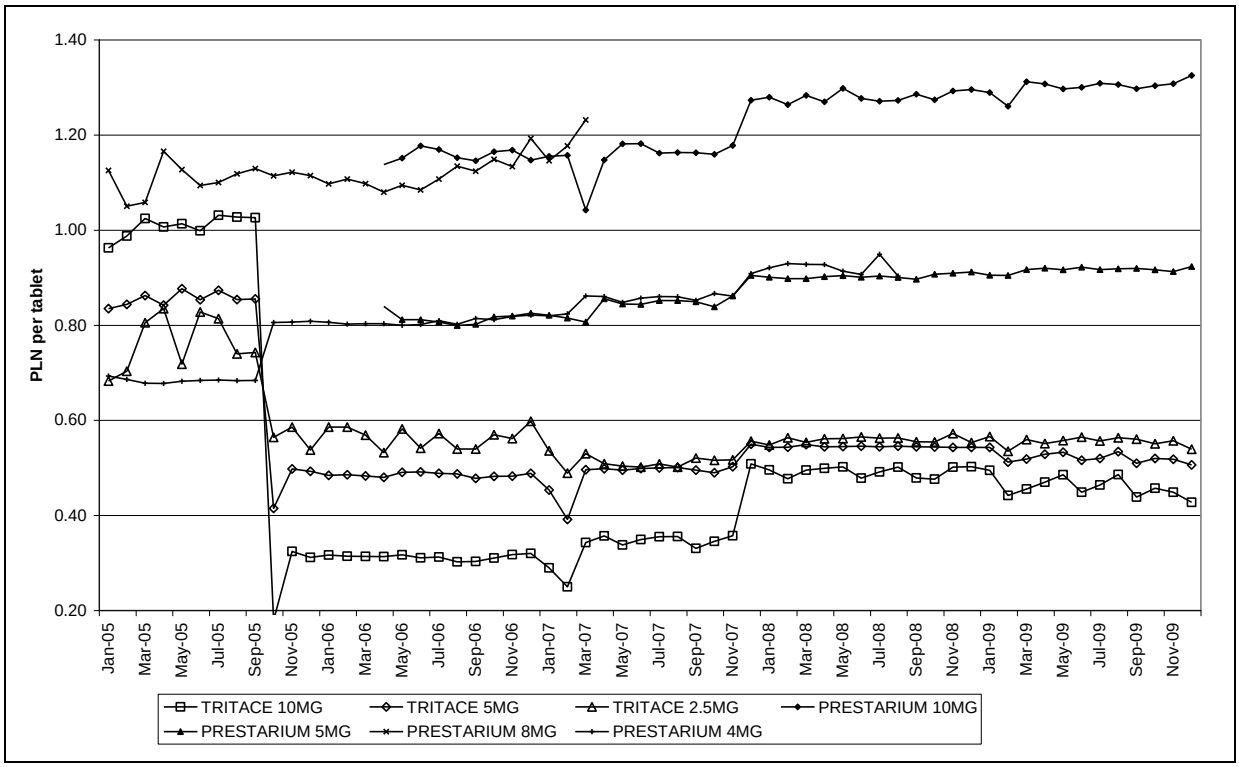
3122 Ramipril was also available from generic suppliers who managed to control a large part of its overall sales in Poland. Source: IMS.

3123 Minister of Health's decree of 22 September 2005, OJ.2005.192.1608.

3124 Information confirmed at: http://www.medicines.org.uk.

attractively priced both in terms of its unit price per DDD and its price per mg at the ex-factory level. As a result, the co-payment for Polish patients was substantially lower in relation to ramipril than perindopril. For example, in the period after October 2005, the best-selling Tritace 10 mg was offered to patients at prices below PLN 0.50 per tablet. In the same period, Prestarium 4 mg/5 mg cost patients more than PLN 0.80 per tablet, while the out-of-pocket payment for Prestarium 8 mg/10 mg gradually increased to PLN 1.30 per tablet.

Figure 11: The comparison of the co-payment amount for different dosages of perindopril and ramipril in Poland.



Source: IMS, ID2909, the Minister of Health's decrees published in OJ.2004.274.2725, OJ.2004.274.2727, OJ.2005.192.1608, OJ2005.192.1610, OJ.2007.31.202, OJ.2007.32.204, OJ.2007.222.1651, OJ.2007.222.1653, OJ.2008.125.806, OJ.2008.125.808, OJ.2009.35.275 and OJ.2009.35.277.

Note: All the changes in the price limits and the reimbursement conditions affecting the amount of co-payments were assumed to be effective in the month succeeding the publication of the relevant decrees by the Minister of Health. Certain minor changes in the price limits may be slightly delayed in the chart, since information from the intermediary decrees selectively amending the global list of the price limits is not included. This does not affect the overall informative value of the above comparison of co-payments.

6.4.4.4 The sales of original and generic perindopril in Poland

(2349) On the Polish market, Krka launched the first generic product, the branded generic Prenessa, in June 2006.[3125] From 27 October 2006 when it signed the license agreement for the alpha crystalline form with Servier, Krka continued selling but with a [0–5]* % royalty fee payable to Servier.[3126] Subsequent generic entries did not take place until the first half of 2009.[3127]

3125 ID1307, p. 62.

3126 The royalty payment stopped in mid 2009. For more details, see paragraph (972).

3127 ID1307, p. 63.

(2350) The Polish market for perindopril grew, in terms of average six-monthly sales, from [80-100] million DDDs in 2004 to [100-140] million DDDs in the years 2008-2009, i.e. an increase of 40%. New sales originated mainly from Krka which gradually increased its market share to [0-30]% in the second half of 2009. Despite the fact that Servier's sales increased slightly, if considered in absolute terms its market share in volume terms went down to [50-99]% in the second half of 2009. During the period around March 2007, there were also certain fluctuations in Servier's level of sales that are apparent even in six-month averages. Part of those variations may have been caused by Servier's defensive strategy targeting Krka. In an internal document, Servier Poland explains that *"[the] level of sales does not reflect the real performance of Servier Polska [Poland] as 500 000 boxes of Prestarium 5mg [15 million DDDs] are overstocked in the distribution channel. This is a part of our anti-generic strategy to saturate pharmacy shelves in order to block Prenessa penetration in the distribution channel at the time of its reimbursement the 1st of March 2007"*.[3128] Moreover, Servier had effected the switching of its patient base from perindopril *erbumine* to perindopril *arginine*, between April 2006 and April 2008. Table 31 provides for a more detailed overview of the sales dynamics on the Polish market in terms of quantities.

Table 31: Sales of perindopril in Poland

	Servier (*erbumine*) in million DDDs	**Servier (*arginine*) in million DDDs**	**Krka (*erbumine*) in million DDDs**	**Other generics (*erbumine*) in million DDDs**	**Total market in million DDDs**	**Total market in PLN millions**
2004H1	[80-100]	0	0	0	[80-100]	[44-80]
2004H2	[80-100]	0	0	0	[80-100]	[44-80]
2005H1	[90-120]	0	0	0	[90-120]	[50-96]
2005H2	[90-120]	0	0	0	[90-120]	[50-96]
2006H1	[35-120]	[0-120]	[0-30]	0	[100-140]	[50-105]
2006H2	[0-120]	[35-120]	[0-30]	0	[100-140]	[50-105]
2007H1	[0-50]	[70-140]	[0-30]	0	[100-140]	[50-105]
2007H2	[0-50]	[70-140]	[0-30]	0	[100-140]	[50-105]
2008H1	[0-50]	[70-140]	[0-30]	0	[100-140]	[50-105]
2008H2	0	[70-140]	[0-30]	0	[100-140]	[50-105]]
2009H1	0	[70-125]	[0-30]	[0-15]	[100-140]	[50-105]
2009H2	0	[70-125]	[0-30]	[0-15]	[100-140]	[50-105]

Source: The Commission's own calculation based on ID1774, ID1857, ID1869, ID1875, ID1886, ID1965 and ID3347.

(2351) Post-generic entry, the average price for Servier and generics decreased from PLN [0.55-0.80] to PLN [0.50-0.75]. During the same period, Servier's own price decreased from PLN [0.55-0.80] to PLN [0.50-0.75] representing price falls of 17% and 7%, respectively. Krka's entry price was set at a level [BUSINESS SECRETS]. Subsequently, during the period 2007 to 2008 Krka increased its price, which nonetheless remained appreciably lower than Servier's. The increase coincides with

[3128] ID0357, p. 619.

the aforementioned grant of reimbursement status to Krka's perindopril. Eventually, Krka's price dropped to its original entry level in 2009. The same year, new generics entered at even lower prices. These developments are shown in greater detail in Table 32.

Table 32: Price developments for perindopril in Poland

Prices in PLN per DDD	Servier (*erbumine* & *arginine* combined)	Krka (only *erbumine*)	Other generics (only *erbumine*)	Weighted average price
2004H1	[0.55-0.80]	n/a	n/a	[0.55-0.80]
2004H2	[0.55-0.80]	n/a	n/a	[0.55-0.80]
2005H1	[0.55-0.80]	n/a	n/a	[0.55-0.80]
2005H2	[0.55-0.80]	n/a	n/a	[0.55-0.80]
2006H1	[0.55-0.80]	[0.20-0.60]	n/a	[0.50-0.75]
2006H2	[0.50-0.75]	[0.20-0.60]	n/a	[0.50-0.75]
2007H1	[0.50-0.75]	[0.20-0.60]	n/a	[0.50-0.75]
2007H2	[0.50-0.75]	[0.20-0.60]	n/a	[0.50-0.75]
2008H1	[0.50-0.75]	[0.20-0.60]	n/a	[0.50-0.75]
2008H2	[0.50-0.75]	[0.20-0.60]	n/a	[0.50-0.75]
2009H1	[0.50-0.75]	[0.20-0.60]	[0.20-0.60]	[0.50-0.75]
2009H2	[0.50-0.75]	[0.20-0.60]	[0.20-0.60]	[0.50-0.75]

Source: The Commission's own calculation based on ID1774, ID1857, ID1869, ID1875, ID1886, ID1965 and ID3347.

(2352) The above-explained developments in volumes and prices, where the former increased slightly more in percentage terms than the latter decreased, resulted in modest market value growth. The comparison of the turnovers from 2005 and 2009 shows that the total value changed from PLN [120-160] million to PLN [120-160] million, respectively with a peak of nearly PLN [140-180] million in 2007.

(2353) Polpharma, a local Polish generic company, attributes the mitigated impact of generic entry in Poland to the high entry barriers that Servier managed to erect through the successful switch to new dosages of perindopril *arginine* and to Servier's *"strong image […] within the medical society"*.[3129] It is worth noting that in the Polish system, the change in dosages (due to the switch from the *erbumine* to the *arginine* salt) effectively prevents generic substitution by pharmacists.[3130]

6.4.5 Other aspects concerning the sales of perindopril

(2354) The purpose of this section is to provide the context to the price and volume developments observed during the investigated period. The section reviews: (i) Servier's planned and actual reactions to the observed movements in prices and volumes of the alleged competitors, as well as Servier's perception of various developments, in particular natural events such as generic entries, (ii) the magnitude of promotional expenditure and of other costs, (iii) the general profitability of Servier's operations, (iv) the extent of co-prescriptions, (v) the lock-in aspects of the patient base and (vi) the inertia of doctors. Each aspect is to a certain extent

3129 ID7956, p. 14.

3130 See paragraph (2343).

interlinked with the others. For example, high profitability can fuel promotional expenditure, but the opposite can be true where high promotional expenditure help to achieve higher profitability within a certain time period. Both the co-prescriptions and lock-in aspects influence the degree of the product's exposure to competitive forces and so may have an effect on profitability as well as expected pay-offs from promotional expenditure. This section also includes a summary of the results from the Commission's survey, the purpose of which was to obtain evidence from practitioners on how they used perindopril at the relevant time.

6.4.5.1 Servier's reaction to and views on price and volume developments prior to generic entry

(2355) The Commission asked Servier to provide information on the natural events relating to allegedly competing products and asked whether these events led to a change in its pricing, marketing, strategic or any other important policy for perindopril.[3131] A natural event was defined as a change of circumstances, which could be attributed to a precise date with potentially lasting effects in the competitive environment. At least the following four categories were considered to constitute events for the purpose of the RFI: the arrival on the market of (i) a new molecule / product or (ii) a generic version of an existing molecule / product with potentially similar therapeutic effects to perindopril; or the publication of (iii) a new study or (iv) a new set of guidelines in light of which the prescription practice was likely to change in favour of / to the detriment of perindopril. Servier was free to add other categories of events, should it have considered that an important category was omitted by the Commission.

(2356) Servier did not identify any additional categories of natural events in its reply.[3132] Instead, Servier singled out seventeen instances of the arrival of new medicines (mainly new combinations of the existing molecules) and generics,[3133] thirty six studies / trials[3134] and five international recommendations for hypertension.[3135] Servier claimed to be unable, from its present perspective, to retrace modifications to its strategy caused by individual events. Moreover, Servier insisted that *"*in general, a change in policy of SERVIER may result from a series of more or less frequent events and not from a specific event"*.[3136] Servier explained that the main modification to its strategy and commercial policy (caused by external factors) was related to the practice of promoting the medicines on the basis of extensive morbidity-mortality studies that had been developed by large originator companies in the 1980s and 1990s. According to Servier, it adapted the commercial strategy by involving itself in the same type of research, examples of which are its flagship studies PROGRESS (2001) and EUROPA (2003). Nonetheless, Servier argued that its efforts were belated; ramipril achieved unprecedented success as a result of the HOPE study published in 2000. Servier claims that ramipril's success is directly linked to the fortunate timing of the study. By contrast, two large originator companies, Bristol-Myers Squibb and Merck Sharp & Dohme, had only started to focus their promotional efforts on ARBs (sartans) much later but had already lost

3131 ID2051.
3132 ID2365, p. 6.
3133 ID6160.
3134 ID2366, p. 13; Studies concerning perindopril are described in section 6.2.10.2.
3135 ID2366, p. 10 – 12. Apart from the medical guidelines described in section 6.2.9, Servier referred to the US guidelines.
3136 ID2365, p. 3.

their position in ACE inhibitors due to generic entry. According to Servier, the efforts of Bristol-Myers Squibb and Merck Sharp & Dohme led to ARBs (sartans) being on an equal footing with ACE inhibitors.[3137]

(2357) More detailed information on the reactions to natural events can be found in Servier's contemporaneous internal documents. The competitive situation was considered in the framework of the SWOT analysis[3138] carried out for the purpose of Servier's strategic planning. In the assessment of Servier's external environment (which is conventionally evaluated under two sections: the opportunities and the threats), attention is, among others, given to generics of perindopril and generics of other hypertensive medicines. Generics of perindopril are clearly viewed as a threat.[3139] Generics of other hypertensive medicines can also be viewed as a threat and an opportunity. They are seen as a threat if a new generic is from the ACE inhibitors class and therefore enhances general accessibility to cheaper products belonging to the same class as perindopril.[3140] But, at the same time, such an arrival usually leads to the end of the relevant originator's branded product's promotional efforts.[3141] Hence, the branded products still being promoted, in this instance – perindopril, can have a higher "share of voice",[3142] which can be viewed as an opportunity.

(2358) The actual perception of threats and opportunities also depends on context. For example, the fact that, after Sanofi-Aventis' exclusivity over ramipril expired, Servier's perindopril became the only ACE inhibitor promoted was noted first as a threat in the broader context of the promotional pressure exercised on ACE inhibitors by ARBs (sartans) (in the *2006/2007 Orientation Plan*: *"High promotional pressure of ARBs (high share of voice) concomitant to the decline share of voice of ACE inhibitors as Coversyl will be the only ACE inhibitor (original brand) promoted"*)[3143] and then as an opportunity in the narrower context of ACE inhibitors (in *the 2007/2008 Orientation Plan*: *"End of global investment on ramipril"*).[3144]

(2359) Table 33 summarises those opportunities and threats drawn from Servier's successive *Orientation Plans* that are considered to be the closest to the notion of a natural event.

3137 For more information on the studies used in its marketing policy by Servier see section 6.2.10.2.

3138 SWOT analysis is a strategic planning tool used to evaluate the strengths, weaknesses, opportunities and threats of a given business project. Strengths and weaknesses are internal to the project, while opportunities and threats come from the external environment.

3139 ID0349, p. 672, 775, 853 and ID0357, p. 257.

3140 ID0349, p. 604, 672, ID0352, p. 37, 91, ID0355, p. 55, 165, ID0356, p. 114, 140, 172 and 227 and ID0357, p. 257.

3141 ID0326, p. 101, ID0349, p. 774, ID0352, p. 37 and 91 and ID0356, p. 114.

3142 Share of voice is the percentage of advertising activities for one brand within the total advertising activity for an entire sector or product type.

3143 ID0349, p. 672.

3144 ID0349, p. 774.

Table 33: Opportunities (O) and threats (T) in relation to the individual events drawn from Servier's *Orientation Plans*

Ref. year	O/T	Individual events	Source
2003/04	O	- *"ARBs and calcium antagonists continue to show disappointing results"* [a claim presumably based on the results of trials and studies] - *"Expected indication in coronary artery disease and recommendations in ESC guidelines"*	ID0349, p. 603-604
	T	- *"Generics: [i] wide availability of ramipril generics; [ii] controlling the risk of Coversyl generics"*	
2004/05	O	- *"New guidelines in HT (ASCOT results) and CAD [coronary artery disease] (EUROPA results)"* - *"Possibilities of differentiation with ACE inhibitors and ARBs: [i] negative results from other ACE inhibitors and ARBs (PEACE, IMAGINE, VALUE), [ii] meta-analysis on ACE inhibitors versus ARBs […]"*	ID0349, p. 672
	T	- *"Ramipril generic (price/clinical demonstrations in CAD)"* - *"Pfizer reaction on ASCOT-BPLA"* - *"Generics of Coversyl"*	
2005/06	O	- *"End of global investment on ramipril"* - *"Lack of positive data of ARBs on cardiovascular protection"* [a claim presumably based on the results of trials and studies]	ID0349, p. 774-775
	T	- *"ONTARGET (ESC 2008)"* - *"New competitors (rennin inhibitors)"* - *"Generics"*	
2006/07	O	- *"Confirmation of ACE inhibitors superiorities (BPLTTC, guidelines…)"* - *"Coversyl is the only ACEi promoted in many countries"* - *"No real innovation from competitors in the next 10 years in HT or CAD"* - *"Guidelines: ACEIs' endorsement in HT and CAD (BHS, ESH,…)"*	ID0349, p. 852-853
	T	- *"New competitors (Aliskiren[#], Exforge[##], ACE-ARB combinations)"* - *"Generics"*	
2007/08	O	- *"Doubts about ARBs due to negative evidence of TRANSCEND and PROFESS trials*" - *"UKPDS [United Kingdom Prospective Diabetes Study] results reinforce the ADVANCE results in diabetic hypertensives"*	ID0349, p. 952
	T	- *"Generics"*	

Source: see table.

Note: Reference years are established on the basis of information that an orientation plan from year T was drafted in year T-1 and mainly drew from the facts of year T-2, which thus can be assumed to be the reference year.

- Aliskiren, a renin inhibitor, was granted a MA by EMA on 22 August 2007. The authorization is held by Novartis under a brand name, Rasilez; Information available at: http://www.ema.europa.eu/.

- Exforge, a combination of amlodipine and valsartan, was granted a MA by EMA on 17 January 2007. The authorization is held by Novartis; Information available at: http://www.ema.europa.eu/.

(2360) In terms of events that were positive for Servier's sales of perindopril, the main opportunities consisted of encouraging results of various trials and studies. The key and persistent threat, however, was generic entry in perindopril. In general, the opportunities are meant to potentially help in expanding sales, while the threats usually report potential risks which may eventually turn into competitive constraints.

6.4.5.2 Promotional expenditure and other costs

(2361) The Commission asked Servier to list the main cost items contributing to the total cost of variants of perindopril at ex-factory level. The question concerned the

following thirteen Member States: Belgium, the Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Poland, Portugal, Romania and the United Kingdom.[3145] The total costs for the thirteen countries as well as the separate values for the UK, France, the Netherlands and Poland in each of the four main cost categories identified by Servier are shown in Table 34.

[3145] ID0904.

Table 34: Servier's costs relating to plain perindopril in the period 2000-2008 (in million EUR)

Year	Promotion			Production and distribution			Research and development			General expenses			Total costs		
	Total	incl. i.a.		Total	incl. i.a.		Total	incl. i.a.		Total	incl. i.a.		Total	incl. i.a.	
2000	[70–80]*	UK	[10–20]*	[10–20]*	UK	[0 - 10]*	[30–40]*	UK	[0 - 10]*	[20–30]*	UK	[0 - 10]*	[130–140]*	UK	[20–30]*
		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*
		FR	[20–30]*		FR	[0 - 10]*		FR	[0 - 10]*		FR	[0 - 10]*		FR	[30–40]*
		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[10–20]*
2001	[80–90]*	UK	[10–20]*	[10–20]*	UK	[0 - 10]*	[40–50]*	UK	[0 - 10]*	[20–30]*	UK	[0 - 10]*	[160–170]*	UK	[20–30]*
		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*
		FR	[20–30]*		FR	[0 - 10]*		FR	[10–20]*		FR	[0 - 10]*		FR	[40–50]*
		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[10–20]*
2002	[70–80]*	UK	[10–20]*	[10–20]*	UK	[0 - 10]*	[50–60]*	UK	[0 - 10]*	[20–30]*	UK	[0 - 10]*	[160–170]*	UK	[30–40]*
		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*
		FR	[10–20]*		FR	[0 - 10]*		FR	[10–20]*		FR	[0 - 10]*		FR	[30–40]*
		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[10–20]*
2003	[80–90]*	UK	[20–30]*	[20–30]*	UK	[0 - 10]*	[90–100]*	UK	[10–20]*	[20–30]*	UK	[0 - 10]*	[230–240]*	UK	[50–60]*
		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*
		FR	[10–20]*		FR	[0 - 10]*		FR	[20–30]*		FR	[0 - 10]*		FR	[40–50]*
		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[20–30]*
2004	[100–110]*	UK	[20–30]*	[20–30]*	UK	[0 - 10]*	[30–40]*	UK	[0 - 10]*	[30–40]*	UK	[0 - 10]*	[200–210]*	UK	[40–50]*
		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*
		FR	[10–20]*		FR	[0 - 10]*		FR	[0 - 10]*		FR	[0 - 10]*		FR	[30–40]*
		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[10–20]*
2005	[90–100]*	UK	[10–20]*	[30–40]*	UK	[0 - 10]*	[0 - 10]*	UK	[0 - 10]*	[40–50]*	UK	[10–20]*	[170–180]*	UK	[30–40]*
		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*		NL	[0 - 10]*
		FR	[10–20]*		FR	[0 - 10]*		FR	[0 - 10]*		FR	[10–20]*		FR	[30–40]*
		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[0 - 10]*		PL	[10–20]*
2006	[BUSINESS SECRETS]														
2007															
2008															

Note: All totals are provided on the basis of the Servier data for the following thirteen Member States: Belgium, the Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Poland, Portugal, Romania and the United Kingdom.

Source: ID1157.

(2362) The distribution of costs reported by Servier shows the general importance of promotion compared to other cost items as well as to the incomes generated by the product (see *Annex B: Perindopril sales - geographic distribution*). However, the figures alone cannot demonstrate the nature of promotional activities. Servier's internal documents such as the *Promotional Campaign* and the *Orientation Plans* provide insight on this point. Servier's strategic goal was to convince practitioners that *"Coversyl has to be prescribed right from the start of the [cardiovascular] disease continuum in everyday hypertensive patients"*.[3146]

(2363) In its promotional materials described in the *2005/2006 Promotional Campaign*, Servier wanted to present to prescribers *"the efficacy of COVERSYL on blood pressure in different patients (newly diagnosed, value of switch to COVERSYL in non-normalized patients, diabetic patients, coronary artery disease with hypertension, elderly patients, hypertensive patients with impaired renal function)"*.[3147]

(2364) In the *2006/2007 Orientation Plan*, Servier commented on the results from a survey of practitioners on how perindopril was prescribed:

"Compared with last year, Coversyl is prescribed more to newly diagnosed and diabetic patients, than elderly and diabetic patients from last year. This is a good indicator that our communication is going in the right direction and we are managing to convince our doctors that they should prescribe Coversyl to less severe patients, ie, newly diagnosed".[3148]

(2365) In the "*2007/2008 Promotional Campaign Plan*" for Coversyl, the following explanation of the product positioning strategy was given:

"We want to continue to explain to practitioners how their hypertensive patients will be treated better by having Coversyl first-line and possibly second-line according to the NICE/BHS recommendations in respectively newly diagnosed patients and from "add-on" treatment when uncontrolled, always positioning Coversyl in the everyday hypertensive patient, who is right at the start of the continuum of the cardiovascular disease".[3149]

(2366) As illustrated by the above quotes, Servier was targeting the reservoir of potential new patients comprising of newly diagnosed hypertensive patients and patients whose conditions were not being controlled satisfactorily by other antihypertensive agents, and specific groups of patients for whom perindopril had particularly good evidence (e.g. the EUROPA study for coronary artery disease).

(2367) The Commission asked IMS Health to provide, among others, information on the level of promotional effort in the UK, the Netherlands, France and Poland.[3150] The information was requested for all the products listed in Table 19. IMS was not able to

3146 E.g. ID0349, p. 6, p. 298.
3147 ID0349, p. 109.
3148 ID0349, p. 643.
3149 ID0349, p. 299.
3150 ID3063.

provide the data for Poland. For the three other countries, the datasets contain information on three types of promotional activities, namely detailing, mailing and advertising in professional journals. The datasets for the UK and France cover the period 2000 to 2009, while information for the Netherlands is only available from the first quarter of 2004. Table 35 provides an overview of promotional expenditure recorded by IMS for the three countries.

Table 35: Promotional expenditure on the nine selected products in the UK, the Netherlands and France from 2000 to 2009 (in '000s local currency)

Year	Perindo-pril	Enala-pril	Lisino-pril	Rami-pril	Amlodi-pine	Irbe-sartan	Lo-sartan	Val-sartan	Val-sartan +HCTZ
United Kingdom									
2000	[1,000–2,000]*	0	859	1,914	2,583	2,840	1,921	3,798	0
2001	[2,000–3,000]*	3	459	3,262	2,939	3,124	1,905	4,096	0
2002	[2,000–3,000]*	0	75	3,294	2,474	3,640	3,018	3,997	0
2003	[2,000–3,000]*	0	0	1,122	1,992	2,579	3,861	4,033	0
2004	[1,000–2,000]*	6	2	34	80	3,562	3,391	5,607	320
2005	[1,000–2,000]*	22	11	0	7	3,421	5,035	5,788	619
2006	[1,000–2,000]*	38	3	0	8	2,327	3,638	3,725	905
2007	[0–1,000]*	54	10	6	14	2,906	2,511	1,402	261
2008	[0–1,000]*	70	24	0	0	3,223	1,828	777	77
2009	[0–1,000]*	86	0	4	16	2,759	761	95	0
Netherlands									
2000	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2001	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2002	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2003	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2004	[1,000–2,000]*	6	1	18	31	1,805	1,495	1,651	833
2005	[0–1,000]*	22	0	7	8	1,886	1,629	1,104	1,507
2006	[0–1,000]*	38	0	0	3	1,410	1,301	1,165	721
2007	[0–1,000]*	54	0	0	0	956	1,163	1,431	346
2008	[0–1,000]*	70	0	0	17	1,242	659	893	263
2009	[0–1,000]*	86	0	0	0	1,179	232	450	157
France									
2000	[6,000–7,000]*	1,822	2,784	3,157	5,982	6,988	4,872	9,431	6,959
2001	[5,000–6,000]*	184	1,443	3,893	4,980	4,963	4,023	8,239	8,112
2002	[4,000–5,000]*	23	1,270	5,788	6,615	5,847	6,086	8,489	4,749
2003	[4,000–5,000]*	147	619	6,225	5,080	5,518	5,513	8,462	11,723

Year	Perindo-pril	Enala-pril	Lisino-pril	Rami-pril	Amlodi-pine	Irbe-sartan	Lo-sartan	Val-sartan	Val-sartan +HCTZ
2004	[4,000–5,000]*	13	3	6,125	5,720	6,646	6,196	10,378	9,931
2005	[5,000–6,000]*	4	11	5,041	6,092	7,398	4,654	10,939	7,209
2006	[6,000–7,000]*	4	11	592	4,012	6,396	4,715	11,768	4,906
2007	[15,000–20,000]*	6	24	50	1,795	13,113	6,548	21,406	6,597
2008	[10,000–15,000]*	1	33	56	176	17,104	940	18,121	5,119
2009	[10,000–15,000]*	67	27	25	111	16,177	587	14,928	3,901

Source: IMS.

(2368) Table 35 shows a sharp discontinuation of the promotional efforts some time before or, at the latest, after the entry of generic products.[3151] This is understandable, since from that point on, the originator company is not in a position to secure the results of its promotion, as any new sales can be captured by cheaper generics. The expected negative pay-off prevents originator companies from further investments of this type. The forward-looking originator company should cease its promotional efforts sometime before actual generic entry takes place. The obvious restriction of such an attempt to optimise promotional efforts is the fact that the date of effective generic entry may remain unknown until the very last moment, as was the case with Servier.[3152]

6.4.5.3 General profitability

(2369) In its RFI dated 6 August 2009, the Commission asked Servier to provide information on plain perindopril's monthly margins achieved during the investigated period. Servier was only able to provide the annual figures based on the total value of sales and the total costs (as presented in the previous section). The resulting figures represent earnings before interest and tax (EBIT).

3151 See Table 21, Table 24, Table 27 and Table 30 for the end dates of relevant periods for individual products in the Member States concerned.

3152 The promotional expenditure on the selected products shows certain common variability. This may be for various reasons ranging from a certain relationship between the products to similar external conditions like the time the practitioners are prepared to spend in meetings with the sales representatives of each company and industry-wide events. Methodological issues may also influence the observed trends as, for example, the use of a common cost denominator by IMS for all medical visits where any revaluations of that dominator across the period necessarily result in introducing common variability in the data (see: ID3842, p. 14).
As a general remark, the IMS data, with respect to the promotional expenditures, is not fully comparable with the data submitted by Servier. It may well be because of the abovementioned methodological issues. Promotional expenditure is much more difficult to observe than such 'core' variables as quantities and prices. Servier's own data and the IMS data on promotional expenditure differ not only in the magnitude, but do not show the same magnitude of differences across the selected Member States. There are also important time discrepancies between the two data sources where the expenditure may rise or fall in a given year depending on the source of data. In view of the existing data discrepancies, the Commission has considered it inappropriate to engage in any correlation studies since their results would be likely spurious. See also section 6.5.1.2.5.1.

(2370) In general, the profitability of perindopril increased throughout the entire investigated period, both in terms of absolute profits and the profitability expressed as a percentage of the sales revenues. The only fall in absolute profits took place after 2007, when the UK and Dutch markets were to a large extent taken over by generics.[3153] Based on Servier's own submission, in 2005, the overall profitability of perindopril exceeded [50–60]* %[3154] and reached values well above [60–70]* % on important markets such as the UK and France.

(2371) Profitability can also be measured in terms of operating margin, i.e. the proportion of a company's revenue that is left over after variable costs of production are deducted. For the purpose of this investigation, Servier only submitted the combined costs of production and distribution of perindopril. If this cost category is used to calculate operating profit margins, the resulting values range on average from [90–100]* % to [90–100]*% in the period 2000 to 2005.[3155] The highest values are observed in France, where the operating profit margin ranges up to [90–100]*%. The above profit margins as a percentage of the perindopril revenues must be regarded as high by any measure.[3156]

6.4.5.4 Co-prescriptions

(2372) The medical guidelines, as described in section 6.2.9, advocate the prescription of combination treatments from 1999. Similarly, Servier in its internal analysis expected a large proportion of the patients initially treated with amlodipine to require Coversyl.[3157] In response to the need for combination treatments, Servier introduced, as described in section 6.3.1, two types of fixed combinations (with indapamide and with amlodipine). Doctors can also prescribe free combinations, where each of the agents is prescribed in its non-combined form and patients are asked to take them together as a single therapy. The use of combination treatments implies that each agent included in a given combination treatment, no matter whether it is a fixed or a free combination, is regarded as necessary and appropriate to achieve desired therapeutic effects.

(2373) The longitudinal study[3158] entitled *"Complements"* contains a comparison of the prescription practices of French general practitioners in the periods May 2006 to April 2007 and May 2007 to April 2008.[3159] Among others, the study presents the distribution of sales for Coversyl, where Servier's perindopril is prescribed either as a mono-therapy, a bi-therapy or more, for hypertension. Table 36 shows the combined figures for all available doses of perindopril: 2 mg, 4 mg and 8 mg, for the

3153 See also Table 10.

3154 Based on the data provided by Servier for thirteen Member States: Belgium, the Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Poland, Portugal, Romania and the United Kingdom. (ID1158).

3155 Based on the data provided by Servier for thirteen Member States: Belgium, the Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Poland, Portugal, Romania and the United Kingdom. (ID1157 and ID1158).

3156 For the sake of comparison, please see the Commission's Decision of 24 March 2004 in Case COMP/C-3/37.792 Microsoft, paragraph 464.

3157 See paragraph (2231).

3158 In response to the Commission's RFI of 17 September 2010, Servier submitted longitudinal studies carried out in respect of France, the UK and Italy. The studies were prepared specifically for Servier by specialist research companies. Similar research papers were not available for the other countries focussed on in the present investigation.

3159 ID2650. There is also a series of other similar studies prepared for the French market, but for shorter periods. Their results do not differ to any significant extent to the results presented in this section.

two periods covered by the study. Almost 70% of the perindopril prescriptions were in multi-therapies. The pattern was largely the same for all doses with the general tendency that the higher the dose, the higher the proportion of prescriptions in multi-therapies. Other longitudinal studies of the prescription practices of French general practitioners and cardiologists show that a majority of the perindopril prescriptions were already in multi-therapies at the beginning of the concerned period, in the years 2000-2001. The same studies indicate that perindopril was most often co-prescribed with diuretics, beta-blockers and calcium channel blockers.[3160]

Table 36: Distribution of the perindopril prescriptions between mono and multi-therapies based on Servier's survey of general practitioners in France

Period	Mono-therapy	Bi-therapy	Tri-therapy	Quad-therapy and more
May 06 - April 07	31.4%	42.9%	20.0%	5.7%
May 07 - April 08	30.6%	42.6%	21.1%	5.8%

Source: ID2650, p. 9.

(2374) The UK survey entitled *"The hypertensive drugs market in HTN in the UK"* provided a more general pattern which was not perindopril-specific. However, the study shows the overall distribution of patients for all ACE-inhibitors, except the number of multi-therapies with four and more agents. Table 37 presents the distribution for ACE-inhibitors prescribed to patients in mono-therapies and free multi-therapies, i.e. by excluding the fixed combinations in order to provide for a basic comparability with the French data above. The lack of data on the multi-therapies with four and more individual agents means that the percentages given in the table may be slightly inflated compared to the actual figures. Nonetheless, it is visible that the ACE-inhibitors class in the UK had a very similar pattern of distribution (in terms of patients being predominantly treated with multi-therapies) to that revealed in the French statistics relating to the perindopril prescriptions. In over 60% of the cases, British patients took an ACE inhibitor with another anti-hypertensive medicine. The largest single category of combinations was the bi-therapy of plain ACE inhibitors with diuretics.

Table 37: Distribution of the patients treated with an ACE-inhibitor between mono and multi-therapies based on Servier's survey of general practitioners in the UK

Period	Mono-therapy	Bi-therapy	Tri-therapy	Quad-therapy and more
July 05 - June 06	37.4%	44.5%	18.1%	?

Source: ID2655, p.9.

(2375) The distribution pattern detailed above indicates the presence of strong complementarities between various anti-hypertensive medicines. Mono-therapy prescriptions are clearly in a minority of cases.

(2376) The mechanism of co-prescriptions in cases where perindopril were not delivering the expected blood pressure levels was studied by Servier. In the *2009/2010 Orientation Plan*, Servier analysed the results of the survey of physicians. Among others it was found that:

"if Coversyl 5 mg is initiated in hypertension treatment, it happens that patients sometimes need more BP control. Physicians will keep on prescribing Coversyl family products in 90% of cases. Uptitration to Coversyl 10 mg and addition of

[3160] ID2658, p. 14, ID2676, p. 14.

amlodipine to Coversyl 5 mg are the most widespread treatment options (27% and 25% of cases, respectively). Replacement by or addition to Coversyl PLUS [the combination of perindopril and indapamide] is also frequent in physicians' practice (20% and 8% of cases), whereas addition to another drug remains rare (10%)".[3161]

(2377) The above quote helps in interpreting the figures presented in this section since it shows that most of the co-prescriptions involving perindopril as one of molecules were likely to include either amlodipine or indapamide as a second molecule.

6.4.5.5 Lock-in effects

(2378) As mentioned in section 6.2.4 on place and duration of treatment using hypertension medicines, hypertension is a chronic condition. The medical guidelines, however, explain (see section 6.2.9) that the ability of any agent used alone to achieve the expected therapeutic goals is limited and that switching to an agent from a different class is mandatory whenever the first agent is not successful i.e. it does not lower blood pressure or induces important side effects. The laborious character of the initial trial process is one of the reasons why co-prescriptions, which can reduce the number of medical switches, dominated the treatment of hypertension.[3162] As already explained, the international medical guidelines started to advise co-prescriptions at least as from 1999,[3163] which as to the practical implementation of the guidelines is confirmed by the available longitudinal studies.[3164] The desire to avoid unnecessary switching also suggests the existence of certain lock-in effects, where patients whose treatment is successful continue their therapies for long periods of time. If the prescriber decides to switch the patient's treatment, a new trial period will be required. In this respect, the trial period can be regarded as an investment which represents a sunk cost for the patient and the health system.

(2379) As shown in section 6.2.10, Servier actively differentiated perindopril from other ACE inhibitors. In view of differentiation a switch from one medicine to another, even within the same class, could be associated with certain costs related to (a) the switch itself[3165] and (b) the health risks accompanying the switch. For example, it was shown that a switch between medicines considered as very close alternatives, such as enalapril and lisinopril, resulted in the loss of optimal blood pressure control followed by a need for readapting the dosage regime for some patients and caused adverse effects for certain other patients.[3166] The switch created direct costs in the form of additional medical consultations and involved risks for patients' health. Even if those risks were short-lived and could be eventually eliminated with an adaptation in the dosage regime or reverse to the previous treatment, they should not be disregarded. The VALUE study showed among others[3167] the clinical importance of the rate of achieving blood pressure control. The study suggested that recommended

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3161 ID0349, p. 923.

3162 See paragraph (2183).

3163 See paragraph (2179).

3164 See paragraph (2373).

3165 As explained in paragraphs (2183) and (2184), the medical guidelines describe the switching procedure as *"laborious and frustrating for both doctors and patients"*.

3166 *Cost of switching hypertensive patients from enalapril maleate to lisinopril*, Am J Hosp Pharm 1991; 48, p. 276-9.

3167 The Valsartan Antihypertensive Long-term Use Evaluation (VALUE) trial was designed to test the hypothesis that for the same blood-pressure control, valsartan would reduce cardiac morbidity and mortality more than amlodipine in hypertensive patients at high cardiovascular risk. The study concluded that as to the main outcome, the two treatments did not differ.

blood pressure goals need to be reached within a relatively short time (weeks rather than months), at least in patients at high cardiovascular risk. The failure to lower quickly blood pressure was associated with a higher likelihood of mortality.[3168] Therefore, even a relatively short period when the optimal blood pressure control is lost because of an on-going switch may have important consequences for patients' health or even life. Such features of antihypertensive treatments are likely to lead to important lock-in effects to the benefit of the successfully established treatments.

(2380) The information on the potential magnitude of the lock-in effect for Servier's plain perindopril can be seen in the Thales studies Servier ordered for the purpose of its internal strategic planning process.[3169] The studies were carried out in order to reveal prescription practices in the period July 2005 to June 2006 and were based on a representative sample of general practitioners in three Member States: the UK, France and Italy.[3170] The first two markets are of particular interest to the present investigation.

(2381) The studies have a common methodology where patients and prescriptions can be divided into subgroups of (a) new diagnoses, where patients receive an anti-hypertensive treatment for the first time, (b) changed treatments, where patients are subject to an add-on or to a switch, (c) renewals, where patients continue their treatments without any modification in the course of the analysed period, except possible changes in dosage.[3171]

(2382) According to the study, in the UK in the period July 2005 to June 2006, [90–100]* % of prescriptions for plain perindopril, Coversyl, were for repeat prescriptions. New diagnoses, add-ons[3172] and positive switches accounted for the remaining [5–10]* % of prescriptions. There were also certain outflows of prescriptions in the form of negative switches and withdrawals. The full structure of prescriptions is given in Table 38. The data presented therein is completed with the net switches calculated for Coversyl alone and for all Servier's products, where the switches from Coversyl to any other product of Servier, such as Servier's fixed combination of perindopril and indapamide, are deducted from negative switches to show the net effect of switches on the company's sales. In general, the switches had a small but positive effect on Servier's sales during the analysed period.

3168 *Outcomes in hypertensive patients at high cardiovascular risk treated with regimens based on valsartan or amlodipine: the VALUE randomised trial*, The Lancet 2004; 363, p. 2022-2031.

3169 In its reply to the Statement of Objections, Servier also refers to other sources of data which at first sight may seem to undermine the Thales studies and suggest a relatively high ratio of patients switching between the available treatments (see Servier's reply to the Statement of Objections, paragraph 1571, ID10114, p. 481-482). However, the data sources referred to by Servier must be interpreted in their proper context. They provide either the general statistics for all the hypertensive medicines or the preselected information on certain aspects such as switches in the process of up-titration (dosage increase). Therefore, they cannot be considered as truly informative for the purpose of the present analysis focused on the sales of perindopril. In the Commission's view, the Thales studies presented in the present Decision remain the most comprehensive data set with respect to the strength of the lock-in effect for perindopril.

3170 ID0349, p. 709.

3171 ID2671, p. 12.

3172 The add-ons category should not be interpreted in relation to the previous section on co-prescriptions, since add-ons only concern the situations in which perindopril is added to an existing therapy. This type of add-on is only a fraction of the total number of co-prescriptions that should, in theory, include the existing co-prescriptions as well as the other type of add-on where another medicine is added to the treatment with perindopril.

Table 38: Structure of the perindopril prescriptions in the UK (July 2005 – June 2006)

	Number of prescriptions	%
New diagnosis	[25,000–50,000]*	[0–5]*
Add-ons	[25,000–50,000]*	[0–5]*
Switches to	[200,000–300,000]*	[0–5]*
Repeats	[0–25 million]*	[90–100]*
Total perindopril prescriptions	*[0–25 million]**	*100.0*
Switches from	[100,000–200,000]*	[0–5]*
Withdrawals	[25,000–50,000]*	[0–5]*
Net switches	+[50,000–75,000]*	-
Net switches excluding Servier product	+[50,000–75,000]*	-

Source: ID2655, p. 17.

(2383) According to the study, in France in the period July 2005 to June 2006, [90–100]* % of prescriptions for plain perindopril, Coversyl, were for repeat prescriptions. New diagnoses, add-ons and positive switches accounted for the remaining [5–10]* % of prescriptions.[3173] There were also outflows of prescription in the form of negative switches and withdrawals. The full structure of prescriptions is given in Table 39. In the same manner as above, the table is completed with the account of net switches. During the period concerned, the switches were largely neutral for Servier's sales. The results for the period July 2005 to June 2006 were confirmed in earlier studies that Servier instructed for the French market. All the available results from those previous studies show that the "fidelity" ratio measured by renewals had been in the range of [80–90]* % to [80–90]* % since at least 1996.[3174]

3173 In its reply to the Statement of Objections, Servier refers to the Thales data from the same period and claims that [10–20]* % of the patients were subject to at least one change in the treatment during the reference year (see Servier's reply to the Statement of Objections, paragraph 1567, ID10114, p. 481). The Commission notes that the figure quoted by Servier relates to all antihypertensive treatments, including perindopril. If only perindopril is taken into account, the annual percentage of patients changing treatment goes down to [10–20]* %. This percentage is largely consistent with the 90.8% retention rate. In addition, the figures are not fully comparable because the statistics referred to by Servier are based on the number of patients, while the Commission refers to the total number of prescriptions. The Commission considers that the latter reflects better the nature of the demand for perindopril (see also footnote 3180).

3174 ID2657, p. 4 and ID2668, p. 8.

Table 39: Structure of the perindopril prescriptions in France (July 2005 – June 2006)

	Number of prescriptions	%
New diagnosis	[25,000–50,000]*	[0–5]*
Add-ons	[25,000–50,000]*	[0–5]*
Switches to	[50,000–75,000]*	[0–5]*
Repeats	[1–25 million]*	[90–100]*
Total perindopril prescriptions	*[1–25 million]**	*100.0*
Switches from	[75,000–100,000]*	[0–5]*
Withdrawals	[1,000–25,000]*	[0–5]*
Net switches	-[1,000–25,000]*	-
Net switches excluding Servier product	+[1,000–25,000]*	-

Source: ID2671, p. 28.

(2384) The comparison of the prescription structures observed in the UK and France shows that there were different numbers of prescriptions written in each country. The observation must be related to the country-specific practices with regard to the frequency of patient visits to doctors' surgeries, the average number of packs per prescription and the way that this type of data is collected. The same phenomenon is visible in other sources of market data, like the IMS statistics, and does not affect the key proportions among various categories of prescriptions.

(2385) The above shows that perindopril prescriptions both in the UK and France were dominated by renewals. In both countries, the "fidelity" ratio was above 90% confirming the presence of lock-in effects. In Italy, the third country for which the longitudinal studies were carried out by Servier, the respective ratio was [90–100]* % in the reference period July 2005 – June 2006.[3175] The high "fidelity" ratio in Italy indicates a general cross-border pattern. There is no reason to doubt that significantly different ratios would be found in the Netherlands and Poland.[3176] The switches had a mitigated and rather balanced effect on the total number of prescriptions.[3177]

3175 ID2654, p. 17.

3176 Cross-border uniformity in this respect is supported by the following observations: (i) both the Netherlands and Poland endorsed the European guidelines (see paragraph (2188)), (ii) the Commission's survey did not indicate any major differences in the prescription practice of practitioners (see section 6.4.5.7 and *Annex D: Survey of prescribers*), (iii) in all the Member States concerned, perindopril was generally used for the same indications (see section 6.3.3), (iv) perindopril was introduced on the markets many years before the beginning of the investigated period (e.g. see Table 21). In addition, the analysis of the medical guidelines (see section 6.2.9) does not indicate any major breakthrough, in terms of a new revolutionary treatment, that would take place during the investigated period.

3177 In its reply to the Statement of Objections, Servier relies on the switching data submitted by Polpharma in the course of the Commission's investigation (ID8331) to argue that in Poland, the switches between treatments were more frequent than indicated in the Commission's Statement of Objections (see Servier's reply to the Statement of Objections, paragraph 1572, ID10114, p. 482 and Servier's reply to the Letter of Facts, paragraph 211, ID10324, p. 64). In its reply Servier refers to the combined figures calculated for both switches between different molecules and intra-perindopril switches between different brands of perindopril. Moreover, Servier disregards more accurate IMS data that was made available in the same data set from Polpharma. According to the IMS data, the perindopril "fidelity" ratio in terms of repeated prescriptions in Poland was at the level of 89.2% in the first half of 2009, which largely remains within the range indicated for other Member States.

(2386) In its reply to the Statement of Objections, Servier relies on a newly ordered study by CEGEDIM to argue that the majority of the perindopril patients stopped the treatment before the elapse of five years.[3178] In order to verify Servier's claim, the Commission carried out its own analysis of the underlying data.[3179] The Commission's analysis allowed for detailed quantification of the switching process in terms of switches away from the perindopril treatment over the period of five years from the first prescription. Figure 12 below illustrates the dynamics and the extent of the switching process.[3180] It reflects both the relatively intensive process of trial-and-error in the first months after the initiation of the perindopril therapy and the much greater stability of the patient base exhibited in the last years of the five-year period. For example, the average net loss in the last two years of the analysed period, i.e. in years four and five, amounted to [0–5]* % per year. After the elapse of five years, every second patient from the initial group was still treated with perindopril.[3181]

3178 Servier's reply to the Statement of Objections, paragraph 1452, ID10114, p. 444.

3179 Servier submitted the underlying raw data in response to the Commission's RFI of 26 April 2013.

3180 The switching process clearly slows down, i.e. proportionally fewer patients switch away from perindopril with the passage of time. This observation allows the CEGEDIM study to be reconciled with the results of the longitudinal study presented in Table 39. The longitudinal study shows the overall stability of the perindopril patient base within a given year. The CEGEDIM data presents switches out of a preselected initial group of perindopril patients, i.e. a single cohort, over the period of five years. The cohort consists of the French patients initiated with the perindopril treatment between July 2002 and June 2003 who consulted the same general practitioner on a regular basis during the subsequent five years (ID9978, p. 3). In addition, it must be noted that the CEGEDIM study relies on the patient switches, while the "fidelity" ratio shown in Table 39 is given in terms of prescription renewals. In the Commission's opinion, the market statistics concerning prescriptions reflect in a better way the nature of the demand for pharmaceutical products. The prescription statistics closely reproduce the actual sales, while the statistics concerning the number of patients show a natural bias towards the switches caused by the trial-and-error process. The statistics on patient switches give the same weight to a continued use patient with multiple repeated prescriptions as to a first-time use patient who might have switched away after a single prescription. However, the two patients substantially differ with respect to their impact on the overall demand as measured in terms of the actual sales.

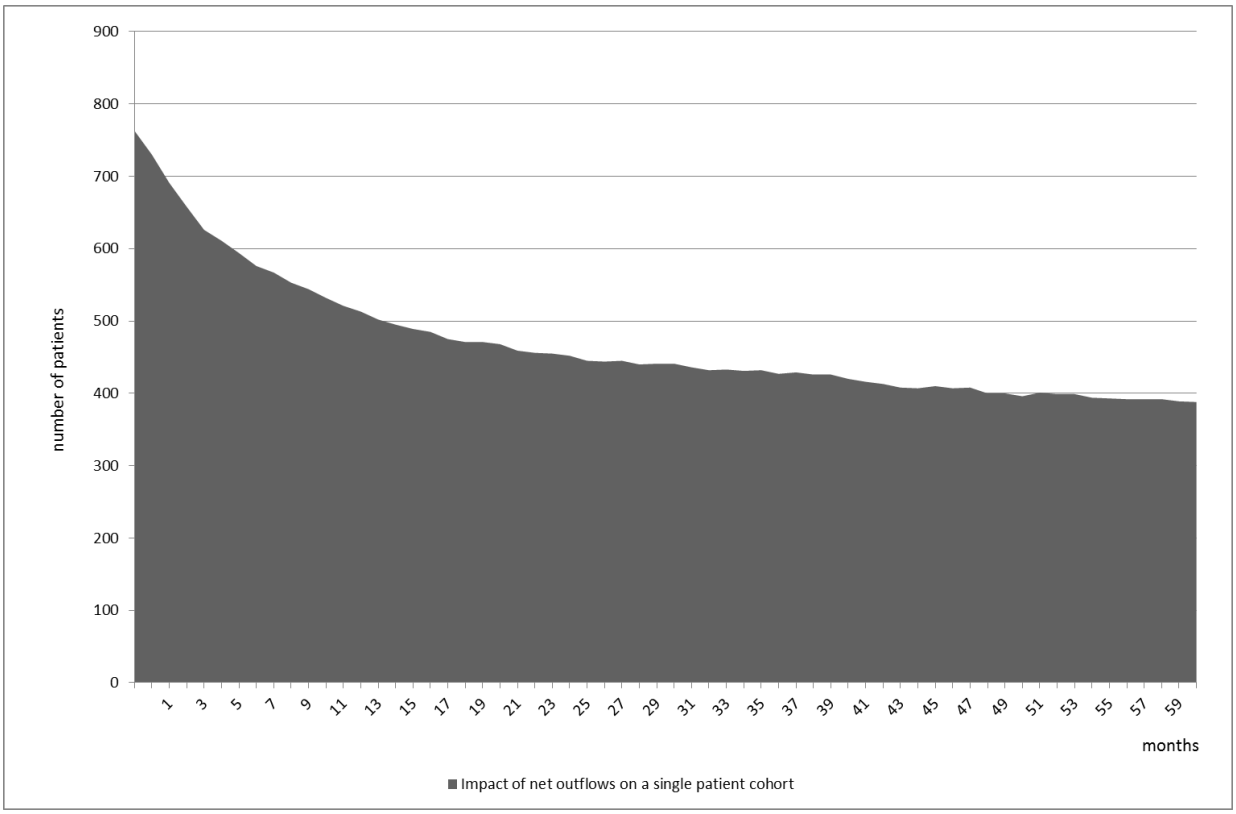
3181 In its reply to the Commission's Letter of Facts, Servier submitted a new study of patient switching in the United Kingdom prepared on 4 December 2013 by IMS Health (see ID10296, p. 2). Servier's economic consultants claims that this study would show that, after the first six months of the treatment, the number of patients taking perindopril decreases by around 20% per year from the second to the fifth year (see ID10324, p. 33-37).

This study cannot be accepted as reliable evidence. It was provided without the underlying data, specification and the information required for its independent replication. In a RFI of 7 February 2014 (see ID10314 and ID10315), the Commission asked for the missing information. In response, Servier only provided the IMS database along with the set of codes supposedly enabling to replicate the IMS results. Servier refused to supply the IMS study's specification alleging it was covered by legal professional privilege.

The supplementary information itself suffers from significant limitations: (a) there is no information predating 2003 which would allow to test IMS' assumptions that patients were newly treated with perindopril, and (b) the submitted code is incomplete and only allows for a partial replication of the IMS study, where the replication does not lead to the final results of the study.

Even leaving aside the manifestly incomplete nature of the IMS study, it does not disprove the finding that patients' perindopril treatments are usually long term. An annual decrease by 20% (or 80% of patients under treatment the year before would remain under treatment) would translate in an average treatment duration of four to five years. This compares to the duration of ”over five years” according to the Commission's own findings based on the survey of prescribers (see paragraph (2400)). The IMS data do not contradict the considerable "lock-in" effect with respect to the bulk of the perindopril sales (see section 6.5 for the full analysis).

Figure 12: Erosion of the perindopril patient base per month – a single cohort study



Source: The Commission's own calculation based on the CEGEDIM data (ID9977).

(2387) To sum up, the available longitudinal studies prepared by Thales show that the perindopril prescriptions were clearly dominated by renewals. The ratio of repeated prescriptions over the year was above 90%. This observation is confirmed by the CEGEDIM study which indicates the general stability of the perindopril patient base, in particular with respect to the patients who were treated for a longer period of time, e.g. four to five years.

6.4.5.6 Inertia of doctors

(2388) The lock-in effects can explain the stability of sales to the existing patient base but this mechanism cannot explain the general positive dynamics of sales shown by perindopril during the investigated period. In this context, it is interesting to note that the inertia of doctors in their prescribing habits can provide an additional mechanism which allows for the gradual building up of the patient base. If the doctors continue to prescribe a given medicine to new patients, those patients who successfully complete the trial period will become part of the stable patient base and will lead to an incremental increase in the total sales. The same is expected when there is an increase in the number of prescribers and/or the number of prescriptions written by them.

(2389) The longitudinal studies obtained by the Commission also include certain interesting information regarding the prescribing habits of French general practitioners. The study defines three groups of perindopril prescribers: big prescribers with over ten prescriptions, medium prescribers with six to ten prescriptions and small prescribers with one to five prescriptions in a given trimester.[3182] The comparison of

[3182] ID2663, p. 15.

prescription habits between trimesters running from April 2003 to June 2003 (T0) and from December 2003 to February 2004 (T2) shows that [80–90]* % of big prescribers from T0 remained in this category in T2. The respective ratios for medium prescribers and small prescribers were [50–60]* % and [60–70]* %. The same comparison also shows that in general, there was a high level of stability in the pool of doctors prescribing perindopril in France. Also, most of the moves between categories happened between neighbouring categories, e.g. from small prescribers to medium prescribers.[3183] This shows the gradual process by which doctors adapted their prescribing habits and supports the general point on the inertia of doctors. The importance of loyal prescribers for Servier can be illustrated with the percentage of all prescriptions written by them, which was close to 70% in both T0 and T2.[3184]

6.4.5.7 The survey of cardiologists, general practitioners and hospitals

(2390) For the purpose of the present investigation, the Commission carried out a survey of different types of prescribers known to use perindopril in the treatment of their hypertensive patients.[3185] The survey was addressed to three groups of respondents: cardiologists, general practitioners and hospitals in the four Member States selected for in-depth analysis, i.e. the UK, the Netherlands, France and Poland. Therefore, there were twelve subgroups of respondents. The purpose of the survey was to obtain evidence from practitioners on how they prescribed perindopril and other anti-hypertensive agents. The respondents were asked to reply according to their best knowledge and recollection of the facts for the period 2000 to 2009.

(2391) The present section provides a brief and generalised summary of the results. The detailed evidence from the survey can be found in *Annex D: Survey of prescribers*, where the results for each subgroup of respondents are provided.

(2392) Table 40 summarises the responses received by providing the average percentages from all the twelve subgroups of respondents.

3183 ID2663, p. 17.
3184 ID2662.
3185 See sections 6.2.4 and 6.3.2.

Table 40: Percentage ranges of replies received from individual respondent groups to the selected questions (reference period 2000 to 2009)

Reply: Respondent reported/considered…	Avg.(*)
perindopril to be a preferred first or second line treatment for essential (primary) hypertension	71%
perindopril to be a preferred first or second line treatment for chronic ischemic heart disease	64%
perindopril to be a preferred first or second line treatment for heart failure	68%
perindopril to be a preferred treatment because of its particular efficacy for certain categories of patients	80%
perindopril to be a preferred treatment because of fewer side effects for certain categories of patients	33%
that with respect to 81% to 100% of patients starting the perindopril therapy there was an equivalent treatment	51%
that the availability of generic perindopril had no significant impact on his/her prescriptions	85%
that the availability of a generic version of other medicine had no significant impact on his/her prescriptions of perindopril	77%
that with respect to patients successfully treated with perindopril during the initial period, from 0% to 24% of them were switched to a different treatment due to medical reasons related to the continuous/prolonged treatment with perindopril	81%
that with respect to patients successfully treated with perindopril during the initial period, he/she did not switch patients to another medicine for any other reasons than medical reasons or only switched a small minority, below 25%, for those other reasons	76%
that patients successfully treated with perindopril and not switched were likely to continue with the perindopril treatment for more than five years	74%
that patients successfully treated with perindopril and not switched were likely to continue with the perindopril treatment for more than ten years	47%

Source: The Commission's survey (ID7687 to ID7698).

Note: (*) – simple average of results from individual respondent groups.

(2393) In all respondent groups, the majority of respondents (on average 71%) considered perindopril to be a preferred first or second line treatment[3186] for essential (primary) hypertension. This result is consistent with Servier's own appreciation of perindopril's position. In the *2008/2009 Orientation Plan*, Servier noted that *"[i]n every country, Servier subsidiaries now agree that the most important market for Coversyl is hypertension. Most of the Coversyl sales are done in hypertension. Increasingly, Coversyl is really seen as a first-line therapy"*.[3187]

(2394) A significant number of prescribers regarded perindopril as a preferred first or second line treatment for chronic ischemic heart disease (on average 64%) and heart failure (on average 68%), the other two indications for which perindopril was principally prescribed.

(2395) In all respondent groups except the UK general practitioners, the respondents most often cited perindopril's particular efficacy rather than its fewer side effects as the reason for it being their preferred first or second line treatment.

[3186] First-line and second-line are terms of art meaning that a given medicine is considered early in the treatment process either as the first medicine that is administered for a given condition or as the second medicine in case another medicine fails to provide satisfactory therapeutic results.

[3187] ID0349, p. 822.

(2396) For patients who started perindopril therapy between 2000 and 2009, many respondents (on average 51%) considered other medicines as equivalent alternatives, at least for a significant proportion of patients (81% to 100%). Within the sample, the perception of the availability of initial alternatives for all or virtually all perindopril patients is only visibly lower among the hospital and general practitioners in Poland (27-28%).

(2397) For patients starting a therapy, the respondents were asked if they prescribed (i) less perindopril when a generic version of another medicine that was considered comparable to perindopril became available or (ii) more perindopril when a generic version of perindopril became available. The majority of respondents (on average 77% and 85%, respectively) considered that neither circumstance had any significant impact on their prescriptions.

(2398) In answer to the question regarding how many of the continued-use group of patients were switched to a different therapy for any medical reasons related to continuous treatment with perindopril, the majority of the respondents (on average 81%) selected the lowest percentage range, i.e. from 0% to 24%, as their reply.

(2399) Concerning switching for other reasons, including relative changes in prices and in perception (because of new information that became available on the relative safety or efficacy of the cardiovascular medicines), in all respondent groups except the Polish general practitioners, the majority of respondents (on average 76%) reported that they did not switch for such reasons or only switched a small minority, of less than 25%, of all patients.

(2400) Finally, the respondents were asked to select between different time ranges for the expected duration of non-switching period. In all the respondent groups, a significant number opted for ten and more years. Such respondents were in the majority among the UK and the Dutch hospitals, the UK and the Dutch cardiologists and the Dutch generalists. If the ranges of the expected durations of five to ten years and over ten years are combined, the clear majority of respondents (on average 74%) indicate that patients who were successfully treated with perindopril and not switched were likely to continue with perindopril treatment for more than five years.

(2401) In general, the Commission's survey is consistent with other facts contained in section 6.4. In particular, it reflects the choice of treatments available to the prescribers before they would decide to initiate the perindopril treatment[3188] and the positive perception of perindopril as an antihypertensive treatment. Importantly, once the perindopril treatment proved to be successful for a given patient, that patient was unlikely to be switched away to other treatments for a prolonged period of time.

6.5 Assessment of dominance on the product market

(2402) Traditionally the Commission assesses dominance in a two-step procedure. First it defines the relevant market in the light of existing constraints and then it assesses the market power/dominance enjoyed by the investigated undertaking. The relevant market will be established with respect to its product, geographic and temporal dimensions. The relevant market is assessed in section 6.5.1. Based on the findings

[3188] The existence of alternative treatments does not exclude or contradicts the presence of doctor's inertia mentioned in section 6.4.5.6. While the practitioners were certainly aware of initial therapeutic alternatives, as reflected in their responses to the survey, they were also consistent in their choices among those available alternatives, which is documented in the longitudinal studies.

with regard to the boundaries of the relevant market, the question of dominance will be subsequently addressed. The assessment of dominance on each of the relevant product and geographic markets will be carried out in section 6.5.2.

6.5.1 Relevant market

(2403) Based on the analysis contained in this section, the Commission has defined the relevant market as being limited to perindopril (originator and generic versions) supplied through retail channels in France, the UK, the Netherlands and Poland in the period 2000 to 2009. Before examining this in detail, it is useful to make the following introductory remarks.

(2404) The Commission's analysis relies among others on a series of natural events. The events relate to several products which were the closest potential competitors to Servier's perindopril[3189] and were subject to multi-fold price decreases in the course of the investigated period. None of the observed events, apart from the entry of generic perindopril, harmed the sales of Servier's perindopril.

(2405) The Commission's analysis shows not only that the natural events did not harm Servier's sales but also it explains for what reasons perindopril was that resistant. Among the relevant reasons, the analysis points at: (a) active product differentiation, (b) perindopril being an experience good, (c) presence of the lock-in effects with respect to the bulk of perindopril prescriptions, (d) presence of loyal prescribers, (e) general price insensitivity observed with respect to both the prescribers and the patients, and (f) the regulatory frameworks that shielded Servier's perindopril from price constraints from other molecules. Cumulatively all those elements enabled Servier to operate on the market for perindopril in a largely unconstrained manner.

(2406) The analysis takes into account the originator-generic context of the case and shows that there were no other potential competitors except the generics of perindopril that would be capable of constraining Servier's perindopril in the same way with respect to the core of its patient base.

(2407) The present section is composed of four subsections explaining respectively: the reasons for excluding the hospital distribution channel from the scope of analysis (section 6.5.1.1), the product dimension (section 6.5.1.2), the geographic dimension (section 6.5.1.3), and the temporal dimension of the relevant market (section 6.5.1.4).

6.5.1.1 Separation of retail and hospital distribution channels

(2408) The Commission is of the view that the markets for perindopril supplied through the retail (pharmacy) and hospital distribution channels should be viewed separately.

(2409) In paragraph 43, the Commission Notice on the definition of relevant market for the purposes of Community competition law[3190] (the Market Definition Notice) states that *"[t]he extent of the product market might be narrowed in the presence of distinct groups of customers. A distinct group of customers for the relevant product may constitute a narrower, distinct market when such a group could be subject to price discrimination"*.[3191]

3189 See section 6.3.4.1 and paragraph (2466).

3190 *Commission Notice on the definition of relevant market for the purposes of Community competition law*, point 7, OJ C 372, 9/12/1997.

3191 Market Definition Notice, point 11.

(2410) As demonstrated in section 6.3.2, the bulk of the perindopril sales took place outside the hospital distribution channel. Most of the annual observations, with respect to both the aggregated sales of perindopril and Servier's sales alone, in terms of both turnover and units sold, show that only a small fraction of the perindopril sales, namely a maximum of [0–5]* %, were achieved within the hospital distribution channel.

(2411) In addition, the cross comparison between Servier's sales in terms of quantities and values reveals that Servier often asked for substantially lower prices when supplying hospitals as compared to the prices it obtained in France, Poland and the UK when selling in the retail distribution channel. On these grounds, the Commission finds that in the above-mentioned Member States, Servier could and did adopt different conditions to the sales of perindopril in the retail and the hospital distribution channel. Moreover, in its replies to the Commission's requests for information, Servier had no difficulty distinguishing between the two channels of sales in any of the countries under scrutiny (see section 6.3.2), which proves that it was possible for Servier to identify clearly to which group an individual customer belonged at the moment of purchasing perindopril in each of those countries, including the Netherlands. Disregarding exceptional circumstances, the quantities purchased by hospitals at lower prices are not subject to subsequent resale.

(2412) With respect to all the investigated national markets, i.e. France, the Netherlands, Poland and the UK, the Commission holds the view that perindopril was predominantly distributed in the retail channel and that the limited sales taking place at hospitals could not affect in any appreciable manner the overall prices and volumes obtained in the retail sales, except for stimulating new treatments. The competitive constraints, if any, that could have prevented Servier or any other perindopril producer from behaving independently of effective competitive pressure with regard to the core sales (that were directed to the existing patient base) were unlikely to originate from the hospital distribution channel. Therefore the Commission will exclude the hospital distribution channel from the analysis of the relevant product and geographic markets for the purpose of the present case. However, Servier's ability to offer hospitals its product at prices that were substantially lower than those observed in the retail channel is in itself indicative of Servier's position in the retail segment. The subsequent analysis concentrates on the retail (pharmacy) channel, see section 6.5.1.2.

6.5.1.2 Relevant product market

(2413) In paragraph 2, the Market Definition Notice states that *"the main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings involved face"*. More specifically, the objective is *"to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings' behaviour and of preventing them from behaving independently of effective competitive pressure"*. The Market Definition Notice also states that *"demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a particular product, in particular in relation to their pricing decisions"*.[3192]

(2414) Second, the Market Definition Notice provides that an *"analysis of the product characteristics and its intended use allows the Commission, as a first step, to limit*

[3192] Market Definition Notice, point 13.

the field of investigation of possible substitutes"[3193] but that this is not sufficient to determine whether two products are demand substitutes. Moreover, the Market Definition Notice states that *"functional interchangeability or similarity of characteristics may not, in themselves, provide sufficient criteria, because the responsiveness of customers to relative price changes may be determined by other considerations as well"*.[3194] The type of evidence relevant to assess whether two products are demand substitutes includes *"evidence of substitution in the recent past". When this type of evidence is available "it will normally be fundamental for market definition"*.[3195] In defining the relevant product market, in the present case, the Commission relies, in respect of all relevant years and national markets, on such fundamental *"evidence of substitution"* in the form of the natural event analysis supported by the analysis of switching patterns.

(2415) In addition, the Market Definition Notice states that supply-side substitutability may also be taken into account when defining markets in those situations in which its effects are equivalent to those of demand substitution in terms of effectiveness and immediacy (i.e. that suppliers are able to switch production to the relevant products and market them in the short term without incurring significant additional costs or risks in response to small and permanent changes in relative prices).[3196]

(2416) According to settled case law, *"[…] the definition of the market in the relevant products must take account of the overall economic context, so as to be able to assess the actual economic power of the undertaking in question. […] it is necessary first to define the products which, although not capable of being substituted for other products, are sufficiently interchangeable with its products, not only in terms of the objective characteristics of those products, by virtue of which they are particularly suitable for satisfying constant needs, but also in terms of the competitive conditions and the structure of supply and demand on the market"*.[3197] The General Court has also stated that *"[…] for the purposes of applying Article [102] of the Treaty, the relevant product or service market includes products or services which are substitutable or sufficiently interchangeable with the product or service in question, not only in terms of their objective characteristics, by virtue of which they are particularly suitable for satisfying the constant needs of consumers, but also in terms of the conditions of competition and/or the structure of supply and demand on the market in question"*.[3198]

(2417) However, functional interchangeability and similarity in characteristics are insufficient to determine whether two products are demand substitutes, because the responsiveness of customers to changes in price is also determined by how customers value different characteristics. It must be recalled that the relevant market is not determined on the basis that certain products competed against each other in a broad

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3193 Market Definition Notice, point 36.

3194 Market Definition Notice, point 36.

3195 Market Definition Notice, point 38.

3196 OJ C 372, 9/12/1997, point 20.

3197 Judgment of 6 October 1994, *Tetra Pak v Commission*, T-83/91, ECR, EU:T:1994:246, paragraph 63.

3198 Judgment of 12 June 1997, *Tiercé Ladbroke v Commission*, T-504/93, ECR, EU:T:1997:84, paragraph 81. Similarly, ECJ, in Judgment in *L'Oréal v De Nieuwe AMCK*, C-31/80, EU:C:1980:289, paragraph 25; in Judgment in Michelin v Commission, C-322/81, EU:C:1983:313, paragraph 37, in Judgment in *AKZO v Commission*, C-62/86, EU:C:1991:286, paragraph 51; General Court in Judgment of 12 December 1991, *Hilti v Commission*, T-30/89, ECR, EU:T:1991:70, paragraph 64; and in Judgment of 6 October 1994, *Tetra Pak v Commission*, T-83/91, ECR, EU:T:1994:246, paragraph 63.

sense but on the basis of whether such products were sufficiently substitutable to significantly constrain each other's market power, in particular as regards pricing. Moreover, a properly defined market does not need to include all functionally interchangeable products, as such interchangeability between products normally only defines the outer boundaries of a product market but may not be a decisive criterion. When products such as pharmaceutical products can be broadly used for the same purpose but differ in terms of price, quality, consumer preferences or other significant attributes, the products are considered to be differentiated. Although differentiated products may "compete" in some dimensions, a relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking's behaviour and of preventing it from behaving independently of an effective competitive pressure.[3199]

(2418) Therefore, a comprehensive analysis of the demand side possibility of substitution has to take into account the economic context, including the objective characteristics of the product and the degree of inter-changeability between the products according to consumer preferences, as measured by changes in consumption patterns in response to price changes and changes in other market conditions.

(2419) However, the list of relevant elements is neither pre-set, nor exhaustive, nor is every element mentioned in the case law necessarily mandatory in every case. Each case will depend on its own facts, and it is necessary to examine the particular circumstances in order to establish whether the investigated product competes with others and to what extent the latter exert a significant competitive constraint on the former, and consequently on the conduct of its producer.

(2420) As explained above for the purpose of assessing dominance traditionally it is first required to define the relevant market. The overall assessment relies on a number of elements including: the product characteristics and intended use (section 6.5.1.2.2.), the natural events that occurred in the course of the investigated period (section 6.5.1.2.3.), the switching patterns (section 6.5.1.2.4.), other factors including the regulatory framework (section 6.5.1.2.5.2) and the strength of generic constraint (section 6.5.1.2.6.). Before the aforementioned sections, Servier's main arguments received in response to the Statement of Objection are summarised.

6.5.1.2.1 Summary of Servier's main arguments

(2421) In its reply to the Statement of Objections, Servier contests the Commission's relevant product market, comprising the original and generic versions of perindopril, as being defined too narrowly. According to Servier, the relevant product market for perindopril also consisted of sartans and, as a strict minimum, of all other ACE inhibitors. On the market for all ACE inhibitors, perindopril accounted for less than 20% of the total volumes sold during the investigated period in each of the four Member States analysed by the Commission. The share of perindopril was even lower on other national markets, such as Italy, Spain and Germany. Cross-border differences in the level of the perindopril sales are argued to imply that perindopril did not have any particular characteristics that would have made it a superior or unique product as compared to other ACE inhibitors. Servier contends that ACE inhibitors were interchangeable on the basis of a class effect.[3200]

3199 OJ C 372, 9/12/1997, point 3.

3200 Servier's reply to the Statement of Objections, paragraphs 1444-1448, ID10114, p. 441-443.

(2422) Regarding the therapeutic substitutability, Servier argues that sartans had the same indications as ACE inhibitors. The latter were recommended by the health authorities in France and in the UK because of their low cost. Servier maintains that it was particularly exposed to competitive pressures from sartans because it did not have any sartan in its product portfolio.[3201]

(2423) Servier insists that perindopril did not distinguish itself in any aspect from other ACE inhibitors. The class effect was recognised by both the authorities issuing the medical guidance and the medical practitioners. Moreover, Servier points out that for the purpose of its past merger decisions, the Commission used to define the class-wide relevant markets comprising all ACE inhibitors.[3202]

(2424) Servier considers that ramipril was the most serious competitor to perindopril. In its claim, Servier among others relies on the facts that (i) Sanofi Aventis, ramipril's original manufacturer ranked perindopril as the closest rival to ramipril and that (ii) Sanofi Aventis' perception was reciprocated by Servier as reflected in Servier's internal documents. Servier argues that perindopril was a "follower" product in relation to ramipril which in turn was a leading ACE inhibitor in terms of not only sales but also available medical evidence.[3203]

(2425) Servier argues that the existing studies did not prove the unique character of perindopril. Other ACE inhibitors were also subject to extensive studies. Notably, the HOPE study concerning ramipril published in 2000 became a reference study in the domain of hypertension treatments.[3204]

(2426) Servier disagrees with the Commission's finding that the regulatory frameworks reinforced the rigidity of the demand for perindopril. Servier argues that the substitutability among ACE inhibitors was generally acknowledged by the healthcare authorities in the way those authorities fixed the prices of medicines. In France, the Transparency Commission compared perindopril to other ACE inhibitors and recognised the existence of therapeutic alternatives to perindopril. In the Netherlands, perindopril was grouped with other ACE inhibitors for the purpose of defining the amount of a reimbursement ceiling. In Poland, Servier points out that at this moment all ACE inhibitors are grouped in the same reference group for reimbursement. In the UK, a number of the PCTs recommended the general practitioners to limit the use of perindopril and instead to favour other cheaper ACE inhibitors.[3205]

(2427) Servier insists that the substitutability of ACE inhibitors was generally recognised by the prescribers. Despite Servier's criticism of the methodology applied in the Commission's survey of perindopril prescribers, Servier considers that the survey's results show that perindopril was not only in competition with other medicines but it was used less frequently than its alternatives. Among alternative treatments the respondents cited other ACE inhibitors, notably ramipril, lisinopril, enalapril and captopril, and sartans. Servier also points out that the Commission's survey confirms

3201 Servier's reply to the Statement of Objections, paragraphs 1468-1480, ID10114, p. 448-452.

3202 Servier's reply to the Statement of Objections, paragraphs 1482-1497, ID10114, p. 453-459.

3203 Servier's reply to the Statement of Objections, paragraphs 1498-1515, ID10114, p. 459-465.

3204 Servier's reply to the Statement of Objections, paragraphs 1516-1524, ID10114, p. 465-466.

3205 Servier's reply to the Statement of Objections, paragraphs 1525-1540, ID10114, p. 466-473 and Servier's reply to the Letter of Facts, paragraph 131, ID10324, p. 41-42.

that the prescribers did not generally take into account prices in their prescription decisions.[3206]

(2428) Servier argues that the Statement of Objections ignored the specific economic context of the market for prescription medicines. The competitive game mainly takes place at the time the prescriber decides on changes in the treatment for medical reasons and not at the moment of periodical renewals. Once the choice of the treatment is made, it is valid for the entire treatment period until it has to be changed again for medical reasons. Servier compares the pharmaceutical market to markets operating on the basis of a framework contract. As to the length of the perindopril treatment, Servier relies on the CEGEDIM study to argue that over half of the patients treated with perindopril stopped the treatment before the elapse of five years. Servier also argues that the switches out of the perindopril treatment were much more frequent than the Statement of Objections suggested.[3207]

(2429) Servier considers that the standard economic analysis is not applicable to the pharmaceutical markets. It refers to the fact that the suppliers cannot freely set their prices and the patients, as the final consumers, are usually not directly charged nor are responsible for choosing the treatment. Servier among others refers to the General Court's decision in the AstraZeneca case[3208] to argue that the relevant market cannot be defined solely on the basis of the price factors analysis. Since in Servier's view the prices should not be decisive, Servier discards the Commission's econometric model presented in the Statement of Objections as leading to the obvious conclusion that the onset of generic competition had significant negative effects on Servier's sales.[3209]

(2430) According to Servier, the Commission should not have analysed the price factors. Instead the Commission should have looked at the respective promotional efforts of different pharmaceutical companies in order to understand the market dynamics. Servier's stable investment in promotion allowed for counterbalancing the impact of the studies sponsored by the competitors. The comparison of the promotional efforts of Servier and its competitors shows the equivalent levels of expenditure.[3210]

(2431) The Commission's reactions to the above arguments advanced by Servier are included in the relevant parts of the Commission's analysis presented below. As far as Servier's arguments rely on new information, notably the CEGEDIM study, the required additions and changes have been also incorporated in the factual parts of the present decision (see section 6.4.5.5).

6.5.1.2.2 Product characteristics and intended use

(2432) This section will assess a number of the facts relating to perindopril's characteristics and intended use, including its place in the medical classification, its main indication, the information flowing from the relevant medical guidelines and medical trials and studies as well as Servier's positioning efforts based on the existing evidence. It will also draw on the views collected by the Commission from the perindopril prescribers as well as the potential competitors short-listed by Servier.

3206 Servier's reply to the Statement of Objections, paragraphs 1541-1555, ID10114, p. 473-477.

3207 Servier's reply to the Statement of Objections, paragraphs 1556-1574, ID10114, p. 477-482.

3208 Judgment of 1 July 2010 *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 187.

3209 Servier's reply to the Statement of Objections, paragraphs 1579-1590, ID10114, p. 483-487.

3210 Servier's reply to the Statement of Objections, paragraphs 1591-1594, ID10114, p. 487-488.

(2433) At the outset, it must be recalled that perindopril is a medicine used for hypertension, which is recognised as the most frequent chronic condition in human population. After a successful initial trial period, hypertensive medicines, including perindopril, tend to remain in continued use for prolonged periods of time. The long expected duration of the perindopril treatment was confirmed by the Commission's survey of prescribers and Servier's internal documents.[3211] Based on the existing evidence, the average length of the perindopril treatment can be estimated at seven to eight years.[3212]

(2434) Given that *"adverse events are the most important cause of non-compliance"*,[3213] hypertension medicines clearly fall within a category of products for which the exact information concerning the qualities of a product tends to be acquired through consumption. Economic literature has classified this kind of products as experience goods. When only imperfect information about the characteristics of a product can be obtained before the actual purchase, the product that is in use has an information advantage in the sense that its consumer knows more about it than about other products that have not been tried. Such a consumer is typically inclined to continue using the product for which the valuation (here: efficacy and side effects) is known rather than switching to another product for which the respective valuation remains uncertain. The said information advantage will reduce the willingness to substitute so that, as a result, other products may face difficulties in inducing switching away from the 'experience good' (here: the successful therapy) through price reductions.

(2435) The 'experience good' nature combined with the prolonged treatment time lead to the situation in which a medicine that becomes established first for a specific patient may have a significant advantage over later entrants or over other medicines that seek to re-launch or reposition themselves as a more effective product.[3214]

(2436) There are two categories of patients that can be defined for the sake of the present analysis: the first-time use patients and the continued-use patients. The first-time use patients were prescribed perindopril in the course of a trial process aimed at identifying the most suitable drug. A first-time use patient who was prescribed perindopril matched (i) a basic profile for which the use of ACE inhibitors was advocated in the medical guidelines (or in the relevant studies) and (ii) other conditions such as previous experience of a prescriber with respect to perindopril (e.g. successful treatments of other patients). However, at that moment, there was no certainty that the patient's blood pressure would be adequately controlled and that side effects would not occur. The period of uncertainty as to the results of the treatment constituted the trial period for the tested medicine. If the perindopril treatment proved to deliver the expected results with a minimum of side effects, the patient could continue with the treatment for a prolonged period of time without a medical need to switch, unless later complications emerged. This group of patients is referred to as continued-use patients. Those patients and their doctors had acquired

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3211 See section 6.2.4 on place and duration of treatment. For perindopril specific data, see section 6.4.5.7 on the survey of cardiologists, general practitioners and hospitals.

3212 See paragraph (2154).

3213 See paragraph (2150).

3214 This process also explains why the same medicine may achieve distinctively different levels of sales on different geographic markets, where the pre-existing experience may differ due to country-specific idiosyncrasies, such as the market presence of a given company, the strength of local sales forces and the related intensiveness of promotional efforts in the early stages directly following the product's launch, which are subsequently reinforced by the lock-in effects and the doctors' inertia.

through the trial period the knowledge as to the exact effects of perindopril on the patients and hence knew that perindopril met their medical needs. The knowledge factor is essential to understand the difference between the two categories of patients. The first-time use patients and their prescribers had to rely on the generally available information like the medical guidelines, the available studies, and the information package provided by the producer. With regard to the continued use patients, there was less need for external information since the first-hand experience as to the therapeutic effects of the medication was available. Obviously, this distinction is only possible in relation to the long-term treatments, in particular with respect to medicines like perindopril. The remaining analysis in this section mainly focuses on the product characteristics relevant for the first-time use patients as opposed to the continued-use patients with respect to whom the established treatment benefits from the information advantage.

(2437) In section 6.2.8, the Commission explained the basic structure of the Anatomical Therapeutical Chemical (ATC) classification system.[3215] There are four main classes of medicines generally considered for the treatment of hypertension at the ATC2 level: C03 – diuretics, C07 – beta blocking agents, C08 – calcium channel blockers and C09 – agents acting on the rennin-angiotensin system. Although the medicines belonging to these four classes have distinctively different modes of actions, they all are intended to lower blood pressure and are recognised as suitable for the antihypertensive treatment. Within the C09 group, there are two important subgroups: C9A/C9B – ACE inhibitors (plain and combinations) and C9C/C9D – angiotensin II antagonists (plain and combinations). Perindopril is one of sixteen plain ACE inhibitors. All of ACE inhibitors share the basic mode of action, i.e. they block angiotensin converting enzyme (ACE) and hence reduce the amount of angiotensin II in the plasma, which in turn relaxes the blood vessels.

(2438) In the view of the Commission, the medical classification provides the broadest possible universe in which potential substitutes may be present. The universe comprising the four above-mentioned ATC2 groups is vast and accounts for over 100 plain medicines. The number of products is further increased by numerous fixed combinations that also appear in the classification. Perindopril shares its basic mode of action with fifteen other ACE inhibitors.

3215 In its merger practice, the Commission has so far strongly relied on the Anatomical Therapeutic Chemical Classification ("ATC") devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS"). The third level of the ATC classification, referred to as ATC3, has been generally taken as the starting point for the product market definition in merger investigations. However, the Commission also stated that it might be appropriate to carry out analyses also at other levels, for example at ATC4 or molecule (based on the same main API) level, or across classes, if specific circumstances indicate that the ATC3 level is not the most appropriate for the purposes of the market definition (see: Decision of 02/11/2010 in case COMP/M.5661 – Abbott/Solvay Pharmaceuticals, para. 8-9.). In its *AstraZeneca* judgment, the General Court recognised that *"the taking into account of the ATC level in which the medicines are placed constituted only a preliminary step in the Commission's analysis"*. See: Judgment of 1 July 2010 *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraphs 154-155. The same approach is adopted in the present decision, i.e. the ATC classification has been taken into account for the initial selection of candidate products. The ATC classification has been helpful in directing the inter-class analysis between the ATC3 classes (see paragraph (2458) for conclusions in this regard). However, for the purpose of the present Decision, the Commission has also taken into account the case-specific evidence relating to the relative strength of the intra-class constraints faced by perindopril from other ACE inhibitors. As a matter of principle, if constraints from other products are gauged insufficient, those other products cannot belong to the same relevant market.

(2439) In sections 6.2.2 and 6.3.3, the Commission summarised the information relating to the main indications for which perindopril and its potential competitors were being prescribed during the investigated period. It was established that the assessment should be primarily focused on the treatment of hypertension. In view of the fact that hypertension remains the largest source of revenue for the entire pharmaceutical industry with several classes of medicines being used for the treatment, the Commission does not regard this specific indication as a differentiating factor.[3216]

(2440) In section 6.2.9, the Commission reviewed several medical guidelines for management of hypertension published in the period 1999 to 2007. The review was subject to the important caveat stating that the best practice as described in the medical guidelines deals with medical conditions in general, while the management of individual patients must be tailored to patients' specific profiles. The European guidelines state that *"thiazide diuretics (as well as chlorthalidone and indapamide), b-blockers, calcium antagonists, ACE inhibitors and angiotensin receptor antagonists can adequately lower blood pressure and significantly and importantly reduce cardiovascular outcomes"*. This statement (along with similar statements from other available guidelines) acknowledges that various medicines may be used to treat hypertension. However, the European guidelines also state that *"**drug classes (and even compounds within a given class) differ** in type and frequency of adverse effects they may induce, and different individuals may be differently prone to develop a given adverse effect. Furthermore, drugs may have different effects on risk factors, organ damage and cause-specific events and show specific protective influences in special groups of patients. **This makes selection of a given agent alone or in association with other drugs mandatory or advisable** according to the circumstances (emphasis added)"*. This shows that hypertension medicines are heterogeneous and the choice of a medicine will depend on the individual patient's reactions. This being said, the degree of heterogeneity varies. In general, it can be assumed to be greater across the classes than within the same class.

(2441) The medical guidelines reviewed in section 6.2.9 point to another important characteristic of the competitive environment in which perindopril was marketed: the co-prescription of antihypertensive agents. Co-prescriptions are said to be a dominant feature in the treatment of hypertension because mono-therapies are unlikely to achieve target blood pressure in the majority of patients. The medical guidelines recommended the use of combinations. The international (WHO-ISH), European and British guidelines specifically recommended the use of ACE inhibitors with diuretics (e.g. hydrochlorothiazide, indapamide) and calcium channel blockers (e.g.

[3216] With respect to the therapeutic use, the General Court stated in its *AstraZeneca* judgment (see Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 71) that the fact that two types of medicines were prescribed to treat the same conditions or constituted first-line treatments is of limited relevance in the cases in which this fact does not make it possible to determine whether the analysed product is subject to a significant competitive constraint. In the AstraZeneca case, one important element was the fact that the product in question was used to treat more severe forms of the relevant medical conditions than the allegedly competing product that the Applicants claimed to be a part of the same relevant market and was used differently from those allegedly competing products. In the Commission's view, there are also other factors that may relieve, in a similar way, a pharmaceutical product from competitive constraints even despite the presence of multiple medicines prescribed for the same condition. The nature of such other factors is a factual and case-specific question. It may be answered only after careful consideration of all relevant information about the product that is being analysed, e.g. the level of complementarities between the product in question and other products, the extent of lock-in effects enjoyed by the product in question, the exposure to price constraints, etc.

amlodipine). This means that the co-prescribed products were no longer potential substitutes but became complementary. This changes the nature of the competitive interaction, because the success of other product is no longer regarded as a threat, but rather as an opportunity. The first recommendation to use combination treatments, made in the 1999 WHO-ISH guidelines, predates the period relevant for the present assessment.

(2442) It should be noted that the general tendency towards multi-agent treatments is also confirmed with respect to perindopril. As shown in section 6.4.5.4, almost 70% of the perindopril prescriptions in France and over 60% of the ACE inhibitor prescriptions in the UK were in multi-therapies by the mid 2000s. The earliest available longitudinal studies of French general practitioners and cardiologists show that a majority of perindopril prescriptions were already in multi-therapies in the years 2000-2001. The same studies indicate that perindopril was most often co-prescribed with diuretics, beta-blockers and calcium channel blockers.[3217] There is no reason to doubt that the prevalence of multi-therapies differed to any large extent in other European countries.[3218] From 2005, Servier profited from the ASCOT study,[3219] thanks to which it acquired scientific evidence that 70% of patients treated with amlodipine in that study were also in need of Servier's perindopril because amlodipine alone could not achieve blood pressure control. For most of the approximately 19,000 patients involved in the study the desired effects could be achieved by combining the two medicines.[3220] Servier's own survey of physicians showed that most of the co-prescriptions involving perindopril as one of the molecules were likely to include either amlodipine or indapamide as a second molecule.[3221] In response to the demand for those two combinations, Servier introduced its fixed combination products of perindopril-indapamide and perindopril-amlodipine.[3222] Pfizer, the original producer of amlodipine, confirmed that perindopril and amlodipine should be regarded as mutual complements and not substitutes.[3223]

(2443) In view of the foregoing, the Commission considers it implausible that diuretics, in particular hydrochlorothiazide and indapamide, and calcium channel blockers, in particular amlodipine, could be the source of a significant competitive constraint for the marketing of perindopril.

(2444) Not all classes of medicines showed complementarities and therefore their combined use was not recommended by the medical guidelines. There was no evidence

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3217 See paragraph (2373).

3218 In all the investigated Member States, the available medical guidelines encouraged prescribing combination treatments to help the practitioners faced with the question how to effectively decrease blood pressure. It cannot be reasonably expected that the efficacy of mono-therapies in one Member State would significantly differ from the low average indicated in the European guidelines (see paragraph (2185)). The European guidelines, which strongly recommended the use of combination therapies, were endorsed among others in the Netherlands and Poland (see paragraph (2188)). The fact that Servier launched its fixed combination products in all the four Member States concerned by this analysis (see Table 16) further illustrates the general need for combination treatments.

3219 The ASCOT study was carried out in the Nordic countries, the UK and Ireland. See: Lancet 2005; 366: 895-906.

3220 See paragraphs (2211) and (2231).

3221 See paragraphs (2376) and (2377).

3222 See section 6.3.1.

3223 See paragraph (2262).

supporting the use of ACE inhibitors with ARBs (sartans).[3224] During the investigated period, ARBs (sartans) were presented in the WHO-ISH and BHS/NICE medical guidelines as an alternative to ACE inhibitors for patients suffering from the ACE inhibitors induced cough. The guidelines recommended the initiation on ACE inhibitors first because of their lower cost as compared to sartans.[3225] Results from such large studies as ONTARGET and TRANSCEND published towards the end of the investigated period, in 2008, did not change the relative position of ARBs and ACE inhibitors.[3226]

(2445) In section 6.2.10, the Commission provided an overview of Servier's efforts to differentiate perindopril from other products. The Commission considers that Servier's statements with regard to the benefits of perindopril are worthy of consideration. Servier disagrees and attempts to diminish the evidentiary value of its own promotional statements.[3227] However, the Commission notes that Servier's promotional efforts were persistent throughout the investigated period which can be only explained by their relative effectiveness.[3228] Otherwise Servier's behaviour would have to be considered economically irrational. Moreover, the Commission notes that the supply of information to practitioners is a regulated activity, where the pharmaceutical companies are obliged to supply information which is accurate, up-to-date, verifiable, sufficiently precise, complete and consistent with the SmPC to enable practitioners to form their own opinion of the therapeutic value of the medicine.[3229]

(2446) Already in the early 2000s, perindopril was recognised for the fact that its *"ability to lower blood pressure is comparable to or better than that of other antihypertensive agents, both of its own class and other classes".*[3230] Its position was strengthened by the findings relating to first dose hypotension, where perindopril was found to cause *"an initial acute BP depression […] less frequently […] than […] other ACE inhibitors"*.[3231]

(2447) In the course of the 2000s, the results of subsequent trials and studies were published. In 2001, the PROGRESS study showed that the perindopril based treatment reduced the risk of stroke. In 2003, the EUROPA study showed that perindopril should be considered in all patients with coronary heart disease. In 2005, the ASCOT study showed that perindopril could be successfully combined with amlodipine and the two were a better combination than atenolol (a beta blocker) and bendroflumethiazide (a thiazide diuretic).[3232] In 2006, the PREAMI study showed

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3224 E.g. the ONTARGET study showed that the combination of telmisartan and ramipril was associated with more adverse events without an increase in benefit. N Engl J Med 358; 15, p. 1547-59.

3225 See sections 6.2.9.1 and 6.2.9.3.

3226 See section 6.2.10.5.

3227 Servier's reply to the Statement of Objections, paragraph 1489, ID10114, p. 456. In this context, it must also be noted that from the perspective of competition analysis, it is more important how Servier communicated the outcomes of perindopril studies to the medical practitioners during the investigated period than Servier's current interpretation of those studies submitted for the purpose of Servier's defence in the present case.

3228 Servier's internal documents reflect the gradual improvement of perindopril's position both in terms of a growing number of loyal perindopril prescribers (see paragraph (2389)) and of its perception as a first-line therapy (see paragraph (2393)).

3229 See paragraph (2140).

3230 See paragraph (2206).

3231 See paragraph (2206).

3232 The results were further confirmed by the CAFÉ study.

that perindopril should be considered as a standard treatment for elderly patients with acute myocardial infarction and preserved left ventricular function. In 2007, the ADVANCE study showed that the combination of perindopril and indapamide reduced the risks of major vascular events for patients with type two diabetes. In 2008, the HYVET study showed that indapamide with perindopril added if necessary to achieve the target blood pressure, was beneficial for elderly patients.[3233] Other publications confirmed that ACE inhibitors should not be regarded as a homogenous class. For example, it was found that ACE inhibitors differed in mortality rates in patients 65 years of age or older after an acute myocardial infarction (heart attack) with lower rates observed among the patients taking ramipril and perindopril.[3234]

(2448) Based on the above mentioned studies, Servier stated in its strategy papers that *"Coversyl is a first-choice ACE inhibitor", "has excellent hemodynamic tolerance and thus minimizes the risk of hypotension episodes, compared with other ACE inhibitors",* has properties that *"are not shared by any other antihypertensive"* and that thanks to ASCOT, Servier's perindopril had a *"definitive clinical proof of Coversyl's superiority to other ACE inhibitors and other antihypertensive agents, at least in terms of cardiovascular protection in hypertension with risk factors"*. Along with the growing scientific evidence listed in the above paragraph, Servier also stated that *"no other antihypertensive or ACE inhibitor can compare with Coversyl"* and *"[a]mong ACE inhibitors, Coversyl has the most complete evidence for benefits along the cardiovascular disease continuum"*.[3235]

(2449) Having regard to the foregoing and contrary to Servier's counterclaims,[3236] the Commission notes that perindopril was recognised for certain characteristics that distinguished it from other ACE inhibitors despite the fact that they all shared the same basic mode of action.[3237] This evidence shows that ACE inhibitors should not be regarded as a simple homogenous class. This finding is in agreement with the European guidelines which recognize that compounds within a given class may differ. The presence of distinctive features that are favourable for certain patients, if only because they are sufficiently recognised by prescribers, is indisputably a factor suggesting, other things being equal, lesser competitive constraints than in the situation of a product facing perfect substitutes, such as the generic versions of the product concerned. The process of differentiation may also rely on differences in the availability of direct evidence with respect to a given medicine. The finding of intra-

3233 For the more detailed overview of the listed studies, see section 6.2.10.2.

3234 See footnote 2928.

3235 For the complete citations, see sections 6.2.10.3 and 6.2.10.5.

3236 Servier claims that *"*Perindopril is indistinguishable from other ACE inhibitors"* (see Servier's reply to the Statement of Objections, paragraph 1483, ID10114, p. 453 and Servier's reply to the Letter of Facts, paragraph 127, ID10324, p. 41). In addition to the evidence to the contrary (see paragraph (2446)-(2448)) Servier's present position cannot be reconciled with its own promotional activities during the investigated period. Any rational economic undertaking will invest in promotion only if it can expect to appropriate, to a sufficient degree, the results of its promotional efforts, which is only possible if that undertaking is in a position to differentiate its promoted good from other goods. As shown in Table 34, Servier consistently kept high promotional outlays with respect to perindopril throughout the investigated period. Servier's economic advisors recognise, even if in an attempt to belittle, the fact that differentiation within the ACE inhibitors class was exploited in Servier's commercial strategy (see CRA's report annexed to Servier's reply to the Statement of Objections, paragraph 29, ID9054, p. 15).

3237 In layman's terms, the same basic mode of action can be reproduced with the use of several chemical compounds, but the existing differences between these compounds can lead to different effectiveness and be responsible for more or less favourable pathways of action, e.g. in terms of hemodynamic tolerance.

class heterogeneity is not in conflict with the existence of certain class effects, where other medicines from the same class may share several characteristics and may be positioned relatively closer to each other as compared to other medicines present in the product space.

(2450) It must be noted that the degree of recognition given to the specific characteristics of perindopril by prescribers was not fully satisfactory for Servier, which in its internal documents on several occasions pointed out that *"Coversyl's specific mode of action and efficacy have still not been sufficiently differentiated from other ACE inhibitors"*[3238] and *"differentiation between Coversyl and Ramipril still needs to be emphasized"*.[3239] The Commission notes that Servier's intention was to clearly establish the supremacy of its product over the medicines that were relatively the most proximate in terms of their mode of action and hence their medical use in the treatment of hypertensive patients. That being said, differentiation is a question of degree. Any rational economic undertaking operating in the sector of differentiated goods wants to position its product in the way that allows for maximizing its profits. It is also natural that a rational undertaking will compare its own performance with that of other undertakings. In its reply to the Statement of Objections, Servier provides a selection of quotes in which the sales of Servier's perindopril are set against other medicines.[3240] However, the quotes do not contain any advanced economic analysis carried out with an aim to define for antitrust analysis purposes the relevant market for perindopril.[3241]

(2451) In section 6.4.5.7, the Commission summarised the results of the survey of cardiologists, general practitioners and hospitals which was carried out in the selected Member States, i.e. France, the Netherlands, the UK and Poland.[3242] The Commission's questionnaires also included the qualitative questions intended to verify the perception of perindopril from the perspective of prescribers. Those questions covered the following topics: (i) the recognition of perindopril as a preferred first or second line treatment for the main medical conditions, (ii) the main reasons for considering perindopril to be a preferred treatment and (iii) the degree to which equivalent treatments were considered for patients starting the perindopril therapy.

(2452) In all respondent groups, the majority of respondents (on average 71%) considered perindopril to be a preferred first or second line treatment for essential (primary) hypertension. This result is consistent with Servier's own appreciation of perindopril's position.[3243] The answers to the twin questions asked with respect to chronic ischemic heart disease and heart failure, the other two indications for which perindopril was principally prescribed, also show that a significant part of prescribers (on average 64% and 68%, respectively) regarded perindopril as a preferred first or second line treatment for those other conditions.

(2453) In the view of the Commission, both the wide-spread recognition of perindopril as a preferred first or second line treatment in its main indications and the conviction on

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3238 See paragraph (2225).

3239 See paragraph (2227).

3240 Annex 11-01 to Servier's reply to the Statement of Objections, ID9064, p. 1-61.

3241 See also footnote 3251 for the distinction between the notions of primary competitive focus and of a significant competitive constraint.

3242 For more detailed results, see *Annex D: Survey of prescribers*.

3243 See paragraph (2393).

the part of a number of responding prescribers about perindopril's particular efficacy confirm that Servier's perindopril was in a good position to be included in the initial trial period or to be added to the existing therapies and eventually to achieve the status of the continued use treatment for the growing number of hypertensive patients.

(2454) That said, the survey also points to the fact that with respect to patients who were starting the perindopril therapy between 2000 and 2009, the responding prescribers considered other medicines as equivalent alternatives at least for a significant proportion of perindopril patients. Judging by the number of respondents (on average 51%) who perceived the broadest choice of alternatives for the first-time treatments, i.e. who considered that with respect to 81% to 100% of patients starting the perindopril therapy there was an equivalent treatment, the perception of alternatives was widespread. Within the sample, the perception of the availability of initial alternatives for all or virtually all perindopril patients is only visibly lower among the hospital and general practitioners in Poland. Despite the idiosyncrasy detected in Poland, the Commission's survey reflects the character of the initial selection process described in the medical guidelines. In this regard, it is also important to note that among the equivalents for starting treatments, the respondents most often included another ACE inhibitor. In France, the UK and Poland, the respondents most frequently indicated ramipril as a potential alternative for starting treatments, while in the Netherlands it appears that enalapril and lisinopril were regarded as more likely alternatives.[3244] These results are not surprising in view of the remaining evidence analysed in this section. The reported ACE inhibitors are in all likelihood the closest alternatives to perindopril in terms of their therapeutic use. However, the results discussed here should be also interpreted in conjunction with other parts of the survey, in particular the information relating to the continued use of perindopril which will be analysed in the next section.

(2455) In section 6.3.4.2, the Commission summarised the views collected from the alleged competitors among the originator companies.[3245] Those competitors were selected on the basis of the ranking of the top five products competing with perindopril as submitted by Servier.[3246] The selected medicines were all leading products that belong to the following classes of hypertension medicines: the plain ACE inhibitors class (enalapril, lisinopril and ramipril), the plain angiotensin II antagonists class

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3244 In its reply to the Statement of Objections, Servier relies on the fact that certain number of the respondents also indicated sartans as potential alternatives for starting treatments to argue that sartans were equivalent to ACE inhibitors (see Servier's reply to the Statement of Objections, paragraph 1471, ID10114, p. 449). In this regard, it must be recalled that the part of the Commission's survey, on which Servier relies, concerned the initial choice of treatments and that other ACE inhibitors were cited more often among potentially alternative treatments. Regarding sartans, Servier also argues that the ONTARGET study demonstrated the equivalence between sartans and ACE inhibitors. The Commission notes that this claim is contradicted by the contemporaneous evidence, as quoted in paragraph (2230) of this decision.

3245 For the avoidance of doubt, any subjective views collected from the investigated or third parties are of secondary probative value in relation to hard evidence relating to the actual use and demand for the product concerned. Given that market definition is essentially an objective exercise, established objective facts (in particular, evidence of reactions to changes in relative prices) will normally prevail over subjective perceptions of developments.

3246 For the sake of completeness, it must be noted that apart from providing the "top five" ranking, Servier claimed to consider a higher number of hypertensive medicines (than the requested five) as reference points for its marketing and pricing policy for Coversyl (ID1151, p. 2-3).

(losartan, valsartan and irbesartan), the combination angiotensin II antagonists class (valsartan+hctz) and the calcium channel blockers class (amlodipine).[3247]

(2456) It can be concluded that the producers of non-ACE inhibitors generally did not consider themselves as immediate competitors to Servier's perindopril.[3248] As regards the producers of other ACE inhibitors, they differ in their perception of the external environment in which various ACE inhibitors were marketed. Notably, Sanofi-Aventis, whose ramipril is the most important competing ACE inhibitor according to Servier, did not regard ramipril and perindopril as substitutes in France because of the very limited switching among the continued use patients and the focus on *"the newly acquired first time treated patients"*.[3249] However, Sanofi-Aventis does refer to Poland as a country where ramipril could gain some patients at the expense of perindopril. AstraZeneca provided some indications suggesting that the company indeed regarded a certain number of ACE inhibitors as a threat to its lisinopril.

(2457) Overall, Bristol-Myers Squibb, Novartis and Ipsen, which produced the medicines from the ARB (sartan) class, were clearly more concerned with other medicines belonging to that class than with perindopril and other ACE inhibitors, while Sanofi-Aventis, Merck Sharp & Dohme and AstraZeneca, as producers of ACE inhibitors, more often perceived perindopril as a competitor.[3250] It must be noted that such a perception of relative proximity of other products is in line with the general structure given by the ATC classification which is often used for the analytical purposes by the companies from the sector. This finding is also consistent with the prescribers' perception of alternatives for the first-use prescriptions, the position of ARBs (sartans) in the WHO/ISH and BHS/NICE medical guidelines and the comments in the medical journals concerning such large studies as ONTARGET and TRANSCEND. In relation to the relative closeness between perindopril and other ACE inhibitors reported by their producers, the Commission must recall the distinction made by the General Court, in its AstraZeneca judgement, between the primary competitive focus and the notion of competitive constraints. The competitive focus on a certain product by other undertakings does not necessarily mean that the product is subject to a significant competitive constraint from those other undertakings.[3251]

3247 The general representativeness of this selection in terms of the coverage given to products that were most likely to constrain the sales of perindopril is confirmed by other elements of the present analysis, in particular the findings relating to the existing complementarities between different classes of hypertension medicines.

3248 Unless otherwise specified, the views of the alleged competitors relate to all the Member States concerned.

3249 ID2867, p. 8.

3250 For the avoidance of doubt, the relevant question that was asked to the potential competitors did not refer to a hypothetical change in relative prices. The question was more general and concerned three aspects: (i) competition for new prescriptions, (ii) switching and (iii) the nature of relationship (substitute v complement), see paragraph (2255).

3251 The General Court stated that the definition of the relevant market consists only in identifying the significant competitive constraints on the product under investigation and is therefore not concerned with those constraints that the product under investigation might have exercised over other products. The fact that another product was the primary competitive focus for the product under investigation does not mean that the other product exercised a significant competitive constraint over the product under investigation. See Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 97.

(2458) To sum up this section, in view of the importance given to the complementary use of ACE inhibitors with diuretics and calcium channel blockers in the medical guidelines (see paragraph (2441)) and the longitudinal studies and surveys pointing at the prevalence of co-prescriptions (multi-therapies), including the combinations of perindopril with indapamide (one of diuretics) and amlodipine (one of calcium channel blockers) (see paragraph (2442)), the Commission considers it less likely that diuretics, in particular hydrochlorothiazide and indapamide, and calcium channel blockers, in particular amlodipine, could be the source of a significant competitive constraint for the marketing of perindopril during the investigated period. With respect to the other three classes of hypertensive medicines referred to in the European guidelines, i.e. beta-blockers,[3252] ARBs (sartans) and ACE inhibitors, it is noted that the closest alternatives for perindopril can be expected to be found within the latter class, which has been confirmed with respect to the first-time use prescriptions by the Commission's survey of prescribers. As compared to ACE inhibitors, the position occupied by ARBs (sartans) must be regarded as more distant in the view of (i) the general perception that they were alternatives for patients suffering from the ACE inhibitor related cough and due to cost considerations[3253] (see paragraph (2444)), (ii) the opinions expressed by the surveyed practitioners (see paragraph (2454)) and (iii) the sartans manufacturers' main competitive focus on other sartan producers (see paragraph (2457)). Based on Servier's perception of perindopril's insufficient differentiation from ramipril (see paragraph (2450)) and the fact that the surveyed practitioners most often pointed to ramipril as an alternative treatment for first-time use patients in three out of four national markets under investigation (see paragraph (2454)), the quantitative analysis of the relationship between perindopril and ramipril will be particularly important for establishing boundaries of the relevant market.[3254]

(2459) The Commission's analysis as to the relative strength of potential constraints originating from ARBs (sartans) as compared to other ACE inhibitors is confirmed by Servier's reply to the Statement of Objections. Despite its general argument as to the wider relevant market covering both ARBs (sartans) and ACE inhibitors, Servier distinguishes between those two classes of treatments and argues that *"*the relevant product market includes both ARBs and ACE inhibitors or at least all ACE inhibitors"*.[3255] Thus, Servier acknowledges the order of importance among potential constraints. In addition, within the ACE inhibitor class, Servier confirms the

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3252 With respect to beta-blockers, there are also indications of certain complementarities with perindopril as evidenced by the longitudinal studies of the French prescribers, see paragraph (2373).

3253 As acknowledged by Servier (see Servier's reply to the Statement of Objections, paragraph 1472, ID10114, p. 450), the authorities encouraged the prescription of ACE inhibitors instead of sartans due to their generally lower cost. This shows that ACE inhibitors might have constrained, in terms of their lower prices, the sales of sartans. But it also means that because of their higher prices sartans were a lesser constraint for ACE inhibitors.

3254 For the avoidance of doubt and contrary to Servier's claim (see Servier's reply to the Statement of Objections, paragraphs 1514 and 1516, ID10114, p. 465), the Commission does not reach any final conclusions on the basis of the qualitative assessment, in particular of Servier's promotional materials, with respect to the boundaries of the relevant market. The qualitative information only constitutes a part of the overall evidence. The Commission uses the qualitative evidence to demonstrate that there existed certain product differentiation that varied as to its degree, e.g. ramipril can be shown to be the closest candidate competitor. Based on the evidence relating to the qualitative characteristics of perindopril the Commission does not regard perindopril as absolutely superior or unique as compared to other ACE inhibitors.

3255 Servier's reply to the Statement of Objections, paragraph 1466, ID10114, p. 448.

Commission's finding as to the importance of the further analysis of the relationship between perindopril and ramipril by stating that *"*ramipril was […] one of the most serious competitors of perindopril"*.[3256]

6.5.1.2.3 Natural events

(2460) The Market Definition Notice states that *"[i]n certain cases, it is possible to analyse evidence relating to recent past events or shocks in the market that offer actual examples of substitution between two products. When available, this sort of information will normally be fundamental for market definition"*.[3257]

(2461) Natural (shock) events analysis relies on past events that are potentially informative about the nature of competition encountered by the product in question. For instance, this type of analysis was already undertaken in the *AstraZeneca* case,[3258] where the Commission's interpretation of natural events was endorsed by the General Court.[3259] Generic entries are in general expected to lower prices of the corresponding molecule/product. Price drops are often substantial and far beyond the usual 5% to 10% threshold applied in the competition cases. When a price of one product decreases, it also means that other products become relatively more expensive. If the two products are close substitutes, then it is generally expected that the shock suffered by one, here a substantial price decrease, will be reflected by another either in terms of adapting its price or its sales or both. In any event, the reaction is expected to be visible in the turnover data which reflects both price and volume changes. A lower price of the close substitute should lead to the lower turnover[3260] of the product in question. In the AstraZeneca case, the General Court also accepted the

3256 Servier's reply to the Statement of Objections, paragraph 1498, ID10114, p. 459.

3257 OJ C 372, 9.12.1997, point 38.

3258 In the present text, unless otherwise specified, all the references made to the AstraZeneca case are meant to refer to the Commission's decision in case COMP/A. 37.507/F3 – AstraZeneca followed by the General Court's judgement in Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266.

3259 In light of the disagreement between the Commission and the Applicant over the meaning of the shock (natural) events presented in the AstraZeneca case (see Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266), the General Court explained its position on how to correctly interpret natural events. In that case, the Commission considered that the natural events constituted "important evidence" (paragraph 200). The General Court upheld the Commission's use of this evidence. In paragraph 213 of its judgment, the General Court indicated that *"[t]he Commission rightly states that the very significant impact of the market entry of generic omeprazole both on sales of Losec [AstraZeneca's omeprazole] and on its price must be viewed in conjunction with the absence of any effect of the introduction of the generic H2 blocker ranitidine [one of the alleged competitors] on prices and sales of PPIs"*. The General Court thus accepted that conclusions could be drawn from comparisons of the effects produced by entries by the generics of the product under investigation and the generics of potential competitors. The General Court also clarified that in order to undermine the Commission's line of reasoning with respect to natural events, an applicant has to submit evidence to the contrary of the Commission's findings. This shows that the General Court regarded the interpretation of natural events as an important and reliable part of the overall evidence on which the Commission drew its conclusions. Servier argues that in the AstraZeneca case, the Commission recognised the auxiliary character of its econometric analysis (see Servier's reply to the Statement of Objections, paragraph 1577, ID10114, p. 483 and Servier's reply to the Letter of Facts, paragraphs 140-141, ID10324, p. 44). In this context, the Commission recalls that in the Astra Zeneca case the natural events analysis was only available for two out of seven geographic markets. Therefore its relative status could not be the same as in the present case in which natural events are reviewed for all the concerned geographic markets.

3260 For the avoidance of doubt, the turnover term means the total value of sales, i.e. the multiplication of quantity by price.

comparative analysis, where the comparison is made between the effects of two events, namely: (a) generic entry in the product concerned and (b) generic entry in the allegedly competing product.[3261]

(2462) The following subsections provide for (i) the discussion of Servier's criticism relating to the Commission's natural events analysis, (ii) the general description of the model and the data used in the Commission's analysis, (iii) the discussion of the results obtained for the Member States under analysis and (iv) other elements of the analysis pertinent to all four Member States.

6.5.1.2.3.1 Discussion of Servier's criticism concerning the Commission's analysis

(2463) Servier criticises the Commission's analysis of natural events for obviousness of its findings. Servier and its economic consultant argue that the natural events based on relative changes in the prices of prescription medicines should not be expected to influence the sales of medicines due to the prescribers' disregard for prices.[3262] However, Servier's line of argumentation is inconsistent. In relation to the natural events analysis, Servier claims that prices are not a relevant factor for defining the market for prescription medicines. But, elsewhere in its response to the Statement of Objections, Servier argues in favour of a broader market by referring to the fact that certain national authorities showed price sensitivity.[3263] In this regard, the Commission wants to point out that the natural events analysis allows for the joint assessment of various factors, such as the prescribers' price insensitivity and the regulatory measures, affecting the demand. In particular the natural events analysis allows for assessing which factors prevailed in shaping the overall demand for perindopril at the relevant time. The Commission also considers that the prescribers' price insensitivity is in itself an important factor explaining the nature of constraints faced by Servier with respect to the sales of perindopril.

(2464) On the basis of its consultant's economic report, Servier argues that the Commission's natural events analysis, notably the conclusions drawn from comparing the effects of various events,[3264] relies on erroneous economic theory.[3265] The argument is based on an extension to the basic Hotelling model of imperfect competition with differentiated products. The model allows the parties to adapt both in prices and in quantities. In selecting this model, Servier's consultant does not take into account that the perindopril price remained stable along the occurrences of consecutive natural events concerning other molecules and only dropped with generic entry into perindopril. This omission renders the model's conclusions inapplicable to the Commission's analysis.

3261 See Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 213..

3262 Servier's reply to the Statement of Objections, paragraph 1455, ID10114, p. 445, CRA's report annexed to Servier's reply to the Statement of Objections, paragraph 113, ID9054, p. 55 and Servier's reply to the Letter of Facts, paragraph 139, ID10324, p. 44.

3263 Servier's reply to the Statement of Objections, paragraph 1533, ID10114, p. 469 and Servier's reply to the Letter of Facts, paragraph 184, ID10324, p. 56-57.

3264 As explained in paragraph (2461), the same analysis was applied and confirmed by the General Court in the *AstraZeneca* case.

3265 Servier's reply to the Statement of Objections, paragraphs 1456 and 1596, ID10114, p. 445-446 and 488-489, CRA's report annexed to Servier's reply to the Statement of Objections, paragraph 139-146, ID9054, p. 63-65.

(2465) In its reply to the Statement of Objections, Servier also claims that the Commission uses the natural events analysis to override the finding of therapeutic substitutability between perindopril and other medicines, in particular ramipril.[3266] The Commission disagrees with Servier's contention. First, the natural events analysis presented in this section is only a part of the Commission's broader analysis. The results of the natural events analysis are fully coherent with the findings established in other parts of this document, including the findings concerning product differentiation (section 6.5.1.2.2.), the importance of the continued use patients for the overall demand for perindopril, the high "fidelity" ratio shown by those patients, the doctors' inertia (section 6.5.1.2.4.) and the rigidity of demand reinforced by the existing regulatory framework (section 6.5.1.2.5.2.). Second, the Commission recalls that the functional substitutability must not be mistaken for the economic substitutability. Even if the functional substitutability is established i.e. two products are known to be able to meet the same needs, it is still necessary to verify whether the two products are also economic substitutes. This requires a thorough examination of other evidence such as examples of recent substitution, behaviour of customers including their reactions to price changes, consumption patterns, etc.[3267]

6.5.1.2.3.2 Description of the model and the data used in the Commission's analysis

(2466) The Commission asked Servier to identify up to five competitors (per Member State) whom the company considered to be reference points in terms of its marketing and pricing policy for plain perindopril in the period 2000 to 2008. Due to the fact that the annual top five lists varied across the period, the Commission established a list of eight reference products. The description of the relevant facts for the present analysis has been provided in section 6.4 and in *Annex A: Price developments*. Obviously, the natural events analysis is possible only for those products where generic entries have taken place, which is not the case for all eight products. At this stage of the assessment, it should, however, be clear that the Commission does not regard amlodipine, due to its complementarities with perindopril, as a likely source of the competitive constraints (see paragraph (2458)). The Commission also notes that the events concerning other ACE inhibitors are the most important due to the relative closeness of medicines from the same class based on the same basic mode of action. It is recalled that Servier expressed internally its dissatisfaction as to the level of differentiation between perindopril and other ACE inhibitors, in particular ramipril.[3268] The Commission's survey of prescribers showed that in France, the UK and Poland, the respondents most frequently regarded ramipril as a potential alternative for starting treatments, while in the Netherlands it appears that enalapril and lisinopril were regarded as more likely alternatives.[3269] Regarding ARBs (sartans), as concluded in section 6.5.1.2.2, they must be regarded as more distant as compared to other ACE inhibitors.[3270]

(2467) In section 6.4 and in *Annex A: Price developments*, the Commission presented the quantitative overview of price and volume developments in the universe comprising perindopril and the eight reference products preselected by Servier. The eight products were comprised of three plain ACE inhibitors: enalapril, lisinopril and

3266 Servier's reply to the Statement of Objections, paragraph 1576, ID10114, p. 483.
3267 See also paragraphs (2417)-(2420).
3268 See section 6.2.10.4.
3269 See *Annex D: Survey of prescribers*.
3270 See paragraph (2458).

ramipril, three plain angiotensin II antagonists: losartan, valsartan and irbesartan, one combination angiotensin II antagonist: valsartan+hctz, and one calcium channel blocker: amlodipine. The overview was carried out with respect to four national markets: the UK, the Netherlands, France and Poland. As far as the products with generic entries are concerned (i.e. perindopril, enalapril, lisinopril, ramipril and amlodipine), the same data also serves as a basis for the present analysis.

(2468) The analysis of natural events can take two forms. The first consists of a preliminary visual assessment of the data. The second relies on a more advanced econometric calculation of the impact that individual natural events have exercised on the sales of the product in question. The econometric method attempts to measure the impact of an event on the sales of the investigated product. It allows for a multivariate analysis controlling for other factors that are more difficult to unearth in the visual inspection of the data, e.g. time trends. In the present case, the Commission used a simple semi-log specification, where the natural logarithm of Servier's perindopril sales in terms of volumes expressed in DDDs[3271] was regressed on the set of dummy variables separating the periods before and after each natural event and the variables controlling for the time trend (a time trend and its square) and the monthly variability (monthly dummies). The fact that the model operates with the natural logarithm of volumes and not turnovers is largely neutral as far as the prices of perindopril remained stable.[3272] The full results of the Commission's econometric model are included in *Annex C: Econometric analysis of natural events*. The model was based on the market data provided by IMS Health. The model was designed to show negative co-efficients for natural events having a negative impact on the dynamics of perindopril's growth.[3273]

6.5.1.2.3.3 Natural events in the UK

(2469) The visual assessment of the UK market provides a textbook example of the dynamic decrease in prices of the products facing generic entry (see Figure 18). In the product universe under analysis, there were five products turning generic during the investigated period. In chronological order those were: enalapril, lisinopril, ramipril, amlodipine and perindopril itself. However, none of the generic entries of the other four medicines along with the related price drops had any noticeable impact on the turnovers generated by perindopril, which continued to steadily grow and topped with the monthly sales of approximately GBP 8 million at the eve of its own generic entry in July 2007. On the other hand, the entry of cheaper generics of perindopril had an almost instantaneous and very significant impact on Servier's branded product.[3274] Even if Servier was able to secure a substantial part of the perindopril market through the co-operation with its authorised generics, the average price of

3271 For definition, see footnote 3027.

3272 The Commission ran robustness checks by, among others, replacing the natural logarithm of volumes with the natural logarithm of values on the left-hand side of the model. The checks did not reveal any major changes with respect to the overall results. See also footnotes 3276, 3278, 3282 and 3286.

3273 Each natural event leading to an important decrease in the price of a given molecule had a direct impact not only on the prices of a relevant monotherapy but also on the prices of all combination therapies comprising that molecule.

3274 See paragraph (2292).

perindopril per DDD dropped over three-fold in the first year after generic entry and almost ten-fold by the second half of 2009 (see Table 23).[3275]

(2470) The econometric specification run for the UK market confirms the observations based on the visual inspection of the market data. The introduction of the generic version of perindopril was by far the most disruptive event in terms of the negative impact on the sales of Servier's perindopril. From other events, in two model specifications: one including all five products that were subject to natural events (perindopril, enalapril, lisinopril, ramipril and amlodipine) and another including only perindopril and enalapril, the generic entry in enalapril was also an event showing a negative and statistically significant coefficient. However, the coefficient for the 'enalapril' event showed a significantly lower value (in absolute terms) than the coefficient established for the 'perindopril' event. The values of the two coefficients for enalapril were (-)0.883 and for perindopril (-)1.792. That was a two-fold difference, which in this case meant the difference between the event that might have negatively influenced the dynamics of perindopril's growth and the event which shifted the quasi totality of the sales from Servier's branded product to generics.[3276]

(2471) In view of the foregoing, the Commission concludes that the natural events observed in the UK do not reveal any significant price constraints from other ACE inhibitors and amlodipine as compared to the strong price constraint introduced on the Servier's market position by perindopril's own generics.[3277]

6.5.1.2.3.4 Natural events in the Netherlands

(2472) The visual assessment of the Dutch market confirms the information contained in section 6.4.2.2 on the regulatory aspects underlying the price and volume developments post generic entry in the Netherlands. Before the introduction of the 'preference policy', generic entries did not have the immediate impact on the prices of respective products. It was only at the moment of the negotiations between the authorities and the pharmaceutical industry related to the wholesale prices of generics and originators' products with generic alternatives that the 'generic status' of a product played an important role. The price decreases of enalapril, lisinopril, ramipril and amlodipine coincide with the initial 40% price cuts agreed between the authorities and the pharmaceutical industry in the years 2004 - 2005 (see Figure 20). Those price decreases did not have any visible influence on Servier's sales of

3275 As to the time period over which price decreases are observed, it must be noted that the markets usually move from one equilibrium state to another over a certain period of time. As long as the process lasts, it may be difficult to assess its full magnitude.

3276 The robustness checks carried out for the UK market, in particular (a) the specification based on the natural logarithm of values, (b) the specification including corrections in the dates of natural events reflecting a two-to-four month time lag between the dates of actual generic entries and of changes in the Drug Tariff and (c) the specification including the lagged changes in the Drug Tariff and the introduction of the so-called M category as a separate regulatory event, confirm the original results. The introduction of the generic version of perindopril was by far the most disruptive event in terms of the negative impact on the sales of Servier's perindopril.

3277 The natural event analysis carried out for the UK market also demonstrates that the measures taken by the local PCTs with an aim to curtail the sales of Servier's perindopril (see paragraph (2280)) did not significantly affect the overall positive sales trend for this product. The overall ineffectiveness of the measures undertaken by the PCTs can be explained by (a) the local and uncoordinated character of the PCT measures, (b) no collective follow up by a larger number of the PCTs, (c) the PCT measures were aimed at GPs, but could not influence the prescriptions made in the specialised care, and (d) the PCTs could only exercise indirect influence since the ultimate prescription decision was left in the prescribers' hands.

perindopril in terms of volumes and turnover. Both the volumes and the turnover of perindopril substantially increased in the period following the said price decreases (see Table 25). The turnover of perindopril only plummeted down when its generic version was introduced. It is important to point out that without generic entry into perindopril, the product would not have been subject to the 'preference policy'. The average price of perindopril per DDD decreased four-fold within a year from generic entry (see Table 26). In the same period, the cheaper generics of perindopril drove down Servier's half-year sales by a factor of eight.

(2473) The econometric specification for the Dutch market has been adapted to take into account the above described situation where the price cuts with respect to the allegedly competing products were introduced with a delay as compared to the arrival of generics. The specification is based on the natural events reflecting on the one hand the collective price decrease of enalapril, lisinopril, ramipril and amlodipine and on the other the entry of generic perindopril. The first natural event occurred in June 2004, when the prices of potential competitors were brought down in line with the agreement between the authorities and the industry. This specification confirms the observations based on the visual inspection of the market data, i.e. the introduction of the generic version of perindopril was the only disruptive event in terms of the negative impact on the sales of Servier's perindopril.[3278]

(2474) In view of the foregoing, the Commission concludes that the natural events observed in the Netherlands do not reveal any significant price constraints from other ACE inhibitors and amlodipine, but point to the strong price constraint introduced on the Servier's market position by perindopril's own generics.

6.5.1.2.3.5 Natural events in France

(2475) The visual assessment of the French market confirms the information contained in section 6.4.3.2 on the regulatory aspects underlying the price and volume developments post generic entry in France, namely that generic entries trigger a statutory price reduction. This price reduction gradually becomes more visible in the aggregated data along with the progress of generic penetration. It is so because the generic product is sold at a lower price than its original reference product that also remains on the market and hence the higher the number of patients shifted to the generic version the lower the average price of the medicine in question. In the product universe under analysis, there were five products turning generic during the investigated period. In chronological order, those were: enalapril, lisinopril, ramipril, amlodipine and perindopril itself. However, none of the entries of those four other medicines, along with the inflicted price drops, had any noticeable impact on the turnover generated by perindopril, which continued to steadily grow and reached a peak with the monthly sales in the range of EUR [1–25]* million on the eve of generic entry of perindopril in September 2008.[3279] As described in paragraph (2316), the modest price reduction with respect to the prices of perindopril 2 mg and 4 mg introduced by the French authorities in January 2007 was accompanied by the launch of perindopril 8 mg at the price that rendered the overall

[3278] The robustness checks carried out for the Dutch market, in particular the specification based on the natural logarithm of values, confirm the original results. The introduction of the generic version of perindopril was by far the most disruptive event in terms of the negative impact on the sales of Servier's perindopril.

[3279] The monthly sales figures are based on Figure 8 and Figure 21.

price measures neutral from the perspective of the turnover generated by perindopril for Servier.

(2476) The arrival of generic perindopril in France did not bring about an immediate decrease in the volumes sold and the turnover generated by Servier (see Table 28 and Table 29). This was because of several reasons including the obstacles faced by the first entrant[3280] and the successful introduction of the *arginine* salt by Servier. Nonetheless the generic competitors were able to capture an incremental increase in the overall market sales and stopped Servier's expansion. The generic entry in perindopril brought down an average price per DDD from EUR [0.60-0.80] in the first half of 2008 to EUR [0.40-0.60] in the second half of 2009, which represented a price decrease of more than 27%. The average price was to decrease even further in 2010.

(2477) The econometrics developed for the French market confirm the observations based on the visual inspection of the market data. The introduction of the generic version of perindopril was the most disruptive event in terms of the negative impact on the sales of Servier's perindopril. As regards other events, in two model specifications: one including all five products that were subject to natural events (perindopril, enalapril, lisinopril, ramipril and amlodipine) and another including only perindopril and enalapril, the generic entry in enalapril was also an event showing a negative and statistically significant coefficient. However, in a similar way as in the UK data, the coefficient for the 'enalapril' event showed a significantly lower value (in absolute terms) than the coefficient established for the 'perindopril' event. The values of the two coefficients were (-)0.064 and (-)0.180, respectively.[3281] That was a three-fold difference, which in this case meant the difference between the event that might have negatively influenced but not reversed the positive dynamics of perindopril's growth and the event which managed to put a hold on the growth of Servier's sales. The econometrics also show a negative coefficient with respect to amlodipine in one of the specifications, but in this respect the results are statistically and economically less robust (see *Annex C: Econometric analysis of natural events*) and are not confirmed in the other data analysed in the previous sections, notably with respect to the existing complementarities between amlodipine and perindopril.[3282]

3280 See section 6.4.3.4.

3281 Servier argues that the coefficients should be also compared across different national markets (Servier's reply to the Statement of Objections, paragraph 1595, ID10114, p. 488). The Commission considers that Servier's argument should be dismissed. The coefficients of natural events measure diversions from the market trend in response to a given shock (event). The market trends, i.e. the coefficients calculated for time and time square, are different for each market. Therefore, the cross-market comparisons of coefficients are not straightforward. In the concrete example of the models regressed for the UK and France, the coefficient of the UK time trend is by the order of magnitude higher than the coefficient calculated for the time trend in France. To represent a meaningful change in the market dynamics, the coefficients of effects in the UK also had to be by the order of magnitude higher (as compared to France). In other words, the absolute values should not be directly compared between markets with different time trends. The inclusion of time square variable further complicates any cross-market comparisons.

3282 The robustness checks carried out for the French market, in particular the specification based on the natural logarithm of values, confirm the original results. The introduction of the generic version of perindopril was by far the most disruptive event in terms of the negative impact on the sales of Servier's perindopril. The specification based on the natural logarithm of values does not show a negative coefficient with respect to amlodipine and shows a positive coefficient next to the ramipril event.

(2478) In view of the foregoing, the Commission again concludes that the natural events observed in France do not reveal any significant price constraints from other ACE inhibitors and amlodipine, but point to the strong competitive price constraint introduced on the Servier's market position by perindopril's own generics.

6.5.1.2.3.6 Natural events in Poland

(2479) With regard to the Polish market, the Commission has not applied the natural events analysis based on generic entries because of the different nature of competitive interactions observed in Poland. The generic companies sell branded generic products which the regulatory system in principle treats with respect to their prices and reimbursement status in the same manner as the products of the originator companies.[3283] Another specific feature of the Polish market is a high co-payment by patients. As a result, generic entries do not represent such a drastic change in the market conditions as is the case of the markets with non-branded generics. However, contrary to Servier's suggestion,[3284] the natural events analysis of the Polish market closely follows the logic adopted for other markets, i.e. the focus remains on abrupt changes in prices of potentially competing medicines.

(2480) In paragraph (2348), the Commission carried out the comparison of the co-payment conditions for Sanofi-Aventis' ramipril branded as Tritace and Servier's perindopril branded as Prestarium. Between September and November 2005, the level of co-payments for various dosages of Tritace dropped by 21% to 68%, including the highest selling 10mg dosage lowering its price by 68%. (i.e. customers had to pay 68% less for Tritace than they did previously). At the same time, the co-payment of the highest selling 4 mg dosage of Prestarium increased by 18%. In weighted terms, as a result of the single price/co-payment change, Tritace became 51% cheaper than Prestarium starting from the point where it had been 29% more expensive than Prestarium. As shown in Figure 11, in the wake of that price/co-payment change, all available dosages of Tritace became significantly cheaper for patients than the available dosages of Prestarium. The situation continued without any downward price adaptations by Servier. It is also important to note that, after the change of co-payment levels, the highest selling 4 mg dosage of Prestarium required the co-payment of almost 80% on the part of the Polish patient. Figure 26 in Annex A shows that as from October 2005 the treatment cost of losartan (the best-selling sartan in Poland) incurred by the patients was also decreased substantially, almost by 50%.

(2481) Against this background, the Commission notes that Tritace as well as other generic ramiprils that also managed to secure competitive conditions for their sales rapidly developed the market for ramipril, which towards the end of the investigated period became the biggest selling antihypertensive agent in the analysed universe (see Figure 10). At the same time and as explained in section 6.4.4.4, the Polish market for perindopril grew, in terms of average six-monthly sales, from the level of [80-100] million DDDs in 2004 to [100-140] million DDDs in the years 2008-2009, i.e. an increase of 30%. New sales originated mainly from Krka that gradually built up its position, while Servier's sales stabilised. In the same period, Servier also managed to successfully switch most of the perindopril patient base to the *arginine* salt and profit from the lack of effective generic substitution between the two salts of

3283 See section 6.4.4.2.

3284 Servier's reply to the Statement of Objections, paragraph 1455, ID10114, p. 445.

perindopril, which along with the branded character of the Polish market explains Servier's resistance to the competitive pressure from Krka. However, it must also be observed that the dynamics of perindopril sales in terms of the year-to-year absolute changes expressed in volumes started to decrease after peaking in 2006 and even turned negative in 2009. The generic presence forced down the average perindopril price per DDD from PLN [0.55-0.80] in the second half of 2005 to PLN [0.55-0.80] in the second half of 2009, i.e. by 17%.

(2482) The econometrics developed for the Polish market confirm the above findings. The relative change, which instantaneously made ramipril significantly cheaper for patients as compared to Servier's perindopril and coincided with the substantial decrease in the cost of the losartan treatment incurred in the form of a co-payment by the Polish patients, did not show any negative effects on Servier's sales. The model developed for Poland includes three natural events: (i) the change in the co-payment amount for ramipril and losartan in October 2005, (ii) Krka's entry with its branded generic in June 2006 and (iii) generic entry by other producers of perindopril in February 2009. The "ramipril/losartan" event showed a positive coefficient tested both alone and with other natural events. Krka's entry also resulted in a positive coefficient, which would seem to be a counter-intuitive result if there were not the specificities of the relation between Krka and Servier (i.e. the licencing agreement, see section 4.3.3.6), which might have weakened the competitive process.[3285] The event related to other generic perindoprils showed a negative coefficient, but in the model specification with all three events the co-efficient was not statistically significant. This may be explained by the general problems that were faced by the producers of generic perindopril related to the branded character of the Polish market and Servier's strategy of moving the perindopril patient base to the *arginine* salt.[3286]

(2483) In the view of the Commission, perindopril showed high resistance to the very strong price shock coming from possibly the closest alternative among all other antihypertensive agents, i.e. ramipril,[3287] and from the best-selling product in the adjacent therapeutic class of sartans, i.e. losartan. That combined shock took place on

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3285 Elsewhere in its analysis (see section 5.5.3.3.3.2), the Commission characterises this relationship as a *de facto* duopoly. Servier argues that the use of the notion of "duopoly" is incongruent, as the market, according to Servier, comprised at least all other ACE inhibitors (reply to the Statement of Objections, paragraph 974, ID10114, p. 338). This claim is flawed and directly contradicts Servier's position from paragraph 970 of its reply. If the market were to be broader and included other ACE inhibitors (contrary to the Commission's conclusion that the product market was limited to perindopril), Krka would *a fortiori* be an actual competitor of Servier, as it was also a supplier of enalapril, However, in said paragraph 970, Servier claims that Krka and Servier were not in competition owing to Servier's patent protection for perindopril, and thus implicitly confirms that a market limited to perindopril is the right framework for the assessment of competitive constraints in this case.

3286 The robustness checks carried out for the Polish market, in particular the specification based on the natural logarithm of values, confirm the original results. The relative change, which instantaneously made ramipril and losartan significantly cheaper for patients as compared to Servier's perindopril, did not show any negative effects on Servier's sales. In the specification based on the natural logarithm of values, the ramipril/losartan event is no longer significant. In this specification Krka's entry results in a negative co-efficient tested both alone and with other natural events. The event related to other generic perindoprils becomes statistically insignificant if tested without the other two events. The specification based on the natural logarithm of values addresses the comments concerning the results of the regressions carried out for the Polish market made by Servier's economic consultant in its reports submitted along with Servier' replies to the Statement of Objections and the Letter of Facts (CRA's report annexed to Servier's reply to the Statement of Objections, paragraphs 119-121, ID9054, p. 56-57 and CRA's supplementary report, paragraphs 17-20, ID10318, p. 11).

3287 See section 6.5.1.2.2 on the assessment of product characteristics and intended use.

a market with very high co-payments, where both doctors due to patient compliance considerations and patients due to direct financial considerations could have been expected to exhibit price sensitivity.

6.5.1.2.3.7 Remaining elements of the natural events analysis

(2484) The above mentioned natural (shock) events that were observed on all four national markets under investigation provide a measure of the low level of price sensitivity of the demand for perindopril. Potentially competing antihypertensive agents often decreased in price by over 50%, which meant that perindopril was – relatively speaking – twice as expensive as prior to a given event.[3288] Those price changes were insufficient to threaten Servier's market position.

(2485) The analysis of natural events necessarily focuses on naturally selected "turning points" thanks to which it is possible to separate the "before" from the "after" period and by comparing the two periods to assess actual substitution between the products in question. In view of the relatively stable competitive environment in which Servier marketed its perindopril,[3289] the natural event analysis based on generic entries can be regarded as representative for the entire period in question. It is important to note that the analysis has been carried out for the product universe in which a number of generic entries took place relatively early in the course of the investigated period (2000-2009) or even predated that period.[3290] The sales of Servier's perindopril persistently grew until the arrival of generic perindopril despite the constant presence of generic (cheaper) versions of other ACE inhibitors throughout the entire period in question.

(2486) In its response to the Statement of Objections, Servier argues that the Commission is wrong to focus on the impact of natural events on the total sales of perindopril and instead should analyse the sales to new patients.[3291] In this context, the Commission wants to point out that the persistent growth of the sales of Servier's perindopril until the arrival of generic perindopril indicates that the presence of generic (cheaper) versions of other ACE inhibitors did not manifestly harm Servier's ability to acquire new patients for its perindopril.

(2487) The evidence on file shows that sartans were regarded as more distant substitutes for perindopril than other ACE inhibitors by the experts preparing the guidelines, by the concerned potential competitors and by the surveyed practitioners.[3292] This is further confirmed by the losartan event in Poland, i.e. on the market with the highest

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3288 The General Court pointed out in paragraph 178 of the *AstraZeneca* judgment that *"the fact […] that patients and doctors display limited sensitivity to the cost of medicines, even where those costs exceed reimbursement levels,* supports *the view that H2 blockers [the alleged competitors] did not exercise, by means of their lower prices, a significant competitive constraint over PPIs [the product under investigation]"*. From the General Court's reasoning, it is apparent that the factors that limit the price sensitivity and thus shield the product in question from competition should be viewed as indicators of the absence of significant competitive constraints over that product. Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266.

3289 Virtually all the major products listed by Servier in Table 19 were launched in the 1980s and the 1990s (see Table 21, Table 24, Table 27 and Table 30). In its internal SWOT analysis, Servier stated *"[n]o real innovation from competitors in the next 10 years in HT or CAD"* (see Table 33).

3290 See Table 21, Table 24 , Table 27 and Table 30; Moreover, captopril, the first ACE inhibitor from the class, became available generically in all the Member States concerned already in the 1990s (see paragraph (2145)).

3291 Servier's reply to the Statement of Objections, paragraph 1456, ID10114, p. 445-446.

3292 See the assessment carried out in paragraphs (2444), (2454) and (2457).

expected price sensitivity of demand among the four selected Member States. The event shows that sartans were unlikely to constrain the sales of perindopril even at substantially lower prices. Therefore, it is considered as highly unlikely that any price event with respect to sartans would reveal significant constraints over the sales of perindopril. In a similar vein as the presence of cheaper ACE inhibitors, the presence of several sartans did not prevent the sales of Servier's perindopril from persistently growing until the arrival of generic perindopril. It is also important to note that perindopril's continuous growth was based on the already substantial level of sales that had been achieved in the 1990s, i.e. the period when sartans were launched individually and as a class.

(2488) The observations relating to the natural events discussed above are confirmed by the results of the Commission's survey of prescribers.[3293] The survey asked among others whether with respect to patients who were starting a therapy, the respondents prescribed less perindopril when a generic version of other medicine that was considered comparable to perindopril became available. In addition, the respondents were asked whether with respect to patients who were starting a therapy, they prescribed more of perindopril when a generic version of perindopril became available.

(2489) The majority of the respondents (on average 77%) in all the twelve respondent groups considered that the availability of a generic version of other medicine considered comparable to perindopril had no significant impact on their prescriptions. In the Member States where generic entries can be closely associated with significant price drops, i.e. the UK, France and the Netherlands, such a response shows that the prescribers were, in their majority, insensitive to relative price changes even with respect to the choice of treatments for patients who were starting a therapy. In its reply to the Statement of Objections, Servier does not contest the Commission's finding that the prescribers were generally price insensitive in their choice of treatments.[3294]

(2490) With regard to the reverse question on the potential quantity/prescription gains of perindopril after the arrival of its generics, which is less relevant for the purpose of the present assessment due to potential asymmetries in the relation between perindopril and other medicines, the majority of the respondents (on average 85%) in all the twelve respondent groups considered that the availability of generic perindopril had no significant impact on their prescriptions.

(2491) In section 6.4.5.1, the Commission summarised Servier's response to the RFI concerning natural events. In the Commission's RFI, natural events were defined as any event leading to a change in the pricing, marketing, strategic or any other important policy of Servier relevant for perindopril. Despite the fact that Servier signalled the substantial number of potential natural events, including new entries, new studies and trials, and new international recommendations (medical guidelines), it was not able to retrace modifications to its strategy caused by individual events including market entry of generic versions of allegedly competing medicines. Instead, Servier pointed to its involvement in such extensive morbidity-mortality studies as PROGRESS (published in 2001) and EUROPA (2003) claiming that the

[3293] See section 6.4.5.7 and *Annex D: Survey of prescribers*.

[3294] Servier's reply to the Statement of Objections, paragraph 1585, ID10114, p. 485.

decision to become involved in those studies was the main modification of its strategy and commercial policy.

(2492) The explanations provided by Servier are consistent with the general lack of immediate effects associated with the individual natural events discussed above (with the obvious exception of generic entry into perindopril). Servier did not refer to any other modifications to its strategy and commercial policy (e.g. pricing policy) related to the identified natural events.

(2493) Contrary to Servier's assertions,[3295] the considerable rise in the sales of ramipril that followed the publication of the HOPE study (in 2000) cannot be interpreted in terms of direct constraints over the sales of perindopril. The potential interpretation that is given to the HOPE and other studies depends to a large degree on the way in which those studies were communicated to the prescribers as a part of producers' promotional efforts. Servier's strategy documents show that Servier viewed ramipril's promotion not only as a threat but also as an opportunity.[3296]

6.5.1.2.3.8 Conclusion of the natural events analysis

(2494) In conclusion, the Commission regards the following points as important for its assessment of natural events:

- the above analysis of natural events clearly indicated the absence of any significant price constraints from other ACE inhibitors and amlodipine and pointed to the strong price constraint for Servier's market position caused by perindopril's own generic (the constraint brought about by generic perindopril in Poland was still present, but not as strong as in the other countries at issue). It also proved unlikely that perindopril faced any significant price constraints from other relatively more distant medicines such as sartans (as compared to the relative proximity of ACE inhibitors and in view of the natural event observed with respect to losartan in Poland);
- the lack of the price and volume reactions in response to the developments concerning other potentially competing products is in a sharp contrast with Servier's vulnerability vis-à-vis its own generics. On the national markets, where Servier was unable to timely introduce its anti-generic strategy, in particular the change of perindopril dosages based on the *arginine* salt, the generic presence led to multi-fold price decreases, namely in the UK and in the Netherlands. On the other markets, where Servier managed to execute its anti-generic strategy, the price decreases were slower, but nonetheless capable of producing meaningful savings for the average consumer of perindopril: by the end of 2009, the average price of perindopril went down by 27% in France and by 17% in Poland;
- the example relating to the sharp decrease of ramipril's and losartan's co-payments in relation to perindopril in Poland reveals the general price insensitivity of doctors and patients with regard to perindopril even in the absence of generous reimbursement;
- Servier did not take any immediate actions, including other dimensions of competition, in response to individual natural events.

3295 Servier's reply to the Statement of Objections, paragraph 1459, ID10114, p. 446.

3296 See paragraph (2358).

(2495) In view of the foregoing, the Commission finds that there is strong evidence demonstrating that Servier's branded perindopril did not face any significant price constraints from other products during the investigated period except the constraint brought by generic perindopril.

6.5.1.2.4 Switching patterns

(2496) In section 6.5.1.2.2, the Commission has among others established that the relationships between certain products involved complementarities, as it was found with respect to the combinations of ACE inhibitors, including perindopril, with calcium channel blockers and diuretics. The Commission has also found that hypertensive products were heterogeneous as regards their relative efficacy and side effects, or at least as a strict minimum, as regards the available evidence with respect to their relative efficacy and side effects. All those factors might have had an impact on the prevailing switching patterns. This section will further look into the evidence relating to the existing switching patterns between perindopril and other anti-hypertensive products.

(2497) The evidence on file demonstrates that continued-use patients were unlikely to switch away from a successful treatment. With respect to the existing patient base, Servier enjoyed the information advantage in the sense that the continued-use perindopril patients knew more about perindopril than about other treatments that had not been tried. However, that informational advantage could not protect Servier's perindopril from substitution with generic perindopril. As a matter of fact, the generic constraint was equally important for Servier's perindopril sales directed to both the first-time use and the continued-use patients, while other potentially alternative treatments could be expected to at best exert influence over the pattern of the first-time prescriptions.

(2498) The European guidelines contain some important observations with regard to the selection process of hypertensive agents. They point to *"the frustration of repetitively and vainly searching for effective monotherapies"* and the fact that the procedure of testing another medicine *"is laborious and frustrating for both doctors and patients, leading to low compliance and unduly delaying urgent control of blood pressure in high risk hypertensives"*. Along with the guidelines' position as to the secondary importance of cost considerations, which *"should never predominate over efficacy, tolerability, and protection of the individual patient"*, the above-mentioned quotes confirm the Commission's findings in the merger case COMP/M.1403 Astra/Zeneca, where it was found that *"the importance of the relative prices of two [anti-hypertensive] drugs is further diminished by the fact that a switch of medication in itself will produce significant costs related to re-stabilisation of the patient and possible side-effects"*. These findings hold in the present case.[3297]

[3297] In that merger case, the Commission was confronted with the claim of the merging parties that the hypertension medicines classified under the various ATC-3 classifications did not constitute separate product markets, but should have been considered at a level which aggregated a number of ATC-2 classifications (beta-blockers, calcium antagonists, ACE inhibitors and angiotensin inhibitors) (see: Decision of 26/02/1999 in case COMP/M.1403 Astra/Zeneca, para. 11). Since the parties in that merger case did not overlap with respect to ACE inhibitors, there was no need to conclude on the exact market definition for these products. In particular, it was left open whether plain and combined ACE inhibitors (belonging to the ATC3 classes C9A and C9B) belonged to the same relevant market. The market test conducted in that case by the Commission showed that (para. 13) *"hypertension medication is a life-long treatment, where no change is normally done once successful treatment has been established*

(2499) In view of the product heterogeneity within the ACE inhibitor class (see section 6.5.1.2.2.), and the fact that this heterogeneity could be related to differences in efficiency and side effects for individual patients, the analysis applied in the AstraZeneca merger case to the entire classes can be also applied at the level of separate molecules from the ACE inhibitor class. As explained in paragraph (2379), a potential switch among medicines from the same class could be associated with the costs related to (a) the switch itself and (b) the health risks accompanying the change of treatments which were potentially very grave given the nature of the heart conditions at issue. The switch required additional medical consultations, could cause side effects and could temporarily lead to suboptimal blood pressure control, which was associated with higher odds of mortality at least in patients at high cardiovascular risk.

(2500) The Commission regards as instructive the comment made by Sanofi-Aventis, the producer of ramipril, which states with respect to its ramipril sales in France that *"switches between ramipril and perindopril [were] very limited"* and that both products were *"building their growth on the newly acquired first time treated patients"*.[3298] This comment points out an important feature of the market interactions relating to hypertension patients during the period in question. According to Sanofi-Aventis, the incremental growth was mainly fuelled by the first-time use patients.

(2501) Section 6.4.5.5 presented the results of a series of longitudinal studies with respect to the rate of renewals in perindopril prescriptions. The studies found that the perindopril prescriptions were clearly dominated by renewals, where patients simply continued their therapies. The "fidelity" ratio was above 90% in terms of prescriptions written for the continued treatments without any modification in the course of the reference year, except possible changes in dosage. The positive and negative switches were below 5%, while completely new diagnoses were at the level of 1-2%. The CEGEDIM study also presented in section 6.4.5.5 shows that the switching process was regressive, i.e. the perindopril patients were less and less likely to switch away from perindopril with the passage of the treatment time.

(2502) The above figures are consistent with Servier's promotional efforts regarding the positioning of perindopril as being the adequate product for new patients comprising

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(unless there is a change in the condition of patient). […] [T]he importance of the cost of the chosen drug is normally a secondary concern to its functionality. However, the importance of the relative prices of two drugs is further diminished by the fact that a switch of medication in itself will produce significant costs related to re-stabilisation of the patient and possible side-effects". Based on the collected evidence, the Commission noted that (para. 18) *"[t]he degree of substitutability is particularly low for patients who are already effectively medicated for their hypertension, since in those cases a switch will include risks for serious side-effects, as well as additional costs"*. The analysis led to the conclusion that *"it is appropriate to assess the impact of the proposed concentration separately for betablockers, calcium antagonists, ACE inhibitors and angiotensin inhibitors"*. In its replies to the Statement of Objections (paragraph 1458, ID10114, p. 446) and the Letter of Facts (paragraphs 143-144, ID10324, p. 45), Servier argues that in the present case the Commission departs from its previous analysis of merger cases and sets a precedent for future merger cases. As already noted in footnote 3215, in its merger practice, the Commission has also tended to identify competition issues at the molecule level. It must be also recalled that the same methodology applied in a merger case and an antitrust case may lead to different boundaries of the relevant market. The antitrust analysis must take into account that competition might have been already distorted, while the merger analysis directly starts from the prevailing market conditions (see the Commission's Market Definition Notice, points 12 and 19, OJ C 372, 9/12/1997).

[3298] For the full overview of the positions expressed by the alleged originator competitors, see section 6.3.4.2.

of newly diagnosed hypertensive patients and patients whose conditions were not being controlled satisfactorily by other antihypertensive agents, and specific groups of patients for whom perindopril had particularly good evidence.[3299]

(2503) In the view of the Commission, these figures are also consistent with the previously cited Sanofi-Aventis statement that the growth was based on the newly acquired first-time use patients. Both switches and add-ons constitute an inevitable part of the trial process during which the first-time use patients may need to test a number of medicines before they find a satisfactory treatment in terms of lowering blood pressure and avoidance of side effects. It is important to note that medical switches are a part of the selection process in which the true characteristics of a given medicine are being discovered for an individual patient. Indeed, the European guidelines recognise the problem caused by repeated medical switches and provide the practitioners with an advice to minimize it, in principle by endorsing the use of combination therapies. In addition, medical switches, where there is an immediate medical necessity for switching, should be clearly distinguished from economic switches where a price change or another economic incentive, e.g. new evidence indicating better value for money of a given medicine, induces a modification of the applied treatment without immediate medical necessity. Contrary to economic switches, medical switches may not be informative with respect to the substitutability based on the price changes and cost valuation of different products. The fact that the patients suffering from the ACE inhibitor induced cough were usually switched to an ARB (sartan) was immaterial from the perspective of the economic substitution, because in any event those patients could not continue the treatment with ACE inhibitors. In other words a medical switch indicated that the two products were not interchangeable for a switched patient. The above economic interpretation of medical switches holds as long as medical switches do not affect the relative valuation of available treatments. For example, the frequent occurrence of adverse effects may lead to fewer prescriptions in the first place. However, that was not the case of perindopril which Servier internally praised for being recognised for its *"high level of tolerance and compliance"*.[3300] In general, the occurrence of ACE inhibitor induced cough was not considered critical enough in order to reverse the relative position of ARBs (sartans) in relation to ACE inhibitors.[3301]

(2504) The stability of the patient base characterised by the above-mentioned low rate of switching is consistent with the incremental growth of perindopril sales (see Figure 4, Figure 6, Figure 8 and Figure 10) fuelled by those first-time use patients who after the successful trial period turned into the continued-use patients.

(2505) In section 6.4.5.7 and *Annex D: Survey of prescribers*, the Commission summarised the results of the survey of cardiologists, general practitioners and hospitals which was carried out in the selected Member States, i.e. France, the Netherlands, the UK and Poland. The Commission's questionnaires also included questions intended to verify switching patterns from the period under investigation as recollected by the perindopril prescribers. Those questions covered the following topics: the likelihood of switching due to medical and non-medical reasons and the expected duration of the non-switching period.

3299 See section 6.4.5.2.

3300 See paragraph (2149).

3301 See section 6.2.10.5.

(2506) Regarding the question of how many of the patients who were successfully treated with perindopril during the initial period, and thus had gone through the trial period and belonged to the continued-use group of patients, were switched to a different treatment for any medical reasons related to the continuous or prolonged treatment with perindopril, the majority of the respondents in all the twelve respondent groups selected the lowest percentage range, i.e. from 0% to 24%, as their reply. This is an additional indication that most of the continued-use patients of perindopril were rarely switched from perindopril to other medicines for medical reasons.

(2507) With respect to the question concerning switching for other reasons, including relative changes in prices and in perception (because of new information that became available on the relative safety or efficacy of the cardiovascular medicines), in all respondent groups except the Polish general practitioners, the majority of the respondents reported that they did not switch for such reasons or only switched a small minority, of less than 25%, of all patients.[3302] The overall results are supportive of the existence of the core group of the continued-use patients of perindopril who were unlikely to be switched for any reasons, both medical and non-medical. The Commission notes that that group could be smaller in Poland, where at least the general practitioners declared distinctively higher propensity to switch the continued-use patients than their colleagues from other respondent groups. With regard to the economic switching, the views declared by the practitioners are fully in line with the outcomes of the natural events analysis undertaken in the previous section. The fact that it is rare that the patients are switched away from a successful therapy was confirmed by Servier's medical expert.[3303]

(2508) As regards the expected duration of the non-switching period, the respondents participating in the Commission's survey were asked to select between different time ranges. In all the respondent groups, a certain number of the respondents (26% and more) opted for ten and more years. Such respondents were in the majority in the respondent groups of the UK and the Dutch hospitals, the UK and the Dutch cardiologists and the Dutch generalists. If the ranges of the expected durations of five to ten years and over ten years are combined together, the clear majority of respondents in all the respondent groups could agree that patients who were

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3302 In its reply to the Statement of Objections, Servier relies on the same data taken from the Commission's survey of prescribers to claim that a non-negligible percentage of the continued-use perindopril patients were switched to other treatments for non-medical reasons (see Servier's reply to the Statement of Objections, paragraphs 1568 and 1569, ID10114, p. 481). The Commission notes that Servier's claim is based on an erroneous interpretation given by Servier's economic consultant to the results of the relevant questions in the Commission's survey of practitioners. In fact, the replies to questions 13 and 14 (as numbered in the questionnaires addressed to general practitioners and cardiologists) should be interpreted together.

3303 *"*Once the right combination therapy is found, doctors, rightly and in good faith, have little tendency to modify the treatment over time in the absence of medical reasons"*, see professor Vanoverschelde's report annexed to Servier's reply to the Statement of Objections, ID9054, p. 276. In its reply to the Letter of Facts, Servier contends that Professor Vanoverschelde's report does not confirm the lock-in effects, but to the contrary stresses the therapeutic equivalence of all ACE inhibitors (Servier's reply to the Letter of Facts, paragraph 125, ID10324, p.40). In the Commission's view, Servier's comment overlooks an important difference between the theoretical availability of alternative treatments for the first-time use patients and the optimal treatment path for the continued-use patients. That being said, Servier correctly notes that Professor Vanoverschelde does not pronounce himself as to the pertinence of the perindopril treatment (Servier's reply to the Letter of Facts, paragraph 134, ID10324, p.42). However, the Commission only relies on the quote in question insofar as it provides a valid rationale for the stability of the existing perindopril (and any antihypertensive medicine) patient base.

successfully treated with perindopril and not switched were likely to continue with the perindopril treatment for more than five years. The results of the Commission's survey are consistent with Servier's own expectations as to a long duration of the perindopril treatment as well as with the nature of hypertension as a medical condition requiring life-long treatment.[3304] In the view of the Commission, the survey confirms the status of perindopril as a long-term maintenance treatment.

(2509) Having regard to the foregoing, the Commission finds that the continued-use patients treated with perindopril were mostly unlikely to switch to alternative medicines once they had settled on the use of perindopril. The evidence advanced above is consistent with the economic assessment that experimentation by renewed exposure of patients to alternative medicines would be suboptimal. The evidence presented above also indicates that the suppliers of alternative medicines were more likely to dedicate their detailing and marketing efforts to attract first-time use patients with respect to which the switching costs were absent.

(2510) Contrary to Servier's assertions that the competitive analysis should not take into account the repeated prescriptions,[3305] the Commission views this type of prescriptions as highly relevant for the overall assessment of competitive constraints faced by perindopril. The repeated prescriptions, which were hardly contestable by the producers of other medicines, represented the bulk of the perindopril sales. Any limitation in exposure to competition, as measured by the relative size of (in)contestable demand, is highly informative as to the strength of potential competitive constraints.[3306] This being said, the sales of Servier's perindopril to the continued-use patients were not completely free of all constraints, notably they faced the generic constraint[3307] and were subject to the regulatory measures that could have potentially been taken in response to relative changes in the costs of other treatments by the relevant authorities.[3308] For the same reasons, Servier's comparison of the perindopril sales to the continued-use patients to the sales under a framework contract[3309] inadequately reflects the nature of competition for prolonged treatments.

(2511) Section 6.4.5.6 also included an example drawn from the longitudinal studies, where among others the prescription habits of the French general practitioners were compared over time. The results showed the gradual growth of the categories of 'big and medium prescribers' and that the so-called 'big prescribers' were likely to continue prescribing more of perindopril than other prescribers and non-prescribers.

(2512) In the view of the Commission, the existence of the growing group of loyal prescribers among the doctors offers a highly plausible explanation for the

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3304 See section 6.2.4.

3305 Servier's reply to the Statement of Objections, paragraphs 1453 and 1561, ID10114, p. 444 and 479.

3306 In its reply to the Letter of Facts, Servier relies on an economic argument that the seller should set the same price with or without lock-in effects (Servier's reply to the Letter of Facts, paragraph 113, ID10324, p. 37 and CRA's supplementary report, paragraphs 37-45, ID10318, p. 16-17). The Commission notes that the argument relies on the assumption of an infinitely iterated game and therefore it does not hold in an originator-generic setting, in which the originator must factor in generic entry, which also means that the number of iterations is finite and the proportion of lock-in buyers is expected to increase in time. In other words, it is not true, as Servier's economic advisor suggests, that the relative size of (in)contestable demand is not relevant with respect to the strength of potential competitive constraints.

3307 See section 6.5.1.2.6.

3308 See section 6.5.1.2.5.2.

3309 Servier's reply to the Statement of Objections, paragraph 1562, ID10114, p. 479.

continuous growth of perindopril's patient base. The existence of loyal prescribers also meant that the constraints from other potentially alternative treatments faced by Servier with respect to the first-time use patients were actually weaker than a mere number of therapeutic options would otherwise suggest.

(2513) Overall, the high switching costs and the prescribers' "loyalty" provide an important part of the explanation as to the underlying reasons for the price insensitivity of the demand for perindopril shown in the analysis of natural events.

6.5.1.2.5 Other factors

(2514) This section discusses two other factors that need to be addressed in the present analysis. These are: (i) the promotional efforts taken by Servier and the producers of other antihypertensive medicines and (ii) the impact of the regulatory framework.

6.5.1.2.5.1 Promotional efforts

(2515) Section 6.4.5.2 sets out an overview of Servier's promotional expenditure, including the information on the goals pursued by Servier in its promotional activities.

(2516) In general, the informative function of promotion in the pharmaceutical industry, as long as the transmitted information is correct, helps in improving allocative efficiency. Promotion may extend the degree of competition if by its means the medical community is informed about additional therapeutic alternatives. This is particularly true for new products or new important indications for the existing products.

(2517) However, for the reasons explained below, the Commission considers that competition in promotion should not be regarded as a source of significant competitive constraints from the specific perspective of the relationship between perindopril and its potential competitors. It is recalled that all the analysed products[3310] were launched some time before the investigated period, before the year 2000. As to perindopril, in 2000, it had been marketed for over ten years. Any new promotional efforts were adding to the existing goodwill capital accumulated over the previous years as reflected in the existence of loyal prescribers among the practitioners.[3311]

(2518) In the previous section, it was established that the continued use patients treated with perindopril were mostly unlikely to switch to alternative medicines once they had settled on the use of perindopril. They constituted the bulk of all perindopril patients and tended to continue their treatment for prolonged periods of time. In view of the existing switching barriers and the predominance of the continued-use patients, the potential impact of promotional efforts taken by the producers of other medicines on the sales of perindopril must be regarded as limited.

(2519) Moreover, the evidence presented in section 6.4.5.2 shows that Servier's promotional efforts were focused on potential new patients comprising newly diagnosed hypertensive patients and patients whose conditions were not being controlled satisfactorily by other antihypertensive agents, and specific groups of patients for whom perindopril had particularly good evidence.

(2520) It is also worth noting that in its strategy documents Servier itself was ambiguous about how to interpret the impact of changes in promotional efforts relating to other

3310 The products listed in paragraph (2271).

3311 See section 6.4.5.6.

ACE inhibitors, such as the end of promotional investment in ramipril caused by generic entry into this product. The ceasing of ramipril's promotion was viewed both as a threat and an opportunity for the sales of perindopril.[3312] As regards the producers of non-ACE inhibitors such as BMS, Novartis, Ipsen and Pfizer, the Commission notes that they did not regard themselves as being in direct competition with perindopril for a significant proportion of new patients.[3313] This also indicates that there was no intention to target perindopril in the promotional policies carried out by those other producers.[3314]

(2521) As Servier itself underlines in its reply to the Statement of Objections, its promotional expenditure was by and large stable throughout the investigated period.[3315] The Commission notes that the expenditure remained stable despite several other producers stopping the promotion of their products in the course of the same period.[3316] In this context, the said stability of Servier's promotional expenditure implies the largely autonomous character of perindopril's promotion and the lack of exposure to significant competitive constraints.

6.5.1.2.5.2 Impact of the regulatory framework

(2522) With respect to the regulatory framework, the Commission has examined its relevance in each of the selected Member States.[3317] It notes that the initial pricing decisions had an *ex ante* character (without knowledge of actual substitution) and thus could not take into account all the market developments in the years to come.[3318] The Commission also observes that Servier's perindopril, at least until the arrival of generic perindopril, received average prices (in terms of price per DDD) comparable, if not higher, to the prices of other ACE inhibitors included by Servier on the list of its closest reference products.[3319]

(2523) The regulatory frameworks that offered more generous reimbursements of treatment costs tended to reinforce the price insensitivity on the part of doctors and patients in the UK, the Netherlands and France. Contrary to Servier's assertions,[3320] the

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3312 See paragraph (2358).

3313 See section 6.3.4.2.

3314 In its reply to the Statement of Objections, Servier argues that nonetheless it was subject to strong competitive pressure from sartans. As a direct reason for the exposure to pressure from sartans, Servier indicates that it did not have any sartans in its own product portfolio (see Servier's reply to the Statement of Objections, paragraph 1477, ID10114, p. 451-452). The Commission must reject this argument since it is largely immaterial for the analysis of competitive constraints over the sales of perindopril. If at all, the possession of a sartan in Servier's product portfolio could have exposed perindopril to premature internal cannibalisation, i.e. the process by which demand is steered between two products within a single company.

3315 Servier's reply to the Statement of Objections, paragraph 1594, ID10114, p. 488.

3316 See Table 35.

3317 See sections 6.4.1.1, 6.4.1.2, 6.4.2.1, 6.4.2.2, 6.4.3.1, 6.4.3.2, 6.4.4.1 and 6.4.4.2.

3318 In this context, the Commission notes an important difference between the AstraZeneca case (COMP/A. 37.507/F3) and the present investigation. The AstraZeneca case concerned the first product in a new class of medicines and focused, to a large degree, on the initial phase of product marketing. The present case relates to a mature class of medicines and focuses on the end of the originator's product life cycle at the eve of generic entry. Therefore, the initial pricing and reimbursement decisions of the authorities, due to their remoteness in time, are less important for the present analysis. On the other hand, any regulatory interventions dating from the investigated period (2000-2009) are regarded as highly pertinent.

3319 See *Annex A: Price developments*. See also footnotes 3031, 3059, 3083 and 3119 for the alternative review of prices per tablet/capsule.

3320 Servier's reply to the Statement of Objections, paragraphs 1527-1532, ID10114, p. 467-468.

administrative decisions to include perindopril in the same reimbursement and reference groups along with other ACE inhibitors cannot be considered as relevant for the purpose of the present analysis insofar as such decisions did not provide for any effective mechanism that would relate the sale conditions of perindopril to changes in the sale conditions of other ACE inhibitors. Only in Poland the reimbursement conditions for perindopril were both reviewed on a regular basis and related to the price of cheaper medicines.[3321] However, as shown in Figure 9, Servier did not adapt its prices to lower reimbursement levels and managed to fully shift the burden of higher co-payments to the Polish patients.

(2524) The rules concerning substitution at the pharmacy level excluded (in the UK, France and Poland), or practically excluded (in the Netherlands), therapeutic substitution that would allow pharmacists to react to changes in the relative prices of available treatments by diverting a part of the existing demand to relatively cheaper medicines.

(2525) Moreover, the regulatory systems did not take any significant steps which would have enabled other ACE inhibitors to exert downward pressure on sales or prices of perindopril, including by reacting to the relative changes in prices of various antihypertensive treatments that occurred before the end of Servier's market exclusivity for perindopril. Notably, the only time during the period of Servier's exclusivity the national authorities administratively reduced the price of perindopril in response to changes in the relative prices of other medicines was when the French authorities decided to lower the prices of two doses of perindopril by only 2 to 5%. This price reduction was a measure adopted in response to the approximately 50% decreases in the prices of other ACE inhibitors that had become available generically in the preceding period. In addition, the said measure was coupled with the launch of the third dose of perindopril at the official price that effectively compensated Servier for the price reduction introduced with respect to the first two doses.

(2526) In its reply to the Statement of Objections and to the Letter of Facts, Servier argues that in the UK the sales of perindopril were under competitive pressure from other cheaper ACE inhibitors due to the policies adopted by certain PCTs that actively encourage local GPs to stop treating new patients with over expensive perindopril.[3322] As explained in paragraph (2280), the Commission takes note of those policies, but their cumulative effects must be at best considered as limited since they did not influence the overall sale trends in the UK during the period of Servier's exclusivity over the sales of perindopril (before July 2007),[3323] which is also reflected in the results of the natural events analysis carried out for the UK.[3324] It must be noted that Servier could only support its argument with fragmented data which is not reflected in the overall data for the UK, therefore its argument must be dismissed.

(2527) Overall, the Commission finds that the regulatory frameworks protected perindopril from competitive constraints from the beginning of the investigated period until the end of Servier's market exclusivity over perindopril. The regulatory systems limited to a large extent Servier's exposure to price constraints and thus allowed Servier to act free of competitive pressure with respect to the sales of its perindopril. This

3321 See Figure 9 and Servier's reply to the Statement of Objections, paragraphs 1532, ID10114, p. 468.

3322 Servier's reply to the Statement of Objections, paragraphs 1536-1540, ID10114, p. 469-473 and Servier's reply to the Letter of Facts, paragraphs 132 and 188-207, ID10324, p. 42 and 57-63.

3323 See section 6.4.1.4.

3324 See section 6.5.1.2.3.3.

finding is supported by the AstraZeneca judgment according to which *"[t]he fact that […] the regulatory systems did not influence the prices or the amount of sales of PPIs [the product under investigation] by reference to the lower prices of H2 blockers [the alleged competitors] leads to the conclusion that the reimbursement levels granted to PPIs to a large extent prevented the lower prices of H2 blockers from exercising a competitive constraint over them".*[3325]

6.5.1.2.6 Strength of the generic constraint

(2528) The purpose of this section is to analyse the strength and nature of the generic constraint as compared to other potential constraints encountered by Servier in its sales of perindopril.

(2529) As already explained in sections 6.4 and 6.5.1.2.3., by the end of 2009, the arrival of generic perindopril on average led to a price decrease of 90% in the UK, 81% in the Netherlands, 27% in France and 17% in Poland. The average price changes are based on the evaluation of the prices of both original and generic products. On each of the markets, generic perindopril was sold at prices lower than Servier's branded product. Table 41 summarises the key data in this respect.

Table 41: Price changes resulting from generic entries (in local currencies, per DDD)

Member State	Reference period (the last half-year before generic entry)	Servier's price in the reference period	Servier's price in 2009H2	Generic price in 2009H2	Average price in 2009H2
United Kingdom	2007H1	[0.20-0.50]	[0.10-0.50]	[0.02-0.10]	[0.02-0.10]
Netherlands	2007H1	[0.40-0.60]	[0.20-0.60]	[0.05-0.20]	[0.05-0.20]
France	2008H1	[0.60-0.80]	[0.40-0.60]	[0.20-0.50]	[0.40-0.60]
Poland	2005H2	[0.55-0.80]	[0.50-0.75]	[0.20-0.60]	[0.50-0.75]

Source: The Commission's own calculation based on ID1774, ID1804, ID1844, ID1846, ID1851, ID1857, ID1861, ID1865, ID1869, ID1872, ID1873, ID1875, ID1884, ID1886, ID1963, ID1965 and ID3347.

(2530) Table 41 shows that the important savings for the consumers in terms of the lower average price were obtained through the market expansion of cheaper generic perindopril, where the generics managed to shift the sales volumes from Servier (the UK and the Netherlands), or at least to take over the incremental growth of the perindopril sales (France and Poland). The generic penetration was slower in those Member States where Servier successfully launched perindopril arginine (France and Poland). This also explains the differences observed with regard to the price and volume developments among the selected Member States. The above table also shows that Servier itself did not match the generic prices with its branded product, which confirms the importance of the generic penetration for providing the consumers with the maximum savings. For the sake of completeness, it must be noted that Servier supplied the so-called friendly generics in the UK (from July 2007) and in France (from October 2009) with non-branded products. With respect to this part of its sales, Servier did match the generic prices.

(2531) As it has been demonstrated above, as a result of generic perindopril entry, the average prices of perindopril were substantially lower (in the range of 17% to 90%)

[3325] See Judgment of 1 July 2010 *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 174 and also 191.

and the volumes were, to a larger or lesser extent, shifted from Servier's original product to its generic substitutes. During the period when Servier totally controlled sales of perindopril, there were substantially higher prices than in the scenario of generic presence. Table 42 shows the figures recalculated in order to demonstrate the hypothetical price increase from the 'generic presence' to the 'exclusive seller' situation. In all four cases, the hypothetical price increases are substantial and range from 19% for Poland to 963% for the UK.

Table 42: Hypothetical price changes resulting from reversing the 'generic presence' into the 'exclusive seller' situation (in local currencies, per DDD)

Member State	Average 'generic presence' price in 2009H2	Reference period for the 'exclusive seller' situation	'Exclusive seller's' price in the reference period	Hypothetical price increase in percentage terms
United Kingdom	[0.02-0.10]	2007H1	[0.20-0.50]	963%
Netherlands	[0.05-0.20]	2007H1	[0.40-0.60]	455%
France	[0.20-0.50]	2008H1	[0.60-0.80]	38%
Poland	[0.20-0.60]	2005H2	[0.55-0.80]	19%

Sources: The Commission's own calculation based on ID1774, ID1804, ID1844, ID1846, ID1851, ID1857, ID1861, ID1865, ID1869, ID1872, ID1873, ID1875, ID1884, ID1886, ID1963, ID1965 and ID3347.

(2532) The strength of generic constraint on Servier's sales of perindopril as compared to other potential constraints brought about by different molecules stemmed from, on the one hand, the bioequivalence of original and generic perindopril and, on the other hand, the effective differentiation of antihypertensive treatments (see section 6.5.1.2.2). Therefore, on the markets where perindopril *arginine* could not obstruct generic substitution (the UK and the Netherlands), the producers of generic perindopril were getting, immediately upon their market entry, access to the entire patient base accumulated by Servier. In this sense, virtually all the perindopril patients were becoming marginal consumers responsive to price changes by individual perindopril producers. The residual demand faced by each producer was characterised by high price elasticity, which explains the rapidity of price decreases in the UK and in the Netherlands. In this context, it must be noted that the high price elasticity of residual demand faced by each of the multiple producers contrasts with the price inelasticity exhibited by the total market demand for perindopril prior to generic entry. This confirms the determinant role of price competition after generic entry.

(2533) On the markets where perindopril *arginine* was successfully introduced (France and Poland), Servier was less exposed to the generic constraint and the generic penetration was effectively slowed down. However, the generic constraint was still much stronger than any other potential constraint.[3326] There were no other potential competitors that would be capable of constraining Servier's perindopril in the same way with respect to the core of its patient base. Nowhere in its reply to the Statement of Objections does Servier point to any equivalent constraint which would be able to counterweight the absence of generic entry. Neither the arrival of the substantially cheaper generics of other ACE inhibitors, nor the continuous promotional efforts on the part of the producers of on-patent sartans were sufficient to constrain the sales of Servier's perindopril in terms of its prices, volumes or associated costs to any similar

[3326] E.g. see paragraphs (2475) - (2483).

extent to generic perindopril. The Commission considers the lack of any equivalent constraint as a highly pertinent factor for its analysis. The Commission's opinion in this regard also takes into account the overall context of Servier's practices that aimed at hindering entry of generic perindopril.

(2534) It is also worth recalling the general stability and composition of the perindopril patient base as confirmed both by Servier's own longitudinal studies (see sections 6.4.5.5 and 6.5.1.2.4) and by the Commission's survey of practitioners (see sections 6.4.5.7 and 6.5.1.2.4). Other antihypertensive medicines could be at best regarded as imperfect substitutes with respect to the sales of perindopril to the first-time use patients who only accounted for a limited fraction of all perindopril patients at any moment of the investigated period. The general inability of other products to price constrain perindopril was also demonstrated in the natural events analysis (see section 6.5.1.2.3), where it was shown that no other molecule exercised a significant competitive constraint on perindopril.

6.5.1.2.7 Conclusion on the relevant product market

(2535) Based on the body of evidence, for the purpose of this investigation, the Commission comes to the conclusion that with respect to the patients supplied in the retail (pharmacy) segment, perindopril faced no significant constraints and therefore the single product market represents the relevant dimension for the product market. For the avoidance of doubt, the market for perindopril supplied to the patients in the retail segment includes any perindopril produced by Servier and its generic competitors. As regards the hospital segment, the Commission sees no need to decide on the precise dimension of that market for the purpose of the present case.

(2536) As a part of this conclusion, the Commission wants to reiterate the main reasons for which a seemingly broad choice of therapies for the pathology in question did not translate into significant constraints over the sales of perindopril.

(2537) Starting from the product that is the subject of the practices under review, a relevant product market comprises all those products which are regarded as sufficiently substitutable by the consumer by reason of the products' characteristics, their prices and their intended use.[3327] Perindopril aims at lowering blood pressure. There were many other medicines with the same therapeutic use. Some used the same general mode of action. Others were more remote. None of them had clear evidence of superiority. Therefore at first sight, it may not seem completely intuitive that a medicine such as perindopril may constitute a market in its own right, where many other similar medicines were available. However, certain functional similarities do not answer the question whether those other medicines represented sufficiently close substitutes to constrain Servier's behaviour given the circumstances of the case.

(2538) Antihypertensive medicines' effectiveness and side effects differ from one patient to another.[3328] Many patients are likely to develop side effects for certain medicines. In other words, for any new patient, only an initially unknown subset of available medicines will be compatible. As soon as it is discovered that a given medicine alone, or in combination, adequately treats the patient's condition without side effects, the doctor is unlikely to risk provoking side-effects by deciding to switch this patient to another treatment. A doctor would be unlikely to risk her patient's well-

3327 See Market Definition Notice, cited above.

3328 *2003 Guidelines for Management of Hypertension*, Journal of Hypertension (2003), Vol. 21 No 6.

being for a few euros of savings in the monthly treatment cost. This does not exclude that the health authorities or the patients who are asked to participate in their medical expenses may attempt to influence the doctor's choice of treatment on the basis of cost considerations.

(2539) The health risks related to switching of successfully treated patients will generally lead to a relatively low propensity to switch for so-called continued-use patients. For first–time use patients, the choice of medicine is guided by the nature of the condition, the doctor's preference and the most likely side effects. The doctors' personal experience accumulated over prescription of drugs and reading literature leads to a narrowed-down array of medicines that each of them is ready to test on new patients. The doctors are surely aware of the broad choice of therapies, but they naturally tend to prescribe new patients with the medicines which have shown to be good for their previous patients. This well-known phenomenon is often referred to as "*the doctors' inertia*".

(2540) The degree of substitutability of a given molecule with other molecules will therefore depend, among other things, on the degree of doctors' inertia and on the relative proportion of continued-use patients out of all patients treated with a given medicine. These may differ over time and depend on the type of pathology. These are empirical questions which require due consideration on a case-by-case basis.

(2541) With respect to perindopril, it is established that perindopril could benefit from both effects. Already prior to the investigated period the medicine had accumulated a large base of continued-use patients. Those patients were expected to continue the treatment for a significant period, while the existing group of loyal prescribers continuously provided for an inflow of new patients.

(2542) The combination of the aforementioned factors, the *ex ante* uncertain effects of treatments and the doctors' personal experience, effectively restricted the substitutability between available therapies.

(2543) Substitutability is an economic concept when examined for the sake of defining a relevant market. Economic substitutability only exists if changes in their relative prices (or other important economic variables) shift a significant proportion of the sales from one product to another.

(2544) In the case of perindopril, decreases in the prices of other medicines that may have well been intended for the same use did not negatively affect the sales of perindopril. The reasons for this are the doctors' general disregard towards prices and the price rigidities induced by regulatory frameworks. Prices still mattered, sometimes because of incentives being gradually built in for doctors to prescribe cheaper medicines and sometimes because of payments by patients, however, not to a sufficient extent. Perindopril was virtually immune to changes in relative prices. There were also no other means to adequately replace competition in prices. Once the continued-use patients were known to dominate the patient base, and the doctors' inertia was established, other forms of competition, such as promotional efforts, could have, at best, a limited impact on the existing sales of perindopril.

(2545) The limited effectiveness of constraints imposed by other medicines stands in stark contrast to the strength of the constraint expected from (and eventually introduced by) perindopril's own generics. In principle, generic perindopril could challenge all the existing sales of original perindopril. The exposure of Servier's perindopril to the generic threat was neither limited by the existence of the continued-use patient base

nor by the doctor's inertia (even if some doctors may prescribe the originator's brand only). Moreover, the regulatory frameworks promoted price competition between original and generic perindopril.

(2546) The generic constraint must be regarded as critical for the assessment of the relevant product market in the case in which the objected practices were aimed at neutralizing the very same constraint. The fact that the generic constraint outweighs by an order of magnitude all other potential constraints facing original perindopril naturally leads to the finding of a narrow market comprising only the medicine in question. If compared to the generic constraint, other sources of constraints for perindopril were insufficient to exercise the effective competitive pressure. Elimination of the generic constraint can be shown to have significant effects in terms of the overall customer spending on perindopril. This being said, the relative strength of various constraints is an empirical question and may not necessarily be similar in other cases, in particular those in which a generic constraint is less eminent.

6.5.1.3 Relevant geographic market

(2547) In the present case, the Commission does not find any particular facts that would point to the need to divert from the earlier practice of defining the markets for pharmaceuticals as national in their geographic scope.[3329] The Commission considers that the national nature of pharmaceutical markets derives from a number of factors. These include in particular different price and reimbursement rules (see section 6.4), differences between national rules on incentives for cheaper generic (see section 6.4), as well as different brand and packing strategies (see section 6.2.7), different distribution and certain, however in the present case minor, differences in prescribing habits of doctors (see section 6.4.5.7 and *Annex D: Survey of prescribers*). As an illustration, reference can be made to the varying prices for perindopril in the selected Member States (see section 6.4). At this stage, Union law harmonisation is mainly limited to rules relating to the authorisation of medicinal products (either nationally or through a centralised EU system), in particular rules aimed at ensuring that the products concerned fulfil requirements in terms of safety, quality and efficacy.

6.5.1.4 Time dimension

(2548) Since the Commission's finding does not hinge on any critical event, but builds on the sum of evidence, the definition of the relevant product market relates in principle to the entire period under investigation, i.e. the period 2000 to 2009. The Commission notes that the key elements for the competitive analysis, in particular the price rigidity of the demand for perindopril and the switching barriers remained unchanged through the entire period.

6.5.1.5 Conclusion on the relevant market

(2549) It is concluded that perindopril faced no significant constraints with regard to the patients supplied through the retail (pharmacy) channel in France, the Netherlands, Poland and the UK,[3330] in the period 2000 to 2009. The relevant market is defined as

[3329] See the Commission's Decision of 15 June 2005 in the *AstraZeneca* case (COMP/A. 37.507/F3), recital 503.

[3330] For the avoidance of doubt, the Commission makes no finding as to the scope of the relevant market for perindopril in other Member States. In the present case, the market definition relies on the economic substitutability, as opposed to those cases in which definitive market boundaries can be already established at the stage of the functional analysis. It means that apart from the review of product

comprising of original and generic perindopril in each of the four national markets defined above.

6.5.2 Dominance

(2550) According to settled case law a dominant position is *"a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers"*[3331].

(2551) Holding a dominant position confers a special responsibility on the firm concerned, the scope of which must be considered in the light of the specific circumstances of each case.[3332]

(2552) Such a position does not preclude some competition but enables the undertaking which profits from it, if not to determine, at least to have an appreciable influence on the conditions under which competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment.[3333] The notion of independence which is the special feature of dominance is related to the level of competitive constraints facing the undertaking in question.[3334] Such power may involve the ability to eliminate or seriously weaken existing competition or to create barriers to entry for potential competitors. As the Court stated, the existence of a dominant position does not however require the producer enjoying it to have eliminated all possibility of competition.[3335] In other words, dominance does not imply the absence of any competitive constraint.

(2553) The assessment of dominance takes into account several factors, including the market position of the dominant undertaking and its competitors, the exposure of the dominant undertaking to competition in terms of future expansion by actual competitors and entry by potential competitors and the bargaining strength of the undertaking's customers. The economic analysis requires that the process of finding dominance involves the assessment of those factors that are relevant for the determination of market power. Subject to the available evidence, this may also include the estimation of economic rents.

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characteristics, the present analysis has required the full analysis of the nature of the demand for perindopril. Therefore, it is not possible to determine whether in other Member States, the relevant market would have taken the same product dimension, in particular without reviewing the impact of potential natural events, the existing switching patterns, the impact of the regulatory frameworks and the degree of exposure to various potential constraints.

3331 Judgment in *United Brands v Commission*, C-27/76, EU:C:1978:22, paragraph 65. See also Judgment in *Hoffman-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraph 38; and Judgment in *Michelin v Commission*, C-322/81, EU:C:1983:313, paragraph 30.

3332 Judgment of 6 October 1994, *Tetra Pak v Commission*, T-83/91, ECR, EU:T:1994:246, paragraph 114; Judgment of 17 July 1998, *ITT Promedia NV v Commission*, T-111/96, ECR, EU:T:1998:183, paragraph 139; Judgment of 7 October 1999, *Irish Sugar v Commission*, T-228/97, ECR, EU:T:1999:246, paragraph 112; Judgment in *Michelin v Commission*, C-322/81, EU:C:1983:313, paragraph 97.

3333 See Judgment in *Hoffman-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraphs 38 and 39.

3334 See Judgment in *Hoffman-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraphs 42-48, and Judgment of 28 February 2002, *Atlantic Container Line and others v Commission*, T-395/94, ECR EU:T:2002:49, paragraph 285.

3335 See Judgment in *United Brands v Commission*, C-27/76, EU:C:1978:22, paragraph 113; and Judgment of 1 July 2010 *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 267.

(2554) The above-mentioned factors will be assessed one by one in the subsequent sections in the following order: (i) position of Servier on the relevant market, (ii) barriers to entry, (iii) position of Servier in terms of economic rents, and (iv) countervailing buying power. These sections are preceded by the summary of Servier's main arguments received in response to the Statement of Objections.

6.5.2.1 Summary of Servier's main arguments

(2555) In its reply to the Statement of Objections, Servier disagrees with the Commission's preliminary finding of dominance. According to Servier, during the entire period under investigation, the sales of perindopril were exposed to the competitive pressure exercised by other ACE inhibitors and sartans. In this regard, Servier refers to the history of perindopril's development as one of the last ACE inhibitors launched on the market, its character of a follower product with respect to ramipril and perindopril's modest market share on the market for ACE inhibitors.[3336]

(2556) Servier contests the appropriateness of the Commission's quantification of Servier's economic rents. Servier maintains that it is inadequate to compare the price of a product under patent protection with the price of the same product after the elapse of patent protection for the purpose of establishing the size of economic rents enjoyed by the originator company during the patent protection period. It adds that because of the omnipresent regulation, the prices of medicines are not freely determined by the manufacturers. Relatively high prices of medicines before generic entry reflect the policy of the Member States aimed at promoting the research and development of new medicines. According to Servier, the Commission's analysis ignored the astronomical costs of the research and development incurred by the originator companies which contrast with a fundamentally different cost structure of generic companies. In its opposition to the Commission's preliminary findings, Servier also refers to its modest size as compared to other originator producers and the fact that the company is managed by a non-profit foundation.[3337]

(2557) Servier argues that its perindopril's market share on the market comprising as a minimum all ACE inhibitors was not higher than 15% throughout the entire period under investigation. On the market comprising both ACE inhibitors and sartans, Servier's perindopril remained below the *de minimis* level of 10%. In terms of volume sales perindopril was not a leader of the ACE inhibitor class. Moreover, the choice of available treatments prevented Servier from behaving independently of its competitors, customers and consumers. According to Servier, the absence of dominance is equally demonstrated by the comparison of promotional expenditure. Servier's promotional efforts never exceeded those of its competitors.[3338]

(2558) Regarding the barriers to entry, Servier recalls that the patent rights are insufficient for establishing of a dominant position. In Servier's view, the existence of a dominant position depends on the market definition and the availability of alternative technologies. Servier insists that none of its (secondary) patents led to a delay in generic entry. Its patents in question only related to certain processes ('339, '340 and '341) and one crystalline form of one salt of perindopril ('947), while the generic companies were fully capable of developing alternative perindopril technologies.[3339]

3336 Servier's reply to the Statement of Objections, paragraphs 1610-1616, ID10114, p. 491-493.
3337 Servier's reply to the Statement of Objections, paragraphs 1617-1631, ID10114, p. 493-497.
3338 Servier's reply to the Statement of Objections, paragraphs 1632-1642, ID10114, p. 497-500.
3339 Servier's reply to the Statement of Objections, paragraphs 1643-1652, ID10114, p. 500-502.

(2559) Concerning the countervailing buying power, Servier argues that the cross-border differences in the prices of perindopril show that the public authorities had strong bargaining power. Several public authorities set the price of medicines with reference to other medicines from the same class or the same medicine in other Member States. In addition, local health and insurance authorities can practically limit the list of medicines available for prescribers. Finally, Servier argues that the fact that the public authorities consider the costs of research and development in setting the prices of new medicines does not indicate the bargaining power of the originator companies but reflects the Member States' policy in support of innovation.[3340]

(2560) The above arguments of Servier will be addressed in the relevant parts of the assessment of dominance that is set out below.

6.5.2.2 Position of Servier on the relevant market

(2561) Market shares provide a useful first indication for the Commission of the market structure and of the relative importance of the various undertakings active on the market. Low market shares are generally a good proxy for the absence of substantial market power. In the case-law, it has been held that market shares of more than 50% constitute very large market shares and are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position,[3341] and that market shares of between 70% and 80% are a clear indication of the existence of a dominant position.[3342]

(2562) The market shares presented below are established on the basis of the value of sales in the retail distribution channel as provided by IMS Health.

(2563) Table 43 shows the market shares of Servier and of other producers of perindopril in the UK in the period 2000-2009. Servier was in control of the relevant product market until the year 2007. In section 6.4.1.4, the Commission also presented the market data directly collected from the sellers of perindopril. Table 22 reveals the abrupt loss of sales by Servier already as of the second-half of 2007. Therefore, based on the gathered evidence, it can be concluded that Servier's control over the relevant product market in the UK lasted from January 2000 to June 2007.

3340 Servier's reply to the Statement of Objections, paragraphs 1653-1658, ID10114, p. 502-504.

3341 Judgment in *AKZO v Commission*, C-62/86, EU:C:1991:286, paragraph 60.

3342 Judgment of 12 December 1991, *Hilti v Commission*, T-30/89, ECR, EU:T:1991:70, paragraph 92; and Joined Judgment of 30 September 2003, *Atlantic Container Line and Others v Commission*, T-191/98, T-212/98 to T-214/98 ECR, EU:T:2003:245, paragraph 907.

Table 43: Market shares on the relevant product market in the UK

Year	Total market (GBP '000s)	Servier	Generics	Parallel traders
2000	25 973	[90–100]* %	[0–5]* %	[0–5]*%
2001	30 001	[90–100]*%	[0–5]*%	[0–5]*%
2002	36 642	[90–100]*%	[0–5]*%	[0–5]*%
2003	46 693	[90–100]*%	[0–5]*%	[0–5]*%
2004	65 272	[90–100]*%	[0–5]*%	[0–5]*%
2005	73 424	[90–100]*%	[0–5]*%	[0–5]*%
2006	88 087	[90–100]*%	[0–5]*%	[0–5]*%
2007	92 039	[70–80]* %	[20–30]* %(*)	[0–5]*%
2008	63 449	[5–10]* %	[90–100]*%(*)	[0–5]*%
2009	25 350	[5–10]*%	[90–100]*%(*)	[0–5]*%

Note: (*) – the figures include the sales from the generics authorised by Servier (Teva and Generics UK). Since the UK consumers profited from the significant price erosion as of the moment of the first lasting generic entry in July 2007, Servier can be given the benefit of the doubt and thus the Commission does not distinguish between the sales of the authorised and independent generics in the period July 2007 to December 2009.

Source: IMS.

(2564) Table 44 shows the market shares of Servier and of other producers of perindopril in the Netherlands in the period 2000-2009. Servier was in control of the relevant product market until the year 2008. In section 6.4.2.4, the Commission also presented the market data directly collected from the sellers of perindopril. Table 25 reveals the abrupt loss of sales by Servier in the first-half of 2008. Therefore, based on the gathered evidence, it can be concluded that Servier's control over the relevant product market in the Netherlands lasted from January 2000 to December 2007.

Table 44: Market shares on the relevant product market in the Netherlands

Year	Total market (EUR '000s)	Servier	Generics	Parallel traders
2000	6,441	[80-90]%	0%	[10-20]%
2001	7,441	[60-70]%	0%	[30-40]%
2002	8,913	[50-60]%	0%	[40-50]%
2003	10,968	[60-70]%	0%	[30-40]%
2004	14,443	[80-90]%	0%	[10-20]%
2005	17,659	[70-80]%	0%	[20-30]%
2006	20,536	[70-80]%	0%	[20-30]%
2007	24,744	[70-80]%	0%	[20-30]%
2008	7,399	[40-50]%	[50-60]%	NA
2009	7,411	[20-30]%	[70-80]%	NA

Source: IMS, ID1774, ID1804, ID1844, ID1846, ID1865, ID1869, ID1873, ID1875 and ID3347.

Note: In its analysis, the Commission has uncovered certain discrepancies between the company data and the IMS data. Therefore, the above presented market shares have been recalculated in the way that the IMS data was used to establish the total size of the market, while the company data was used to establish the market positions of Servier and generics. The residual was allocated to the parallel traders. The resulting figures may be slightly distorted by the fact that the company data relate to both the retail and the hospital distribution channels; however this fact is of minor significance for the overall assessment.

(2565) Regarding the role of parallel traders, the Commission observes that by their very nature, parallel traders are not engaged in the marketing of products differing from the original reference product, in this case from Servier's perindopril. After repackaging and re-labelling as the case may be, parallel traders in fact sell the originator product which they have obtained, directly or indirectly, from the same originator in another Member State. In the present case, parallel traders were entirely dependent on whether and to what extent Servier decided to supply markets in low-price Member States. As shown in section 6.2.7 on product brands, Servier introduced local brands that could effectively prevent parallel traders from getting involved in arbitrage between certain pairs of markets. For these reasons, the market shares held by parallel importers at any given time in the markets concerned overstate their actual market power.

(2566) Table 45 shows the market shares of Servier and of other producers of perindopril in France in the period 2000-2009. Servier was in control of the relevant product market until the end of the period. Based on the gathered evidence, it can be concluded that Servier's control over the relevant product market in France lasted at least from January 2000 to December 2009.

Table 45: Market shares on the relevant product market in France

Year	Total market (EUR 000's)	Servier	Generics	Parallel traders
2000	59,903	[90–100]* %	[0–5]* %	[0–5]* %
2001	62,939	[90–100]* %	[0–5]* %	[0–5]* %
2002	67,418	[90–100]* %	[0–5]* %	[0–5]* %
2003	73,601	[90–100]* %	[0–5]* %	[0–5]* %
2004	89,128	[90–100]* %	[0–5]* %	[0–5]* %
2005	102,094	[90–100]* %	[0–5]* %	[0–5]* %
2006	118,984	[90–100]* %	[0–5]* %	[0–5]* %
2007	133,992	[90–100]* %	[0–5]* %	[0–5]* %
2008	152,547	[90–100]* %	[0–5]* %	[0–5]* %
2009	145,093	[80–90]* %	[10–20]* %	[0–5]* %

Source: IMS.

(2567) Table 46 shows the market shares of Servier and of other producers of perindopril in Poland in the period 2000 - 2009. Servier was in control of the relevant product market until the end of the period. Based on the gathered evidence, it can be concluded that Servier's control over the relevant product market in Poland lasted at least from January 2000 to December 2009.

Table 46: Market shares on the relevant product market in Poland

Year	Total market (PLN 000's)	Servier	Generics	Parallel traders
2000	96,173	[90–100]*%	[0–5]*%	[0–5]*%
2001	108,321	[90–100]*%	[0–5]*%	[0–5]*%
2002	111,062	[90–100]*%	[0–5]*%	[0–5]*%
2003	116,264	[90–100]*%	[0–5]*%	[0–5]*%
2004	121,595	[90–100]*%	[0–5]*%	[0–5]*%
2005	139,558	[90–100]*%	[0–5]*%	[0–5]*%
2006	136,129	[90–100]*%	[0–5]*%	[0–5]*%
2007	145,355	[90–100]*%	[5–10]* %	[0–5]*%
2008	153,485	[80–90]*%	[10–20]*%	[0–5]*%
2009	144,477	[80–90]*%	[10–20]*%	[0–5]*%

Source: IMS.

(2568) The high market shares of Servier are not surprising in view of the fact that the relevant product market comprises only perindopril, i.e. the product over which Servier enjoyed exclusivity for most of the period in question. In addition, Servier was successful in its strategy of replacing the *erbumine* salt with the *arginine* salt in France and Poland, which effectively impeded generic penetration in these two Member States.

(2569) In its response to the Statement of Objections, Servier does not point out any material mistakes or omissions with respect to the Commission's calculation of shares within the market for perindopril. However, since Servier disagrees with the Commission's

market definition, it presents its own calculation of market shares based on a broader product market.[3343] The Commission addresses Servier's arguments pertaining to the market definition in section 6.5.1. The Commission also notes that Servier's own calculation is not based on the value of sales but on the volume of sales measured in DDDs.[3344]

(2570) Regarding Servier's claim of being exposed to strong competition from other medicines even within the relevant market narrowly defined by the Commission,[3345] for the sake of clarity, it is reiterated that neither other ACE inhibitors nor sartans have been included in the relevant market. The competitive pressures exercised by other ACE inhibitors and sartans must be regarded as insufficient. In particular, Servier's claim is at odds with the substantial economic rents collected by Servier in the course of the investigated period (see section 6.5.2.4).

6.5.2.3 Barriers to entry

(2571) The most obvious barriers to entry in the present case are the patents detained by Servier. In *AstraZeneca* the General Court recalled that *"it cannot be argued that intellectual property rights do not constitute a relevant factor for the purposes of determining the existence of a dominant position. Although the mere ownership of an intellectual property right cannot confer [a dominant] position, their possession is none the less capable, **in certain circumstances**, of creating [such a] position, in particular by enabling an undertaking to prevent effective competition on the market (see, to that effect, Magill, paragraph 229 above, paragraphs 46 and 47) [emphasis added]"*.[3346] The General Court also stated that *"[t]he mere possession by an undertaking of an exclusive right **normally** results in keeping competitors away, since public regulations require them to respect that exclusive right. [emphasis added]"*[3347] The notion of barriers to entry does not require that barriers are absolute in order to include them in the assessment of dominance. The analysis of barriers to entry includes factors affecting timely and sufficient entry.

(2572) Given the definition of the product market and the range of patents owned by Servier, Servier was in a strong position to control the market of perindopril and to behave independently on this market. For most of the investigated period, Servier could rely on the patent protection of perindopril[3348] dissuading the generic competitors from entering the relevant market. Before the expiry of SPC for perindopril's compound, the patent protection had an absolute character unless the compound patent had been revoked. After its expiry, Servier benefited from the three process patents ('339, '340, '341), other secondary patents in particular from the '947 patent excluding from the market all perindoprils containing the alpha crystals. In France and in Poland, where Servier successfully shifted the existing patient base to the *arginine* salt, the relevant patents protecting that salt constituted an additional barrier to expansion for the generic producers offering the products based on the *erbumine* salt of perindopril.[3349]

3343 E.g. Servier's reply to the Statement of Objections, paragraph 1446, ID10114, p. 441.

3344 For the effects of the DDD conversion on the reported figures, see footnote 3027.

3345 Servier's reply to the Statement of Objections, paragraph 1614, ID10114, p. 492.

3346 Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 270.

3347 Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, para. 362.

3348 See sections 4.1.1.2 and 4.1.2.1.

3349 In its reply to the Statement of Objections, Servier points at the Court's judgment in the Synthon case to argue that the different salts of perindopril were fully substitutable (see Servier's reply to the Statement

(2573) Servier did not hesitate to enforce its secondary patents even those that it internally classified as paper patents or patents with zero inventive step either by means of warning letters sent to the potential entrants informing about a possible infringement of Servier's rights[3350] or by litigating against generic entrants before the courts. Servier's enforcement actions resulted in among others an interim injunction against Apotex, which delayed the effective generic entry in the UK by eleven months.[3351]

(2574) Therefore, the Commission concludes that Servier's market position was strengthened by important barriers aimed at dissuading potential competitors from entering the relevant product market for most of the investigated period. The secondary patents, e.g. the process and crystalline form patents, required potential competitors to incur additional costs by seeking alternative processes and crystalline forms, and exposed them to the threat of litigation with Servier. The patents relating to the *arginine* salt must be viewed as barriers to expansion whenever Servier was successful in carrying out its switching strategy.

(2575) In its reply to the Statement of Objections, Servier claims that its patents did not dissuade the launch of generic perindopril.[3352] The Commission notes that such assertions are not supported by the basic facts of this case. It is recalled that despite a number of generics repeatedly attempting entry, the first entries happened only several years after the expiry of the primary patent protection, i.e. only after the considerable time which was required by the generic companies to overcome the barriers to entry erected by Servier on the top of the primary patent protection over perindopril's compound. In view of the foregoing it is self-evident that Servier's secondary patents had in general a dissuading effect on generic entry.

(2576) The fact that the Commission relies on the significant economic rents (see section 6.5.2.4) and on the intellectual property rights in establishing Servier's dominant position should be viewed as natural in the context of the present case where Servier made recourse to the patent settlements and acquisitions to prolong its economic rents beyond the basic patent protection period. However, for the avoidance of doubt, the Commission wants to underline that neither enforcing the intellectual property rights nor enjoying the high economic rents during the legitimate period of legal protection[3353] would have received its attention if not for Servier's practices that are the subject of this investigation.[3354]

(2577) The position of market power is inherent in the system where innovation is rewarded by the exclusivity that intellectual property rights confer on the author of the innovation. The prospect of economic rents is precisely meant to give incentives for

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of Objections, paragraph 1652, ID10114, p. 502). Servier's argument hinges on the general point of principle, but does not take into account that the principle of full substitutability between different salts of the same molecule is not confirmed by the case facts (see paragraphs (2322) and (2343)). For example, regarding the Polish market, Servier's argument is contradicted by the contemporaneous evidence (see paragraph (2343)) that demonstrates Servier's awareness of the fact that the *arginine* and *erbumine* salts were not substitutable due to the differences in their molecular weight.

3350 See paragraph (153).

3351 See paragraph (2289).

3352 Servier's reply to the Statement of Objections, paragraph 1647, ID10114, p. 501.

3353 Contrary to Servier's allegations (Servier's reply to the Statement of Objections, paragraph 1643, ID10114, p. 500), the term "legitimate protection" as used by the Commission does not distinguish between primary (compound) and secondary (e.g. process) patents. Legitimate patent protection is offered by any valid patent.

3354 See sections 4, 5 and 8.

new innovation and so fuel the economic progress. However, if the commercial success of the protected product is prolonged through abusive practices, the holder of the rights may indeed be held liable for violation of Union competition law. The Commission wants to recall that the prohibition only concerns the abuse of a dominant position, not holding the position as such.

(2578) The Commission regards dynamic competition in R&D as an important mechanism of economic growth. This mechanism requires that the market power needed to attract innovation is restricted in time and in scope as foreseen in the applicable legislative framework. These restrictions are necessary in order to keep incentives for the undertaking enjoying temporary market power to further develop through genuine innovation and avoid being overtaken by competitors. Prohibition of the abuse of a dominant position is only aimed at the attempts of circumventing the existing restrictions of market power that originate from the mechanism of dynamic competition and not at its exercise in terms of collecting the economic rents during the legitimate period of legal protection.

6.5.2.4 Economic rents

(2579) The position of economic strength enjoyed by Servier is confirmed by the economic rents that Servier managed to extract in the period 2000 to 2009, with exception of the post-generic entry periods in the UK and in the Netherlands. For the avoidance of doubt, the notion of economic rents refers to the difference between the actual returns from an activity and the returns necessary to attract resources to conduct that activity. Substantial economic rents are equivalent to monopoly profits, that is persistent significantly high returns relative to those which would prevail in a competitive market for the product in question, which a dominant undertaking can gain when it is able to prevent effective competition on the relevant market. Such market power includes the ability to charge high prices independently from its competitors.[3355]

(2580) In the view of the Commission, there is no systematic evidence or *a priori* reason to believe that the originator companies suffer from higher average production (or distribution) costs as compared to their generic competitors. Thus, and save proof to the contrary, the steady post-generic entry price covers costs, both of the generic and originator companies. It follows that it is possible to estimate the amounts of rents enjoyed by the originator company, in the present case by Servier, prior to generic entry by multiplying the gap between pre- and post-entry prices with quantities sold by the originator company. This implicitly assumes that generics are in vibrant competition and that the steady post-generic entry price indeed reflects effective competition. Since in the present case the Commission has not investigated the nature of competitive relations between generic companies, the observed post-generic entry price can only be assumed to be a conservative estimate of the effective competition price level.

(2581) To recall the basic facts, prior to generic entry, Servier was able to charge on average prices that were substantially higher than the above mentioned steady post-generic entry prices, which are assumed to represent the competitive price level for the purpose of quantifying the economic rents enjoyed by Servier.[3356] Table 47

3355 See Judgment in *Hoffman-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraph 38.

3356 Servier argues that both the prices of patent protected products and of generics are regulated and consequently cannot be relied upon to establish a dominant position (Servier's reply to the Statement of

summarises the relevant data. Servier's average price per DDD was set at the average level from the last six months in which Servier was still considered to be in control of the relevant product market. The steady post-generic entry price was calculated as a weighted average price of generic perindopril per DDD in the last six months of 2009. The difference between the two prices was multiplied with the quantities supplied by Servier during the period of its control over the relevant markets. The results can be viewed as a proxy of the economic rents that Servier was able to appropriate on each of the relevant markets during the period in question. Table 47 clearly shows that the economic rents were substantial both in terms of their total amount and of the price gap over the generic price.

Table 47: Economic rents enjoyed by Servier

Member State	Period concerned	Servier's price	Steady generic price	Servier's quantities (in million DDDs)	Economic rents (in million local currency)
United Kingdom	2000H1-2007H1	[0.20-0.50]	[0.02-0.10]	[500-1,500] (#)	[a three digit figure]
Netherlands	2000H1-2007H2	[0.40-0.60]	[0.05-0.20]	[75-225] (#)	[a two digit figure]
France	2000H1-2009H2	[0.40-0.60]	[0.20-0.50]	1,400 (##)	[a three digit figure]
Poland	2000H1-2009H2	[0.50-0.75]	[0.20-0.60]	[750-2,000] (#)	[a three digit figure]

Source: The Commission's own calculation based on the IMS data and ID1774, ID1804, ID1844, ID1846, ID1851, ID1857, ID1861, ID1865, ID1869, ID1872, ID1873, ID1875, ID1884, ID1886, ID1963, ID1965 and ID3347.

Notes: # - the company data were recalculated to reflect the boundaries of the relevant market: the retail segment (0.95 – discount factor); ## - the IMS data from the retail panel.

(2582) In view of the foregoing, the Commission finds that Servier was in a position to operate on the relevant market without facing any significant constraints that would introduce a downward pressure on its substantial economic rents enjoyed during the investigated period. The only constraint capable of restricting Servier in terms of its economic rents was effective generic entry as observed in the UK and the Netherlands.

(2583) The Commission also notes that by means of its anti-generic strategy, Servier was capable of delaying the entry of cheaper generic products and on top of that in France and Poland, of substantially slowing down generic penetration, and thus Servier is found to be able to behave independently vis-à-vis its only significant competitive constraint on the relevant markets.

(2584) In its reply to the Statement of Objections, Servier claims that the comparison of prices before and after patent expiry cannot provide the adequate basis for finding of dominance since higher pre-expiry prices and related economic rents serve the purpose of incentivising pharmaceutical companies to innovate and develop new

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Objections, paragraphs 1622 and 1623, ID10114, p. 494). The Commission disagrees with Servier's reasoning. Dominance is an objective notion. A source of market power may be important in explaining how that market power came into being but is immaterial as to the question of its presence or absence. The Commission wants to point out an analogy to the General Court's judgment in the AstraZeneca case, where it was found that the fact that competitive constraints are absent (or insignificant) due to the regulatory framework does not affect the very finding of the absence (or insignificance) of competitive constraints (see Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 174).

products.[3357] The Commission considers that it is incorrect to differentiate between market power protected with intellectual property rights and other forms of market power, and to deny that the former can be interpreted in terms of dominance. Servier's argument is not supported by the existing case law which stipulates that the ownership of an intellectual property right is capable, in certain circumstances, of creating a dominant position.[3358]

(2585) Furthermore, Servier argues that the Commission does not take into account that the originator companies are burdened with the substantial costs of developing new medicines contrary to the generic companies that specialise in much less resource intensive copying of the existing products.[3359] The Commission considers that for the purpose of discussing the amount of economic rents and the level of prices, any incurred costs must be considered as sunk. There is no guarantee that the sunk costs will be recouped nor any obligation to lower the prices once it happens. The analysis of the originator's business model and its sustainability, where the originator company has to indeed recoup the initial investments across its product portfolio in order to sustain its business in the long run, should not be confused with the market analysis concerning an individual product. For the avoidance of doubt, the Commission notes that Servier cannot claim that it was not given ample opportunities to recoup its investment into the perindopril product. Apart from several patents, Servier could and did benefit from additional protection provided by the SPC.[3360]

6.5.2.5 Countervailing buyer power

(2586) In section 6.1, the Commission has already explained that the demand for prescription medicines is generated through the interaction of the number of actors: patients, doctors, pharmacists and national health (insurance) systems. The inclusion of the centralised buyer (health system) on this list necessarily raises the question of countervailing buyer power. For the avoidance of doubt, the other agents involved on the demand side, i.e. patients, doctors and pharmacists, cannot exert countervailing buying power given their high degree of fragmentation vis-à-vis the single seller.

(2587) The prices of original products are either agreed in the direct bargaining process between the authorities and the originator companies (e.g. France) or are subject to certain forms of caps restricting the amount of public financing via profitability limits (e.g. the UK) or reference pricing (e.g. the Netherlands and Poland).[3361] However, the initial bargaining power of the public authorities is largely restricted by their objective of sustaining the continuous research and development of new medicines. The Court recognised this characteristic of the price setting process in the judgement delivered in the Lelos case, by stating that *"[a[s the second and third recitals to Directive 89/105 state, the task of the authorities when setting prices of medicines is not only to control expenditure connected with public health systems and to ensure the availability of adequate supplies of medicinal products at a reasonable cost, but also to promote efficiency in the production of medicinal*

3357 Servier's reply to the Statement of Objections, paragraph 1620, ID10114, p. 493.

3358 See Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 270.

3359 Servier's reply to the Statement of Objections, paragraph 1626, ID10114, p. 495.

3360 See section 4.1.1.2.

3361 See section 6.4 for the more detailed description of the regulatory mechanisms used in relation to perindopril.

products and to encourage research and development into new medicinal products. As the Advocate General indicated in points 90 to 93 of his Opinion, the level at which the selling price or the amount of reimbursement of a given medicinal product is fixed reflects the relative strength of both the public authorities of the relevant Member State and the pharmaceuticals companies at the time of the price negotiations for that product".[3362]

(2588) In this context, the Commission observes that with respect to its perindopril product, from the beginning of the investigated period till the end of its exclusivity over perindopril, Servier received the average price comparable, if not higher, to the original prices of other ACE inhibitors included by Servier as its closest reference products.[3363] The Commission also notes that the initial pricing decision had an *ex ante* character (without knowledge of actual substitution) and thus could not take into account all the market developments in the years to come.

(2589) Furthermore, as the General Court confirmed in AstraZeneca, *"it may be in the strategic interest of pharmaceutical undertakings not to market their products on certain markets, where the prices which national authorities are prepared to pay do not meet their expectations".*[3364] However, in the present case, it remains beyond any doubt that Servier found it highly profitable to sell its perindopril on each of the relevant markets.

(2590) As evidenced in the facts of the case,[3365] the public authorities did not take any measures during Servier's period of exclusivity over perindopril which would seriously undermine Servier's position and thus its ability to acquire the economic rents.[3366] In particular, the public authorities did not effectively react to the entries of cheaper generic versions of other antihypertensive medicines, nor to the fact that Servier were able to steadily increase its absolute profits from perindopril until the arrival of generic perindopril. This is understandable, since by intervening the public authorities would risk creating an inter-temporal inconsistency in their policy towards the entire pharmaceutical sector that would potentially be damaging for the general incentives to innovate in that sector.

(2591) Against this background, the Commission concludes that Servier was not faced with countervailing buying power that would prevent it from acquiring the significant economic rents during the period when it was in control of the relevant markets. Moreover, the public authorities were not in the position to influence the entry of cheaper generic products, while as already mentioned, Servier proved to be capable of delaying generic entry. Therefore, the Commission is persuaded that Servier was able to behave, to a significant extent, independently vis-à-vis the public authorities.

3362 Joined Judgments in *Sot. Lélos kai Sia*, C-468/06 to C-478/06, EU:C:2008:504, paragraph 63.

3363 See *Annex A: Price developments* and footnotes 3031, 3059, 3083 and 3119.

3364 See Judgment of 1 July 2010 *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 257.

3365 See sections 6.4.1.1, 6.4.2.1, 6.4.3.1 and 6.4.4.1.

3366 The high (even if not absolute) stability of the official prices of Servier's perindopril prior to generic entry are demonstrated in Figure 3, Figure 5, Figure 7 and Figure 9. Small modulations of prices, especially for reasons such as fluctuations in exchange rate (e.g. Poland) or industry wide schemes (e.g. UK), cannot be regarded as an exercise of buying power. To be effective countervailing buyer power must deter an attempt by the undertaking to profitably increase or maintain prices.

(2592) Servier opposed the Commission's preliminary findings similar to those above by claiming that (a) the cross-border price differences,[3367] (b) the use of cross-border price reference mechanisms[3368] and (c) the power to exclude certain medicines by the local authorities such as the PCTs in the UK[3369] demonstrate the existence of strong countervailing buyer power. The Commission cannot accept Servier's arguments. Despite differences in demand preferences and the resulting cross-border differences in prices, on each of the concerned markets Servier enjoyed considerable economic rents (see Table 47). The cross-border price reference mechanisms cannot be regarded as the exercise of buyer power if they do not lead to a considerable reduction in the price of the product in question (see section 6.4 for more details on the relevant regulatory systems). Finally, the measures put in place by certain PCTs in the UK cannot be considered as sufficient to moderate Servier's market power in the UK as a whole (see also paragraph (2526)).

6.5.2.6 Conclusion on dominance

(2593) In view of the foregoing, it is concluded that Servier held a dominant position within the meaning of Article 102 of the Treaty on the market of original and generic perindopril in the following countries and in the following periods which are relevant to the present case: the UK from January 2000 to June 2007, the Netherlands from January 2000 to December 2007, France from January 2000 to December 2009 and Poland from January 2000 to December 2009.

(2594) In addition, the Commission wishes to point out that – irrespective of the market definition set out in section 6.5.1 – there is strong evidence indicating that Servier held a dominant position in its sales of perindopril. This view is based on the fact that in the present case, the Commission observes the direct manifestation of market power enjoyed by Servier.

(2595) For the purpose of conducting the competition analysis, market power refers to the ability of an undertaking to behave independently and to among others increase its price above the level that would prevail under competitive conditions and thereby to enjoy the economic rents.[3370]

(2596) The direct assessment of market power becomes possible at the moment the existence of the economic rents can be positively verified against the benchmark of the outcome under conditions of effective competition. The said benchmark is rarely available in cases concerning the on-going conduct, when the effective competition outcome remains unknown. In this respect, the Servier case is different because most of the conduct under investigation belongs to the past and therefore the Commission could establish the likely effects of introducing effective competition.

(2597) The Commission also considers that the prices observed in the period before effective competition was actually put in place had not been the result of normal market forces. In this regard, the Commission refers to the General Court's observation in AstraZeneca *"that, since prices are influenced by decisions of public authorities as regards reimbursement levels or maximum prices, those prices are not the result of normal market forces. It is not therefore possible to argue that the level*

3367 Servier's reply to the Statement of Objections, paragraph 1654, ID10114, p. 503.
3368 Servier's reply to the Statement of Objections, paragraph 1656, ID10114, p. 504.
3369 Servier's reply to the Statement of Objections, paragraph 1657, ID10114, p. 504.
3370 See section 6.5.2.4 for the definition of the economic rents.

of a price set in such a context is competitive, since it has been set in the absence of competitive mechanisms for ascertaining where such a competitive level lies".[3371]

(2598) The Commission considers that the existence of the substantial economic rents demonstrated in section 6.5.2.4 is the first and decisive element in making the direct finding of dominance. The other necessary conditions are met when calculating the economic rents. These conditions are: (a) the ability to establish the equilibrium post-generic entry prices, which are assumed to represent the competitive price level, and (b) the actual competitive entry by generics, which not only proves that the pre-entry prices could attract generic entry but also that the market was sufficiently large in order to accommodate such an entry. From the fact that the reference is made to the post generic entry equilibrium, it should be also inferred that the generic entries in question were long lasting.

(2599) The Commission notes that the economic rents enjoyed by Servier had the long-lasting character due to the existing barriers to entry that dissuaded potential generic competitors from entering the relevant product market for most of the investigated period and in certain cases (France and Poland) due to the barriers to expansion that Servier erected by switching the patient base to the *arginine* salt (see section 6.5.2.3). Servier was also free of the significant constraints from the buyers' side (see section 6.5.2.5). Therefore, there was no effective mechanism of dissipating the substantial economics rents of Servier, which is tantamount to the ability to behave to an appreciable extent independently of its competitors and its consumers.

(2600) The Commission considers that the direct finding of dominance can be made in relation to the entire period under investigation except the periods after the effective generic entries in the UK and in the Netherlands. Such a time dimension is based on the fact that at least from the year 2000, Servier and its generic competitors were persuaded that generic entry into perindopril was economically viable and would take place as soon as the barriers to entry were overcome by a potential entrant. In this context, the Commission wants to recall that both Servier with its anti-generic strategy and [company name]* with its generic project decided to put into action their respective plans already in the second half of the year 1999.[3372]

3371 Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 265.

3372 See sections 4.1.2 and 4.2.1.1, respectively.

7 TECHNOLOGY MARKET

7.1 Introduction

(2601) This section will assess the boundaries of the technology market at issue in the present case.

(2602) The practices of Servier as described in sections 5 and 8 respectively relate to removing the sources of API technology by means of patent settlement agreements between Servier and a number of generic counterparts and the acquisition of technology developed by Azad. Technology can be described as an input integrated either into a product or a production process.[3373] Patent settlement agreements and transfers of technology can affect competition both in input and output markets. In the case of vertically integrated generic producers such as Krka and Lupin, the originator company's strategy of eliminating generic threat may, and in the present case did, combine the blocking of generic entry into the final product market, for example by means of non-compete clauses, with the practices aimed at foreclosing the relevant technologies upstream. Such practices are complementary. Therefore, in addition to the final product market for perindopril formulations (see section 6) where the effects of the investigated practices could be conceivably felt by the final consumer (the downstream market), this Decision addresses the technology market for the production of perindopril API (the upstream technology market).

(2603) This section starts by examining the competitive constraints that the holders of perindopril API technology were facing as far as the demand is concerned. It then turns to supply side substitutability. It concludes that the relevant technology market is limited to perindopril API technology and is at least an EU-wide market.

(2604) First, functionally, only those API technologies that the generic companies considered at least at one point as a potentially reasonable route to the EU markets could potentially constrain the market position of the holders of perindopril API technology, in particular the position of Servier as the incumbent.

(2605) Second, using the demand for perindopril API (which incorporates perindopril API technology) as a proxy, this section assesses the propensity of generic companies to switch to another supplier of perindopril API in response to a 5-10% price increase for the chosen API source or in the extreme to discontinue the pursuit of perindopril API technology. It finds that for almost the entirety of the relevant period the demand for perindopril API, and therefore for API technology was price inelastic.

(2606) Third, given that the underlying demand for perindopril formulation does not consider other APIs/medicines as substitutable in terms of price competition, the demand for API technology, which is derived from the downstream demand, had to be also price inelastic. As the cost of perindopril API was only a small part of the total production cost of perindopril formulations[3374] and an even smaller part of the price of perindopril formulations, price inelasticity for the downstream product translates into an even greater inelasticity with respect to the upstream technology.

3373 E.g. see *Commission Notice - Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*, Official Journal C 101, 27.04.2004, p. 2-42, paragraphs 23-24 (the "Technology Transfer Guidelines").

3374 See also paragraphs (2653) – (2655) and footnote 3432.

(2607) The revocation of the '947 patent that eventually unblocked several suppliers of the API and API technology resulted in more elastic demand for individual sources of perindopril API and API technology.

(2608) The lack of price sensitivity of the demand for perindopril API technology points to a market for such technology. Turning to supply side substitutability, the section concludes that technologies to produce alternative molecules could not constrain the technology for perindopril API. Companies which had already developed API technology for other medicines could not easily switch to making perindopril API technology and indeed there is no single example of such a switch taking place within a reasonably short period of time. Moreover, the evidence relating to switching shows that the consumers of perindopril API technology would not switch away from perindopril API technology in response to 5-10% permanent increases in price.

(2609) Regarding dominance, the review of potentially viable sources of non-Servier perindopril API technologies does not reveal any sources of technologies sufficiently substitutable to those of Servier. In view of the considerable barriers to entry in the form of Servier's own patents relating to the perindopril API technologies and in the absence of countervailing buyer power, the section concludes that at the relevant time Servier was not confronted with significant constraints on the relevant technology market for perindopril API technology.

Summary of Servier's main arguments

(2610) In its reply to the Statement of Objections, Servier disagrees with the Commission's definition of the technology market and the subsequent finding of Servier's dominance on the relevant technology market for the perindopril API technology.

(2611) Servier argues that in view of the absence of Servier's dominant position on the relevant downstream market,[3375] where the perindopril formulation products were sold, Servier could not be dominant on the derived upstream market for the API technologies required for entering the downstream product market. Servier stresses the fact that during the concerned period there were readily available technologies for the production of APIs of ACE inhibitors other than perindopril and of sartans. Therefore, according to Servier, the competitors who were unsuccessful in obtaining the perindopril API technology could have easily switched to other technologies that would have provided them with an entry opportunity to the same broad product market on the basis of selling another ACE inhibitor or a sartan.[3376]

(2612) Servier also submits that, apart from multiple non-perindopril technologies, potential entrants had an unrestricted access to the perindopril technologies of which many were not controlled by Servier. In making this argument, Servier relies on the number of perindopril patents obtained by third parties as a result of their research activities aimed at crystalline and non-crystalline forms (as well as other salts) of perindopril other than those covered by the Servier patents.[3377] Servier also lists multiple suppliers who were allegedly prepared to deliver perindopril API to the generic companies during the investigated period.[3378] Furthermore, Servier argues

[3375] See sections 6.5.1.2.1. and 6.5.2.1 for a summary of Servier's main arguments pertaining to the product market and dominance on that market.

[3376] Servier's reply to the Statement of Objections, paragraphs 1683-1702, ID10114, p. 507-510.

[3377] Servier's reply to the Statement of Objections, paragraphs 1703-1715, ID10114, p. 511-513.

[3378] Servier's reply to the Statement of Objections, paragraphs 1774-1890, ID10114, p. 522-542.

that it itself facilitated generic entry by offering licenses to its own technologies to the interested generic companies.[3379]

(2613) Based on the example of [company name]*'s technology with its initial development cost of EUR [50,000–150,000]*, Servier submits that the perindopril technologies were relatively easy to obtain through the interested companies' own research efforts.[3380] Moreover, Servier recalls that [company name]*'s patent was eventually annulled for lack of an inventive step as compared to the prior art relating to indolapril, i.e. another ACE inhibitor. In Servier's view, the latter fact proves that the relevant technology market was not restricted to the perindopril API technology.[3381]

(2614) As a point of law, Servier refers to the Sanofi-Synthélabo / Aventis[3382] and Abbott/Solvay[3383] merger cases to argue that in its previous investigations the Commission accepted the general substitutability among different APIs.[3384]

(2615) Finally, Servier criticises the Commission's delineation of the geographic market as "at least EU-wide in scope" and maintains that the market was world-wide.[3385]

7.2 The relevant technology market

(2616) The pharmaceutical supply chain is very complex and may include several levels upstream of the final product. The supply chain can comprise the following levels: (i) R&D for development of new/improved molecules (compounds); the (ii) technology to viably[3386] produce an API of a given molecule; (iii) the manufacture and supply of the API; (iv) the technology to produce final formulations (e.g. tablets, drops etc.), including know-how for regulatory approval; (v) the production of final dosage forms; and (vi) the marketing of final formulations. Generic companies carry out all or certain activities referred to in points (ii) to (vi), while the originator's core distinctive feature is their involvement in R&D for new or improved medicines.

(2617) In general, the development of an API technology consists of several steps. As a first step, the specific chemical route to the target molecule is chosen (the *"route of synthesis"*). As with perindopril, such steps may also relate to how crude API may be

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3379 Servier's reply to the Statement of Objections, paragraphs 1761-1773, ID10114, p. 520-522.

3380 Servier's reply to the Statement of Objections, paragraphs 1752-1760 and 1859-1899, ID10114, p. 519-520 and 543-544.

3381 Servier's reply to the Statement of Objections, paragraph 1716, ID10114, p. 513.

3382 COMP/M.3354 – *Sanofi-Synthélabo / Aventis.*

3383 COMP/M.5661 – *Abbott / Solvay*; The Commission notes that in Servier's reply to the Statement of Objections (paragraph 1695, ID10114, p. 509-510) Servier relies on a truncated quote, the full quote reads: *"In previous decisions, the Commission concluded that active ingredients (APIs) form separate product markets which are upstream of the market of the finished pharmaceutical products. The Commission has looked at each individual API as potentially constituting a relevant market by itself. However, it cannot be excluded that certain APIs may be substitutable with each other for all, or for a range of, applications"* (see paragraph 14). It is evident that for the purpose of the merger decision in question, the substitutability between different APIs was regarded as an exception and not the rule.

3384 Servier's reply to the Statement of Objections, paragraphs 1695 and 1717-1722, ID10114, p. 509 and 513-514.

3385 Servier's reply to the Statement of Objections, paragraphs 1742-1751, ID10114, p. 518-519.

3386 Viability is understood as the regulatory and economic viability of technologies in view of their commercialisation on the EU markets. In this sense the API production technology cannot be separated from the subsequent steps in the supply chain. For a generic company, it is critical that the API production technology is at least potentially viable to a degree that allows the generic company and its potential business partners to expect a positive rate of return on the investments incurred in further product development that may eventually lead to commercialisation of the final product.

further modified to achieve a specific solid form, for example by crystallisation. This is followed by a period of optimisations of the route of synthesis to improve process efficiency (fine tuning of conditions for each step of the synthesis route). Analytical methods, which serve to control the quality of the API, are also developed. The process is then scaled-up with a view to industrial production. Once the scale-up is achieved, the process must be validated to ensure that it delivers products of consistent quality, and the DMF, compiling data on the API and the way it is produced, is prepared for the MA application. After this, any process changes must be carefully assessed with respect to product quality.[3387]

(2618) The potentially viable technology to produce generic API will essentially comprise the technology for production processes, but can also relate to bioequivalent forms of the API (i.e. different salts, crystalline forms). [3388] For the purpose of the present assessment, the API process technology, including relating to other bioequivalent forms, will be simply referred to as "API technology".[3389] The technology is not simply geared towards producing the API, but towards meeting the requirements for obtaining marketing authorisation for the final formulation based on the API. Notably, a marketing authorisation application needs to contain the DMF. The API technology may form a bundle of proprietary rights including patent rights, know-how and other proprietary information, which are necessary to produce and successfully commercialise an API, as well as final products based thereupon.[3390] The API technology can also be transferred independently of the actual manufacturing, either by licensing or acquisitions of IPRs.

(2619) In this case, it is appropriate to focus on the market for API technology for the following reasons. First, the investigated conduct related to the API technology. Either the technology was removed by means of acquisition, or patent settlements prevented the possibility for the technology to become established as non-infringing. Although patent settlements primarily concerned perindopril formulations, they had the practical effect of blocking the API technology by both the non-challenge obligation (inability to attempt to establish the API technology as non-infringing) and the non-compete obligation (inability to commercially use the API technology).

3387 See for example, Adler, Brunner, Fichtner et al. *"Process Development for Active Pharmaceutical Ingredients Following a Development Cascade"*, Chimia, vol 60, No. 9, 2006.

3388 Servier claims that an imprecise definition of the relevant technology does not allow it to exercise its rights of defence (see Servier's reply to the Statement of Objections, paragraph 1707, ID10114, p. 512). Paragraph 1520 of the Statement of Objections explains that *"the API technology to produce a given molecule shall be the focus of this section"*. It is evident from paragraph 1609 of the Statement of Objections that the API technology *"needed to enable production on an industrial scale […] allow for efficient production […] meet relevant regulatory (MA) requirements"*. It means that the technology in question had to encompass all the necessary aspects (including production processes, crystalline forms, salts…) required to obtain a perindopril API that would represent *"a reasonable route to the market"*. In view of the foregoing, Servier's claim concerning the Commission's imprecise definition of the relevant technology must be dismissed.

3389 The term "perindopril API process technology" is used at several instances in this section to remind that the technologies in question concerned the production process of perindopril API. However, in most instances, the term is shortened to "API technology". For the avoidance of doubt, the shortened term also refers to the technologies to make the API and not to the knowledge contained in the compound patent.

3390 There is also technology to produce perindopril formulations (such as tablets or other finished dosage forms), which can be patent protected. In this specific case, however, the formulation technology was not decisive for the competitive process and is therefore not further assessed in this Decision.

(2620) Second, Servier's position on the technology market determined the competitive conditions on the directly downstream market for API supplies and further downstream markets. For generic companies, it was important to obtain a supply of perindopril API which was produced under a viable technology. The technology needed to enable production on an industrial scale. It also had to allow for efficient production. It had to meet relevant regulatory (MA) requirements for perindopril. In addition, the actions of generics also show concern with respect to the patent position of the technology in question.[3391] For generic companies, the question how the API is produced (i.e. what process technology was used in view of the patent situation) can be of equal importance as the qualitative attributes of the API itself in choosing where to source the API.

7.2.1 Method and context for defining the technology market

(2621) The basic principles applied in market definition assessments are set out in detail in section 6.5.1.2 above. However, it is useful to recall that *"[t]he main purpose of defining a market in both its product and geographic dimension is to identify in a systematic way the competitive constraints that the undertakings involved face"*.[3392] With respect to the technology market, the main question is whether there were other sources of API technology that were capable of constraining Servier and capable of preventing it from behaving to an appreciable extent independently of effective competitive pressure.

(2622) Technology markets consist of the intellectual property that is licensed and its close substitutes, that is to say, other technologies which customers could use as a substitute.[3393] Substitute technologies are other technologies which are regarded by the licensees as interchangeable with or substitutable for the licensed technology, by reason of the technologies' characteristics, their price and their intended use.[3394]

(2623) The methodology for defining technology markets follows the same principles as main product market definitions. Starting from the technology relevant for the assessment of market definition and market power, in this case Servier's perindopril API technology, those other technologies to which customers could switch in response to a small but non-transitory increase in relative prices need to be identified.

(2624) In the context of the present case, it is important to distinguish complementary groups of knowledge which are subject to patent protection. An originator company will consider filing patent applications at different stages of the R&D process for a given medicinal product. The first applications usually concern the API (the molecule, or compound). The resulting patent is often referred to as a "primary", or "basic" patent because it is the first patent for a given API, typically offering the broadest protection to the patent holder. Later during the development phase and, not uncommonly, also after the product launch by the originator, further patent

3391 It seems that generics preferred technology which was not covered by any of Servier's patents. However, as these were scarce, it appears that generic companies may have been more open to using an API technology covered by the '947 patent (which was widely seen as vulnerable to attack) than API technology which would risk infringing the process patents.

3392 *Commission notice on the definition of the relevant market for the purposes of Community competition law*, Official Journal C 372, 9.12.1997, p. 5 - 13, point 2.

3393 *Communication from the Commission - Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, point 116.

3394 *Commission Notice, Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*, O.J. C 101 (27 April 2004) p. 2-42, point 22.

applications are made for other aspects of that API (such as salts, crystalline forms, etc.) or for particular pharmaceutical formulations (for example, ways how the medicine itself is administered, mixtures of active ingredients and other substances which may influence how the active substance is released in the body). Process patents refer to a different group of patents which relate to the way to synthesise the API (or other substances, for example raw materials for the production of the API) and how to produce formulations (for example, tablets). Such patents are often referred to as "secondary patents".[3395]

(2625) Because of its earlier filing date, the compound patent is usually the first to expire. Often a compound benefits from additional protection provided by an SPC. But this additional protection may also expire before the lapse of key secondary patents covering the production process or processes used by the originator company. Therefore there is a moment in time when the knowledge relating to the API (the compound) becomes a public good, while the originator's production process is still patent protected. As a result, generic companies may try to establish alternative processes to produce the API. The routes of chemical synthesis may differ. However, since all these process technologies lead to synthesising the same API, they can in principle be regarded as functionally substitutable. Economic substitution depends on whether a given process technology is sufficiently efficient at the industrial scale and also depends on the prevailing market conditions. As noted in paragraph (2618), the technologies in question had to be viable in both regulatory[3396] and economic terms at the relevant time. Contrary to Servier's suggestions,[3397] the analysis is not limited to Servier's production technology of perindopril in its alpha crystalline form, but is premised on the question of viability of concerned technologies.

(2626) In the present case, perindopril API technologies were not only developed but also traded (assigned or licensed), confirming the existence of a market for technology to produce perindopril API. For the investigated period, the Commission received detailed information on a number of actual transactions or failed discussions concerning acquisition or licensing of API technology in the form of patents and know-how (and in certain cases also concerning the formulations). This information comprises 14 transactions regarding perindopril API technology from September 2001 to September 2008, of which (i) four transactions were only attempts which eventually did not materialise; (ii) eight transactions were acquisitions; and (iii) six transactions were licences. Of these 14 transactions, 12 transactions involved Servier, which benefitted from the transferred technology in seven instances and provided it in five. Of the five actual transfers to Servier, four were acquisitions, and only one was a licence. All of the four transfers from Servier were licences, three of them back-licences for acquired technologies.[3398]

3395 Final report on the pharmaceutical sector inquiry, Commission Staff Working Document, para. 138. The report is available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

3396 Any viable technology for manufacturing of an API has to meet the regulatory requirements. Except the patent related matters, those requirements are verified in the course of the market authorisation procedure. The ability to meet the requirements should be regarded as an intrinsic feature of a given technology, i.e. it depends on the technology whether the product based on this technology can meet the regulatory requirements.

3397 Servier's reply to the Statement of Objections, paragraphs 1711-1712, ID10114, p. 512.

3398 See sections 4.2.1.3., 4.2.1.5., 4.2.2.5., 4.2.2.8.4., 4.3.3.6.2., 4.3.3.7.1., 4.3.3.8. and 4.3.4.7.1. as well as ID3764, ID3924, p. 8 and ID4778, p. 2. This summary is non-exhaustive, see for example a reported series of discussions between Sandoz and various sources of API (ID1480, p. 18-19). Transfers of

(2627) Generic companies could obtain the benefit of perindopril API technology in different ways. It was possible for a generic company to be licensed with the technology and to manufacture the API itself. However, the main way for a generic company to obtain the benefit of perindopril API technology was by directly obtaining supplies of the API itself from a company producing the API, together with the required documentation for the DMF so that the generic company could take the necessary measures to obtain regulatory approval.

7.2.1.1 Intended use and characteristics of the perindopril API technology

(2628) The API is the active ingredient of a given medicinal product, and will thus determine its therapeutic characteristics, efficacy, safety and quality. For chemical reasons, it is essential to have perindopril API in order to produce the final perindopril formulations (i.e. in order to obtain the chemical formulation in perindopril medicine it is necessary to include the perindopril API compound). Thus, from the perspective of functional substitutability, perindopril formulations cannot be produced by using the API of another hypertension medicine, even if the APIs (or the medicines) are chemically similar. For these reasons, it is obvious that perindopril formulations can only be produced from perindopril API and no other API.

(2629) For the same reasons, it is necessary to have perindopril API technology in order to produce perindopril API. Given the complexity of the development of API technologies for commercial use (see, for example, paragraph (2617)), the technology to produce API on an industrial scale, and meeting all quality and patent requirements, is highly specific for the given compound. The API technologies which are used to produce APIs for other hypertension medicines cannot be used to produce perindopril API. This critical issue is examined in detail below in section 7.2.1.3 with respect to supply side substitutability.

7.2.1.2 Patterns of substitution by perindopril API users – demand side substitution

(2630) According to the Market Definition Notice, *"[t]he assessment of demand substitution entails a determination of the range of products which are viewed as substitutes by the consumer"*. In order to determine this, *"[t]he question to be answered is whether the parties' customers would switch to readily available substitutes or to suppliers located elsewhere in response to a hypothetical small (in the range 5 % to 10 %) but permanent relative price increase in the products and areas being considered"*.[3399]

(2631) The demand for perindopril API (which incorporates perindopril API technology) can be used as a proxy to assess the competitive constraints that the holders of perindopril API technology were facing.[3400]

7.2.1.2.1 Observed demand-side substitution patterns by generic companies

(2632) The demand for API technologies is determined in particular by generic companies, both as regards the technology itself (proprietary information on the production of the API), as well as the API incorporating the technology. Generic companies first take the decision to develop a specific medicine on the basis of the prevailing and

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DMFs and know-how carried out in the framework of cooperation/supply agreements between API suppliers and undertakings developing generic perindopril formulations are also not included in this overview.

3399 *Commission Notice on the definition of relevant market for the purposes of Community competition law*, OJ C 372, 9/12/1997, points 15 and 17, and paragraph (2623).

3400 See paragraph (2627).

expected market conditions (barriers to entry, degree of present and future competition, competitive advantages). This in turn determines their demand for the API, including the price sensitivity of generic demand for perindopril API. This is exemplified by Krka's feasibility study for the in-house development of both perindopril formulations and perindopril API.[3401]

(2633) The Commission carried out an investigation into price-related substitution patterns concerning perindopril API based on eight generic companies[3402] which were developing their own perindopril formulations and thus had actual experience with the sourcing of perindopril API.[3403] Replies were sought for three time periods to reflect the developments in the availability of potentially viable API sources: 2000 - 2004, 2005 - 2008, and 2009 - 2011.

(2634) In a first step, generic companies were asked whether they would consider switching to a different source of perindopril API in case of a permanent 5-10% increase in the price of their chosen API source. The first question was aimed at verifying the elasticity of the residual demand for individual sources of perindopril API.

(2635) Generally, the companies reported that price was only one amongst the relevant factors which they took into consideration in choosing an API supplier. These factors also included the patent position, the ability to supply commercial quantities, the ability to meet regulatory requirements, and the overall availability of such alternative sources.[3404] A switch to a different API could entail the need for further testing, bioequivalence studies, and regulatory changes with the implied costs and delays, which would put the viability of such a switch into question.[3405]

(2636) The replies by generic companies somewhat differed according to the three periods. Concerning the first period, 2000 - 2004, generic companies for the large part reported that price was not an important consideration in view of the limited availability of potentially viable alternative sources, in particular potentially non-patent-infringing sources.[3406] None of the generic companies reported that it would thus consider switching perindopril API suppliers in the event of a 5-10% permanent price increase. The second period, 2005 - 2008, provides for a more mixed picture. Two companies which would not have considered a switch in the first period did not exclude that such a switch would be possible in the second period (always provided that there were potentially viable alternatives).[3407] By contrast, another company which would not have considered a switch in the first period contended that such a switch would also be unlikely in the second period (2005 - 2008) due to

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3401 See section 4.3.3.1.

3402 Servier's economic consultant criticises the Commission for drawing its conclusions based on a too small sample of generic companies (see Annex 00-01A to Servier's reply to the Statement of Objections, paragraph 152, ID9054, p. 67-68). However, the Commission did not carry out a classic survey for the purpose of which the number of respondents in relation to the entire population may be indeed relevant for assessing the robustness of obtained results. The Commission sent its requests for information to the undertakings best placed to provide informative responses. The fact that not all addressees could reply should not undermine the value of answers received from other respondents. It must also be noted that in its reply to the Statement of Objections, Servier has not identified any generic companies that would have been omitted in the Commission's investigation.

3403 ID4968, p. 5-6, ID4952, p. 4-5, ID5609, p. 2, ID5036, p. 9-11, ID5041, p. 3-4, ID5055, p. 6-7, ID5071, p. 11-12. ID5080, p. 9-11.

3404 ID5080, p. 9, ID4952, p. 5, ID5055, p. 6.

3405 ID5080, p. 9, ID5071, p. 12.

3406 ID5080, p. 9, ID5055, p. 6, ID4968, p. 5.

3407 ID4968, p. 5, ID5080, p. 10. See also ID4952, p. 5.

unavailability of alternative potentially viable, in particular non-infringing, sources of API.[3408] The three remaining companies also considered that they were unlikely to switch supplier in the event of the specified price increase.[3409] In the third period, from 2009 onwards, which largely coincided with the annulment of the '947 patent (and post-dated the abuses analysed in the present Decision), the majority of replies (four out of six) suggest that generic companies were more likely to consider switching to other potentially viable sources of perindopril API.[3410] Two generic companies claimed that they would not consider switching in view of the switching costs and limited impact of API prices on overall commercial viability of perindopril formulations, as explained above in paragraph (2635).

(2637) In a second step, the question whether generic companies would switch to other suppliers in case their perindopril API supplies faced a 5-10% price increase was complemented by the question of whether generic companies would stop the development of perindopril products if the price for all sources of perindopril API increased by 5 - 10%.[3411] The second question was aimed at verifying the elasticity of the overall demand for perindopril API as a proxy for the overall demand for the perindopril API technology.

(2638) In contrast with the responses regarding switching between different perindopril API suppliers, the generic companies' replies to this question did not differentiate between the three periods. Moreover, not a single generic company indicated that it would abandon the development of perindopril products in case of a 5-10% increase in prices for all perindopril APIs. On a more general note, one company explained that a 5-10% increase in API price would generally not be deemed as

3408 ID5055, p. 6.

3409 ID5036, p. 9, ID5071, P.11 – 12, ID5609, p. 2.

3410 ID5080, p. 10, ID4968, p. 5, ID4952, p. 5, ID5055, p. 6.

3411 In its reply to the Statement of Objections (see Servier's reply to the Statement of Objections, paragraphs 1726-1733, ID10114, p. 515-516), Servier criticises the fact that the question asked to generic companies related to an exit from the development of perindopril products and not a potential switch to the development of other ACE inhibitors or sartans. To support its criticism Servier relies on the examples of Lupin and Krka which developed and commercialised other ACE inhibitors. For example, Lupin was known to switch its production facilities between manufacturing of different ACE inhibitors. In advancing its argument, Servier errs in two respects. First, Servier attempts to disentangle the functional and the economic substitution. This is methodologically flawed. The correct test first verifies whether two products or technologies can meet the same needs, in this case whether a given technology can be used as a viable method of manufacturing perindopril API. Only then the subsequent question is asked whether alternative technologies meeting the same needs are regarded as economic substitutes, i.e. what happens to the demand in response to changes in the prices of alternative technologies. To ask the second question without having first decided on the first one is likely to lead to spurious results of the entire market test. Second, as far as Servier's argument hinges on Lupin's ability to accommodate its production facilities between various ACE inhibitors, Servier misinterprets the notion of supply substitution. To be taken into account for the purpose of defining markets, supply-side substitutability must be feasible in the short-term without incurring significant additional costs or risks. It is recalled that in order to enter the market for perindopril, Lupin had to undertake a separate development programme entailing additional investments, time delays and uncertainties (see sections 4.3.4.1.-4.3.4.3.). In view of the foregoing, the Commission cannot consider supply substitution in its market definition and can only view Lupin as a potential entrant interested in the perindopril market. In other words, even if Lupin already developed the technology to produce [product name]*, it nonetheless needed to embark on a discrete development programme to produce perindopril which took no less than six years. Lupin faced the dilemma of how to allocate its production capacity between perindopril and [product name]* only after this long development period.

considerable.[3412] In view of the negative replies, contrary to Servier's suggestions,[3413] it would be immaterial to investigate whether after abandoning the development of perindopril products, the demand would be diverted to the development of other ACE inhibitors or sartans and whether such a diversion would take place with the aim of developing another product that would subsequently compete with perindopril on the downstream product market.[3414]

(2639) In addition to these hypothetical questions, it is useful to look at the actual demand substitution patterns of companies which were, for extraneous reasons, forced to look for a substitute following a disruption of cooperation with a source of perindopril API technology.

(2640) As described in section 4.2.1.2, Teva was in 2001 engaged in discussions on a draft Memorandum of Understanding for co-development and supply of perindopril API with [company name]*, which commercialised the API for [company name]*, the earliest known source of alternative perindopril API technology. [Company name]* offered a decreasing price scale for its API, starting at the higher of USD [< 35,000]* or [20–30]* % of Teva's net sales, and decreasing to the higher of USD [5,000–35,000]* or [20–30]* % of Teva's net sales.[3415] Once these discussions were terminated as a result of [company name]*'s agreement with Servier, Teva began searching for a new source of perindopril API, and started cooperating with Azad, which was developing a technology to produce a non-infringing form of perindopril API. While there is no written trace of any discussions on prices for commercial batches of API, Azad declared that its intention was to sell commercial batches at around USD [< 35,000]* per kg.[3416] Following Azad's conclusion of an agreement with Servier in November 2004, Teva regarded Lupin as a possible alternative supplier, although Lupin's API technology led to the alpha crystalline form. Lupin was reportedly selling the API for USD [15,000 – 25,000] per kg (which was not considered expensive).[3417] Teva also seriously considered [company name]*'s API as a potential second source of supply. [Company name]* had API technology which was claimed to yield non-infringing API, and was selling API at USD [< 100,000]* per kg.[3418] However, Teva abandoned discussions as: "*the product did not meet* [company name]* *claims, especially in relation to patent non-infringement as the crystalline form was the ß-form"*.[3419]

3412 ID5071, p. 12. According to one of the generic companies, the decision to abandon formulation development would depend on the competition in the market, including the number of API suppliers, the number of generic competitors, and the prevailing price level. Ability of in-house production, capacity and constraints may also influence the decision of whether to continue development under such circumstances. ID4968, p. 6.

3413 Servier criticised the Commission's RFI for not asking the generic companies an additional question on other products to which those companies would have turned if they had decided to abandon their respective perindopril development projects (see Servier's reply to the Statement of Objections, paragraph 1726, ID10114, p. 515). Given that the generic companies did not report any diversion to other development projects in response to a 5-10% increase in prices, if asked, the question suggested by Servier would have necessarily remained unanswered. Therefore the Commission must dismiss Servier's claim that the relevant evidence is incomplete.

3414 See also footnote 3411.

3415 ID2477, p. 1-3.

3416 ID1112, p. 6.

3417 ID2478.

3418 ID2478.

3419 ID5055, p. 3.

(2641) There are also other examples of companies opting between various sources of perindopril API technology (for example Krka, Sandoz) in particular depending on the validity of the '947 patent. In these cases, non-alpha infringing API technology was given priority at the times when the '947 patent was still valid, in particular after the intermediate decision of the EPO Opposition Division in July 2006.[3420]

(2642) [Name of Lupin business partner]* was also at an advanced stage of development based on Azad's non-infringing API technology which was terminated following the deal between Servier and Azad. Like Teva, [name of Lupin business partner]* also restarted the development cooperation with Lupin, and eventually ordered a commercial batch of [30-60] kg of API in September 2007 at USD [15,000-25,000] per kg (the same price as quoted to Teva in 2005). However, following delays and in view of the significant decrease of generic perindopril prices in the UK following the annulment of the '947 patent, [name of Lupin business partner]* did not launch in the UK but negotiated supplies from Glenmark (a potentially infringing source) on "*more economic terms*".[3421] Thus, after effective generic entry, the price sensitivity of demand for perindopril API appears to have increased.

7.2.1.2.2 Assessment of observed substitution patterns

(2643) The Commission's investigation[3422] showed that the propensity of generic companies to switch to another supplier of perindopril API in response to a 5-10% price increase for the chosen API source differed according to the time period. In the initial period 2000-2004, price sensitivity of generic companies was very low (no generics would switch in response to such price increases), and more importance was given to securing a source of API which would be potentially viable from a regulatory, patent and industrial production perspective. For the intermediate period from 2005-2008, two of the sampled generics expressed willingness to change the perindopril supplier if the prices of the chosen API increased, provided that an alternative potentially enabling supplier could be found. This further changed in the last period as of 2009, which coincided with the annulment of the '947 patent as the most important patent barrier, and in which the majority of respondents indicated that they would consider switching suppliers of perindopril API in case of such a price increase. The conclusion may be drawn that for almost the entirety of the relevant period the demand for perindopril API was price inelastic. However, generic companies became more price sensitive when the annulment of the '947 patent rendered a number of API technologies non-patent infringing, which in turn led to generic competition. The evidence also shows that, only in the very last period after the '947 patent was annulled, generic companies would arbitrage between different sources of perindopril API in the event the price for their API supplies increased.[3423]

3420 See, for example, section 4.2.2.8.4.

3421 ID1571, p. 21.

3422 See paragraphs (2633)-(2636).

3423 Servier's economic consultants claim that the low propensity to switch between suppliers of perindopril API revealed by the Commission's test implies that the relevant technology market was even narrower than the market for the perindopril API technology (Annex 00-01A to Servier's reply to the Statement of Objections, paragraph 152, ID9054, p. 67-68). In this context, the Commission reiterates that the availability of viable perindopril API was the main concern for interested generic companies. As soon as the availability problem was solved, the generic companies were willing to switch between sources of perindopril API in response to hypothetical small but permanent relative price increases. The initial scarcity of supply sources may indeed imply that at certain periods of time, the relevant market was restricted to the only available supplier. This does not however mean that there were multiple relevant

(2644) On the other hand, none of the generic companies indicated that a 5-10% increase in the price of all perindopril API would make them consider abandoning the development or commercialisation of perindopril products and seek other business opportunities.[3424] Therefore, if such price increases resulted from the situation on the perindopril API technology market, the demand for the perindopril API technology would not be diverted to the technology for APIs for other medicines.[3425]

(2645) The above findings are corroborated by actual observations of how generic companies developing perindopril products formed decisions on sourcing perindopril API technology.

(2646) Generic companies which for some reason had to discontinue cooperation with an API supplier, sought to continue the development of perindopril with another API supplier, even if it meant a price increase often exceeding 5 - 10%. As explained in paragraph (2640), Teva was initially discussing API supplies ranging from USD [5,000–35,000]* to USD [< 35,000]*/kg for the initial batches, and later considered supplying API at prices possibly […]* higher. Similarly, companies like Specifar and Arrow[3426] repeatedly sought alternative supplies of perindopril API after their previous sources became unavailable. This shows that even after repeated failures to complete the product development cooperation with a source of API technology, generic companies continued with the development of perindopril formulations even when it implied, in addition to longer lead times and extra development cost, a significant price increase of the API prices in the period from 2001 to approximately 2008. Potential viability of the API technology in terms of patent and regulatory requirements, as well as of the ability of industrial application, was considered more important than API prices.[3427] Only in the last period from 2009 on (coinciding with the annulment of the '947 patent) did generic companies indeed become more price sensitive. For example, Arrow changed its supplier in order to source its perindopril API "*on more economic terms*".[3428]

(2647) The Commission's investigation into generic companies' hypothetical switching patterns, as backed by the actual evidence on the switching behaviour in the investigated period 2001 - 2009, confirms that the demand for perindopril API prior to the annulment of the '947 patent in the respective jurisdictions was rigid. Although generic companies were sometimes faced with repeated development failures, and/or were confronted with acute lack of available potentially viable perindopril API technologies, they nonetheless persisted in the development of perindopril formulations based on cooperation with the API suppliers. There is no evidence on the file that high prices of perindopril API would lead generic companies to desist

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markets. The file demonstrates that the generic companies, e.g. Ratiopharm, actively arbitraged between various development programmes in their pursuit of viable entry (see paragraphs (353), (354), (448) and (868)).

3424 The Commission notes that Servier claims that the generic companies provided contradictory replies. In particular, Specifar is said to report that a 5-10% increase in the price of all perindopril API would make it abandon its development project (see Servier's reply to the Statement of Objections, paragraph 1738, ID10114, p. 517). The Commission wants to point out that Specifar did not answer to the question concerning the exit from the development of perindopril products. Specifar's answer referred to by Servier relates to a potential switch to another source of perindopril API (see question 5, ID4826).

3425 See paragraph (2637)-(2638).

3426 See paragraph (2641).

3427 See paragraph (2635).

3428 See paragraph (2641).

from developing generic perindopril. This shows that various perindopril API technologies not only faced limited, if any, price-related constraints from other sources of perindopril API technology for most of the investigated period, but also that 5 - 10% price increases would not lead generic companies to abandon the development of generic perindopril. In other words, the observed substitution patterns allow for excluding the hypothesis under which the generic companies developing the perindopril product would regard the technologies used to manufacture APIs for other medicines as a demand substitute for the technology used to make perindopril API.

7.2.1.2.3 The demand for perindopril API technology is derived from demand for final perindopril medicine

(2648) In the present case, the demand for perindopril API process technology is derived from the demand that suppliers of perindopril formulations faced in the final product market. The patent protection for the perindopril compound started to lapse as of 2001 which, together with high prices enjoyed by, and considerable quantities sold by Servier, provided the incentive for generic companies to develop their own production processes for manufacturing perindopril.

(2649) All other things being equal, the higher the price of the final formulation, the higher the willingness of generic companies to pay a relatively high price for the input on the upstream market. A similar observation can be made with respect to the quantities of the final formulation. Assuming positive operational margins, the larger the demanded volumes of the final formulation, the higher the interest of generic companies in acquiring the API and the API technology.[3429] This being said, contrary to Servier's suggestions,[3430] the derived nature of the demand for perindopril API technology does not mean that the demand conditions exactly mirrored those of the primary demand for the final formulation.[3431]

(2650) Taking into account that the demand for the API and API technology is derived from the demand for perindopril formulations, the conclusions reached in section 6.5.1.2 are also relevant for the present section. In section 6.5.1.2, the Commission's natural events analysis demonstrated that generic perindopril was the key driver for price-based competition for perindopril. The natural events included significant downward changes in the prices of alternative medicines. The abrupt change in the relative costs of those treatments did not have the effect on the sales of perindopril that would be expected in the case of closely competing goods. The sales of perindopril were virtually immune to the identified market shocks. At the downstream level, the existing regulatory framework in each of the national markets at issue tended to reinforce the price rigidity of demand for perindopril. The first generic entrants could expect to launch their generic perindopril at relatively high prices that could be only decreased as a result of the intra-molecule (perindopril-to-perindopril) competition. The expectations of high premium for the first entrants naturally translated into high demand for the required technologies, in particular the perindopril API technology. Potential suppliers of this technology were not constrained in their price choices by the immediate need to deliver the API at the lowest possible cost. As already

3429 In terms of volume, the demand for the API input is also defined by the production function, where each tablet of final formulation must contain a precise quantity of the API (for example, a 4mg perindopril tablet will contain 4mg of the API and a given quantity of excipients).

3430 Servier's reply to the Statement of Objections, paragraph 1683, ID10114, p. 507.

3431 See section 7.2.1.2.4 on production cost considerations.

explained in the preceding section, the price was a secondary factor as compared to availability.

(2651) In light of the above, it can be concluded that, based on the underlying demand for perindopril formulation, where no substitutability with other APIs/medicines was established in terms of price competition, the demand for API process technologies was also likely to be price inelastic. The revocation of the '947 patent that eventually unblocked several suppliers of the API and API technology resulted in more elastic demand for individual sources of perindopril API and API technology, in other words, it increased the elasticity of the residual demand faced by individual suppliers.

7.2.1.2.4 Production cost considerations

(2652) In general, the smaller proportion of total costs of the final product allocated to a given input, the lower the elasticity of the derived demand as compared to the primary demand for the final product. The inelasticity of demand for perindopril API process technology, which was derived from the inelastic demand for perindopril formulations as explained above, was further strengthened by the fact that the cost of perindopril API was only a small part of the total production cost of perindopril formulations and an even smaller part of the price of perindopril formulations.[3432]

(2653) The Commission asked a number of the generic companies for their estimates of the percentage cost of the API supplies in the ex-factory sales prices of perindopril formulations. Those generic companies were known to either eventually enter or actively pursue entry during the relevant period. Table 48 below summarises the answers received.

Table 48: Share of the API cost in the ex factory price of perindopril formulations[3433]

Company	Percentage (ranges)
Generic company 1	[=< 35%]
Generic company 2	[=< 75%] (*)
Generic company 3	[=< 35%]
Generic company 4	[=< 55%]
Generic company 5	[=< 35%]

3432 In this context, the relation between the primary and the derived demand can be illustrated with a simple example. If a producer prices according to its cost, an increase of 10% in the price of an input responsible for 25% of the total production cost will lead to an increase of 2.5% in the final product's price. For example, if the own-price elasticity of the demand for the final product is 1, the derived demand for the input will have the elasticity of 0.25, i.e. it will be more inelastic than the primary demand. Servier's economic consultant agrees with the general relationship between the primary and the derived demand, but notes that if the marginal revenue curve is less steep than the demand curve, then the standard result may not hold. The Commission is criticised for not carrying out the analysis to show that the "standard" result does hold (see Annex 00-01A to Servier's reply to the Statement of Objections, paragraph 157, ID9054, p. 69). The Commission disagrees with this criticism. The Commission's analysis contains sufficient evidence to rely on the "standard" result. The marginal revenue curve is less steep than the demand curve only for the demand curve that is convex and only for its elastic part. The Commission has carried out an extensive analysis of the demand for the final product, which has been found price inelastic. The analysis of the derived demand explicitly relies on this finding.

3433 Source: ID5080, p. 11 - 12, ID5071, p. 12, ID4968, p. 6, ID4952, p. 6, ID5041, p. 4, ID5609, p. 2 - 3, ID5055, p. 7, ID5036, p. 11.

Company	Percentage (ranges)
Generic company 6	[=< 35%]
Generic company 7	[=< 55%] (**)
Generic company 8	[=< 35%] (***)

Notes: (*) – the observation considered as an outlier (**) – an earlier project with the API cost at the level of [>55%] was considered non-viable for commercialization; (***) – an earlier project with the API cost at the level of [>55%] was not launched

(2654) Most of the generic companies estimated the API costs at 20%-35% of the ex-factory sales prices of perindopril formulations. It was also noted that the share of the API cost in the price of perindopril formulations decreased over time. Towards the end of the investigated period, the generic companies were already engaged in intra-molecular (perindopril-to-perindopril) competition. This means that even under much tighter profit margins brought about with generic competition, potential changes in the price of perindopril API were only partly defining changes in the price of perindopril formulations.

(2655) However, in the present case, the API costs must be also considered in relation to Servier's pre-generic prices, which constituted a natural price reference for the first generic entrants. Based on the UK price of 4 mg tablets, one kilogram of plain perindopril formulation was sold at over EUR 100,000 (net price) at the beginning of 2006.[3434] At the same time, Servier was able to produce one kilogram of perindopril API at […]* EUR [0–2,500]*[3435] while other costs were most likely to be in the range of EUR [5,000–7,500]* to [10,000–12,500]*.[3436] For Servier, the cost of perindopril API constituted only a tiny fraction of the price of perindopril formulations. In order to undercut Servier's price, the first generic entrants could even rely on those perindopril API process technologies that were substantially less cost-efficient as compared to Servier's technology.

(2656) Based on the production costs considerations, the Commission considers that the demand for the perindopril API process technologies was in all likelihood less price-elastic than the primary demand for perindopril.

7.2.1.3 Supply side substitution

(2657) The assessment of observed substitution patterns (see section 7.2.1.2.2.) allows for excluding the demand-side substitutability between technology used to manufacture APIs for other medicines and the technology used to make perindopril API. This sub-section will examine whether there is any supply substitutability between any potentially alternative technologies and the technology used to make perindopril API.

(2658) The Market Definition Notice defines supply side substitutability as a situation where the "*suppliers are able to switch production to the relevant products and market them in the short term without incurring significant additional costs or risks […]*". However, when "*supply side substitutability would entail the need to adjust significantly existing tangible and intangible assets, additional investments, strategic*

3434 ID1861.

3435 ID4517, p. 3.

3436 This range is based on Servier's net price of 4mg tablets in the UK in December 2009, where it is assumed that the product's price reached the level close to zero economic profit.

decisions or time delays, it will not be considered at the stage of the market definition".[3437]

(2659) Developing potentially viable technology to produce perindopril API, whether with prior specific know-how from partly similar, non-perindopril compounds which can be extrapolated to certain parts of the perindopril production process, or without such expertise, is a clear example of absence of supply side substitution. This is for the following reasons.

(2660) General know-how and expertise in a related group of chemicals and/or therapeutic category, such as ACE inhibitors, may provide significant advantages (for example in the form of specific technological solutions for a certain synthesis problem[3438]) for the development of a technology for a given API.[3439] However, the production on the basis of the API technology needs to lead to an API/final formulation which is bioequivalent to the originator's product, implying strict specifications concerning the impurities, stability, water content, etc. Very strict specifications may also apply to intermediates (raw materials for the synthesis of the API), which may need to be produced for the specific purpose of the API synthesis. In the present case, the fact that Servier held several process patents on both of the intermediate substances (perhydroacid and carbanine) for the synthesis of perindopril API[3440] shows that raw materials were not commodities and that the overall synthesis process was highly complex and compound-specific. This means that API production process technologies for other compounds (i.e. non perindopril) significantly varied from the processes to produce the perindopril compound (API), and that the technology to produce perindopril API essentially needed to be established anew up to the stage of optimising industrial-scale production, with the ensuing development lead times and investments.

(2661) The evidence shows that the development of perindopril API technology required significant R&D capacity commitments (for at least two to three years)[3441] and financial resources (reaching EUR [1-4 million]).[3442] These investments were all the more important given the significant risks of failure due to patent and regulatory barriers. Moreover, the development implied significant delays even if the generic/API company already had some expertise with other ACE inhibitors. This is

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3437 Commission notice on the definition of the relevant market for the purposes of Community competition law Official Journal C 372, 9.12.1997, p. 5 – 13, paragraphs 20 and 23.

3438 Servier argues (see Servier's reply to the Statement of Objections, paragraphs 1691-1693, ID10114, p. 509) that the annulment of [company name]*'s patent in […]*, which was based on the existence of the prior art relating to indolapril, implies that the technologies used for the production of other ACE inhibitors' APIs were interchangeable with the perindopril API technology. First, the Commission wants to point out that the fact that inspirations or even a ready production method can be derived from other technologies does not mean that these technologies are necessarily substitutable, since their application may require further adaptations and development. Second, in the particular case of indolapril and perindopril, even if the costs of and the time required for adapting the indolapril technology to the production of perindopril are disregarded and it is assumed that the indolapril and perindopril technologies were indeed interchangeable, it must be recalled that during the relevant period any attempts to use the indolapril technology for manufacturing perindopril API were blocked by [company name]*'s patent application acquired by Servier.

3439 ID2301, p. 11.

3440 See, for example, ID9972, p. 78, 79, 81, 82, 84, 91.

3441 See for example, Commission Decision M.5295 – *Teva/Barr*. This has been largely confirmed by the development times for various companies developing perindopril as described in section 7.3.3.1.

3442 See paragraph (920).

demonstrated by the fact that the long development times (i.e. two to three years) for perindopril API technology applied even for companies like [company name]*, Azad, and Krka,[3443] which had previously already developed APIs of an ACE inhibitor other than perindopril. There are also no indications in the file that Servier considered that the technology used to produce APIs other than perindopril API could constitute a threat to its position with respect to perindopril API technology.

(2662) In view of this, the decision to embark on the development of a new API, such as perindopril, amounts to a strategic decision within the meaning of the above-cited paragraph 23 of the Market Definition Notice. As can be seen from section 7.3.3.1, the decision to develop perindopril API determined the R&D and commercial focus of the generic/API companies for years to come.

(2663) Therefore, the intended use of the perindopril API technology is limited to the production of perindopril API[3444] as a key raw material for the production of final medicinal products. Servier claims that the generic undertakings which were unsuccessful in obtaining the perindopril API technology could have easily switched to other technologies that would have provided them with an entry opportunity to the same broad product market on the basis of selling another ACE inhibitor or a sartan.[3445] This is incorrect. None of other API technologies could be directly used to produce perindopril API. Those other technologies and related products could have potentially constrained the market for perindopril technology only through the market for formulations. In section 6, it has been demonstrated that such constraints were absent. However, even if they had existed, they would not have had to be necessarily transmitted to the market for perindopril technology to a degree imposing a significant constraint on the holders of the perindopril API technology.[3446] There is therefore no supply side substitution from technologies used to produce APIs other than perindopril which could be relevant for the purposes of defining the relevant market.

7.2.1.4 Perindopril API technology as the relevant technology market

(2664) In conclusion, the Commission considers that the relevant technology market is limited to that of perindopril API technology. It has been shown in sections 7.2.1.1 to 7.2.1.3 above that only that technology can be used to make perindopril formulations – it was not possible to use API technology for other medicines to make perindopril API so demand was inelastic. The companies which had already developed API technology for other medicines could not easily switch to making perindopril API technology and indeed there is not one single example of such a switch taking place within a short period of time. The relevant generic development processes lasted at least two to three years. Moreover, the evidence relating to switching shows that the consumers of perindopril API technology would not switch away from perindopril API technology in response to 5-10% permanent increases in price. In fact, there are a number of examples of generic companies investing considerable effort in obtaining perindopril API technology despite previous sources being cut off. The demand for perindopril API technology is derived from the underlying demand for perindopril formulation, where the formulations were sold in considerable quantities

3443 See sections 4.2.1.1, 4.2.2.1, 4.3.3.1, 4.3.3.8.

3444 See, for example, Servier's statement that its patents could not be readily used for the production of other medicines. ID2365, p. 19.

3445 See paragraph (2611).

3446 See footnote 3432 for a theoretical example of differences in the demand for final goods and for inputs.

at high profit margins. Together with the fact that perindopril API technology forms only a small proportion of the total cost of perindopril, this demand inelasticity downstream helps to explain why the demand for perindopril API technology was inelastic.

7.2.1.5 Geographical dimension – at least EU-wide perindopril API technology market

(2665) A short overview of the sources of various perindopril API technologies suggests that the relevant geographic market is broader than national, and probably world-wide: perindopril API technology was being developed within the Union (e.g. Servier, [company name]*, Krka, Sandoz), and outside the Union: for example Switzerland (Azad), Canada (Apotex), India (Glenmark, Hetero, Cipla and others). Contrary to Servier's comments,[3447] irrespective of whether the relevant geographic market is world-wide or at least EU-wide, the market will comprise the same set of technologies, that is to say perindopril API technologies viable for serving the Union demand, with a characteristic patent situation and regulatory requirements (for example, European Pharmacopoeia). Thus, even if the market was world-wide, this would not impact the assessment of Servier's position on the technology market.

(2666) Thus the Commission maintains its view that the relevant geographic market is at least EU-wide in scope.

7.2.2 Conclusion on the relevant technology market

(2667) In view of the foregoing, the relevant technology market is limited to perindopril API technology and is at least an EU-wide market in its geographic scope. The present finding is made for the whole period under review, i.e. the period 2001 to May 2009.

7.3 Dominance in the perindopril API technology market

(2668) Dominance in an API technology market may be expressed in several ways, as power to dispose with own technology, or by having a degree of control over the barriers to enter the technology market. Dominance can be manifested in the technology market itself (e.g. by having the power to determine the terms of licensing to an appreciable extent independently of other possible licensors) or with respect to the output markets for products incorporating the technology.

(2669) It is appropriate to recall that, an undertaking which is capable of profitably increasing or maintaining prices above the competitive level for a significant period does not face sufficiently effective competitive constraints. This is a useful indication suggesting that the undertaking in question has a dominant position if the other conditions are fulfilled. In the present case, concerning vertically related markets for perindopril API technology, perindopril API and perindopril formulations, the expression of dominance may not only be found in the relevant market for technology, but may also affect directly related downstream markets.

(2670) The assessment will examine, in a general way, (i) barriers to entry (or expansion), essentially in the form of patent and regulatory compliance (including Servier's degree of control over such barriers), (ii) the question of existence of countervailing buying power, (iii) perindopril technologies with the potential to constrain Servier's own technology, and (iv) Servier's position on the market for perindopril API technology as the incumbent holder of an unrivalled technology portfolio. On this basis, a specific assessment of Servier's market position will be carried out for the

[3447] Servier's reply to the Statement of Objections, paragraph 1748, ID10114, p. 519.

period relevant for the assessment of Servier's conduct, i.e. from 2001-2007, with an emphasis on years when the investigated practices took place, the period from 2004 until 2007.

7.3.1 Barriers to entry

(2671) With respect to the reference made to Servier's patents as an important barrier to entry and expansion, the Commission's analysis is supported by the General Court's judgment in the AstraZeneca case, where the General Court confirmed the prior case law by stating that *"[a]lthough the mere ownership of an intellectual property right cannot confer [a dominant] position, their possession is none the less capable, in certain circumstances, of creating [such a] position, in particular by enabling an undertaking to prevent effective competition on the market"*.[3448] The General Court also stated that *"[t]he mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right"*.[3449] The notion of barriers to entry does not require that barriers are absolute, or insurmountable, in order to include them in the assessment of dominance. The analysis of barriers to entry includes factors affecting timely and sufficient entry.

(2672) In the present case, for most of the investigated period, Servier could rely on the patent protection of perindopril[3450] limiting the scope for potential or actual competition. While perindopril API technologies could be developed, these would only be able to threaten Servier's market position to the extent they would also be able to overcome any patent barriers standing in their way to successfully enter the market. Before expiry of the SPC for perindopril's compound, the patent protection had an absolute character unless the compound patent had been revoked. After its expiry, there was scope for viable generic API technologies, even though Servier continued to rely on the three process patents ('339, '340, '341) and other secondary patents, in particular the '947 patent,[3451] potentially excluding from the market all perindopril containing the alpha crystals. Almost all generic companies considered that the '947 patent was the single most constraining patent of Servier.[3452] Servier systematically attempted to neutralise by means of patent settlements and acquisitions (see section 5.7) generic companies' efforts to surpass this entry barrier (by developing a product not covered by Servier's patents and/or by means of non-infringement or invalidity actions). In France and in Poland, where Servier successfully shifted the existing patient base to the *arginine* salt, the relevant patents protecting that salt constituted an additional barrier to expansion for the generic producers offering the products based on the *erbumine* salt of perindopril.[3453]

3448 Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 270.

3449 Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 362.

3450 See section 4.1.2.1.

3451 Servier maintains that the Commission assesses differently the role of the '947 patent in its analysis under Articles 101 and 102 of the Treaty, respectively (see Servier's reply to the Statement of Objections, paragraphs 1739 and 1900, ID10114, p. 517-518 and 544). The Commission disagrees with Servier's opinion. The fact that the '947 patent was contested does not mean that the existence of that patent was necessarily neutral from the perspective of potential generic entrants. Patents under dispute may and often do constitute a barrier to entry (which however does not necessarily bar all scope for competition – see section 5.1.3). In this particular case, it is evident that the annulment of the '947 patent had an important impact on generic entries.

3452 See paragraph (126).

3453 See sections 4.1.2.7.3 – 4.1.2.7.4.

(2673) In addition, perindopril API technology was subject to compliance with strict product specifications of the European Pharmacopoeia monograph for perindopril. Non-compliance with the monograph would increase the likelihood of problems and/or delays in the marketing authorisation procedures. These standards acted as an additional limitation to the development of API technologies already subject to significant patent barriers. Servier participated in the elaboration of the monograph aiming to secure that *"*the standards announced lead to the use of protected processes"*.[3454]

(2674) In its reply to the Statement of Objections, Servier insists that the perindopril monograph never constituted a barrier for any generic.[3455] In Servier's opinion, Krka's assertion that the monograph constituted the second most significant barrier to entry for generic companies is opportunistic and at odds with the fact that Krka obtained an MA and launched its perindopril product in several CEE markets in late 2005-2006.[3456] In this context, the Commission must point out that Servier has not explained what was the rationale of its endeavours to secure that *"*the standards announced lead to the use of protected processes"* if not for raising the barriers to entry for generic companies. It must be also recalled that in late 2005-2006, Krka entered the CEE markets with the alpha crystalline form of perindopril; the form subject to Servier's '947 patent. In other words, for the purpose of that entry, Krka used what Servier considered to be a part of its *"*protected processes"*.

(2675) Therefore, the Commission concludes that Servier's market position both in the API technology as well as related downstream markets was protected by important barriers to entry, which were not insurmountable, but nonetheless limited the scope for potential and actual competition in the relevant product market and API technology market for most of the investigated period. These barriers to entry were however evolving in the investigated period, and it will be therefore necessary to separately examine Servier's market position in the periods of the relevant practices (see section 7.3.4).

(2676) In its reply to the Statement of Objections, Servier argues that there were no barriers to entry. According to Servier, many pharmaceutical companies could develop their own perindopril API technologies. Servier's contention relies on the modest size of [company name]*'s investment, where [company name]* had incurred a development cost of EUR [50,000–150,000]* before Servier acquired [company name]*'s perindopril API technology.[3457] The Commission disagrees with Servier's argument. First, the size of an investment in R&D is often not decisive for the valuation of the resulting technology. In the present case, it is recalled that Servier was prepared to pay approximately EUR [1–25]* million for acquiring [company name]*'s technology.[3458] Second, in the Commission's view, the situation before and after [company name]* filed a patent application for its technology are not comparable. From the moment of [company name]*'s patent filing, the patent landscape changed and other interested companies had to seek alternative technologies. This also implies that the development costs of [company name]* and of other companies are not truly comparable. Contrary to Servier's opinion, the

3454 See also paragraph (132).

3455 Servier's reply to the Statement of Objections, paragraph 1912, ID10114, p. 546.

3456 Annex 00-08 to Servier's reply to the Statement of Objections, ID9054, p. 1-6.

3457 Servier's reply to the Statement of Objections, paragraphs 1755-1759, ID10114, p. 520.

3458 See section see section 4.2.1

barriers to entry proved to be considerable, as shown by the Commission's analysis carried out in section 7.3.4 below.

(2677) Furthermore, Servier's emphasis on the relatively low costs of research programmes aimed at developing generic perindopril[3459] does not take into account that the development of viable technology was not only a question of financial resources. The development process also required time. Time was a critical element in the perindopril development programmes, even where generic companies with certain experience of developing other ACE inhibitors, like Krka, required at least two to three years to develop potentially viable perindopril API technologies.

7.3.2 Countervailing buyer power

(2678) In the context of the assessment of Servier's position in the EU-wide market for perindopril API technology, the question of countervailing buyer power is essentially limited to the question whether the generic companies were in a position to (i) extract from Servier a transfer of Servier's perindopril API technology, or (ii) facilitate/accelerate the development of an independent source of API technology, capable of constraining Servier's unilateral conduct.

(2679) In the present case, generic companies did not have the power to extract a technology transfer from Servier. Servier was all but willing to abandon the exclusive use of its perindopril API technology. For example, enabling generic entry was seen as the "*nuclear weapon*" to be used only if absolutely necessary.[3460] There was one limited exception, as Servier granted the licence to Krka to use the '947 in seven CEE markets in the context of a reverse payment settlement agreement terminating Krka's patent challenge across the EU, and wider. However, for most of these markets, the licence was granted after Krka had already launched, and before the national equivalents of the '947 patent were granted to Servier. Moreover, the terms of the licence allowed only a limited degree of competition between Servier and Krka.

(2680) Concerning the facilitation/acceleration of development of API technology, there were a number of generic companies highly interested in such cooperation. Other generic companies were developing API technology in-house. However, the development lead times were in any event significant, two to three years, which means that this was not an expression of buyer power vis-à-vis Servier.

(2681) Against this background, it can be concluded that Servier was not confronted with a significant degree of countervailing buyer power across the EU as the relevant geographic market.

(2682) The following subsections will examine the various perindopril API technologies which were completed or in sufficiently advanced development, in particular to ascertain if and when these technologies could constrain Servier. Finally, Servier's market power will be examined for the period 2001-2007.

3459 Servier's reply to the Statement of Objections, paragraphs 1895-1899, ID10114, p. 543-544.

3460 See paragraph (203).

7.3.3 Overview of perindopril API technologies potentially able to constrain Servier

7.3.3.1 Generic perindopril API technologies

(2683) This section will identify and describe possible sources of perindopril API on the basis of companies' replies to RFI and inspection documents.[3461] The facts relating to these various actual or potential sources of perindopril will be presented on a company by company basis, according to whether a particular source should be considered relevant as a potential source of API technology for: (a) the period until the end of 2001, (b) the period 2002 to 2004, and (c) the period 2005 to 2009.

7.3.3.1.1 Companies possibly representing a source of viable perindopril API technology emerging by the end of 2001

(2684) The companies which started their generic perindopril projects and reached an advanced stage of development in the period until the end of 2001 were limited to [company name]* and Matrix. Concerning [company name]*'s and Matrix's development of potentially viable perindopril API technology, reference is made to sections 4.2.1 and 4.3.1 above. The development based on these sources was expected to be completed roughly in the period 2004-2005.

7.3.3.1.2 Companies possibly representing a source of viable perindopril API technology emerging in the period 2002-2004

(2685) The period relevant for the assessment of the competitive situation in which Azad emerged as a potential supplier of perindopril API spans from the end of 2001, roughly coinciding with the conclusion of the [company name]* Agreement, to the end of 2004, the period when the acquisition of Azad technology took place.

(2686) Servier's '947 patent application was filed on 6 July 2000 and eventually led to the grant of the '947 patent on 4 February 2004. Therefore, it was important, as explained below, whether the alternative API being developed infringed that '947 patent.

(2687) The '947 patent represented an entry barrier which was subject to numerous invalidity actions by generic competitors, which considered to have realistic chances to have the patent annulled. On the other hand, generic quotes suggest that it was difficult to overcome the '947 patent by developing new perindopril API forms not covered by this patent. As a consequence, the availability of API sources not covered by the '947 patent (sometimes referred to as "non-alpha API") was even more limited during the entire period from 2001 to 2009 than the already limited sources of perindopril API potentially infringing the '947 patent.

(2688) For example, in Teva's internal correspondence concerning perindopril dated 28 June 2006 (i.e. after IPR to Azad's independent delta and epsilon polymorphs had been acquired by Servier), the following statement is made: "*If Servier wins the Alpha Polymorph patent, it would effectively shut everyone out of the market*".[3462]

(2689) Krka's reply to the RFI of 5 August 2009 confirms that there were very few alternatives to the alpha polymorph API, even as late as 2006:[3463]

[3461] Depending on the nature and scope of information on the various development projects from these sources of information, the Commission undertook further fact finding where the information was not sufficient to assess whether and/or in which period a given company could be considered as an actual or potential source of API supplies.

[3462] ID0078, p. 192.

[3463] ID1307, p. 97.

"On the other hand after 2006, companies have been trying to develop non infringing crystalline forms, like Cipla, but the technical solution was not practical from industrial point of view – there were only proposals developed on a laboratory scale, with no realistic perspective to scale up an economical manufacturing technology; consequently, even if MAs could have been obtained, the product could not have been launched.

There was one competitor (Sandoz), which developed stable and non infringing crystalline form in formulation, but they were not offering the product for cooperation.

Krka has analysed samples from various sources, but has not found any viable alternative source of API.

For those reasons, we had to develop our own non-alpha containing product. "

(2690) In view of the above, the subsequent overview will first present the potential sources of API technology potentially not infringing the '947 patent which emerged in the period from the end of 2001 to the end of 2004. According to the information on the file, which corroborates the above Krka statements, such potential sources were limited to Azad, Cipla and Sandoz. Next, sources of API technology potentially infringing the '947 patent will be presented. The development of formulations based on these sources was expected to be completed roughly in the period 2006-2008. Sources of perindopril API technologies leading to the alpha crystalline form of perindopril covered by the '947 patent were considered viable only subject to revocation of the patent in question. Therefore, they can be at most regarded as potentially viable technologies for the period when and the teritorries where the '947 patent stayed in force.

Azad

(2691) Concerning Azad's development of potentially viable perindopril API technology, reference is made to section 4.2.2 above.

Sandoz

(2692) Concerning Sandoz's development of potentially viable perindopril API technology, reference is made to section 4.2.2.8.4.

Cipla

(2693) Cipla is one of the leading Indian generic companies, active in the development, manufacture and supply of both APIs and formulation products in several therapeutic categories, including cardiovascular.[3464] Cipla's development of perindopril API was initiated in 2001 and was completed at the end of 2005, according to its reply to the RFI of 22 February 2011.[3465]

Initial development - anhydrous perindopril erbumine API

(2694) In 2002, Cipla had discussions with the Swiss company Sochinaz about the possibility that Cipla would develop a form of perindopril API which it would share with Sochinaz by means of a technology transfer agreement. The initial form developed by Cipla was anhydrous perindopril erbumine API in a form that appeared to match the alpha form protected by the '947 patent. According to Cipla, Sochinaz

[3464] ID3924, p. 2 - 3.
[3465] ID3924, p. 7 - 8.

confirmed this. Moreover, the initial process development led to a process which was, in Cipla's (and reportedly also in Sochinaz's) view covered by Servier's '341 process patent.

(2695) According to a reply by Arrow, which was seeking sources of perindopril API in the period around 2002, potential sources other than Azad (e.g. Sochinaz SA/Cipla) involved a pure alpha polymorphic form, which Arrow considered to clearly infringe the '947 patent (assuming its validity).[3466]

(2696) This is also corroborated by the explanations provided by Neolab, Cipla's cooperation partner for the UK, in the reply to the RFI of 12 December 2010. Neolab stated that Cipla first developed an alpha crystalline form of perindopril API in cooperation with Sochinaz, and offered it in the EU. According to Neolab, Cipla may have developed more than one crystalline form of perindopril depending on the target markets.[3467]

(2697) Once Cipla established that its anhydrous perindopril API and associated process matched the patented Servier perindopril API and associated process, Cipla's next step was to search for alternative forms of perindopril API and associated processes.[3468] This was also confirmed by Teva, which was looking for alternative sources of API supply after the discontinuation of negotiations with [company name]*. Teva stated that it considered the API offered by [company name]* (as the developer of the molecule) and [company name]* (as the developer of the polymorph) in 2002. According to Teva, "*[t]he development was not continued with this API as it was not proven that the polymorph was indeed a novel and pure polymorph. In 2005, [company name]* claimed to have another novel polymorph. Negotiations did not proceed since [company name]* wanted to exclude the UK […]**".[3469]

Alternative development - monohydrate

(2698) Towards the end of 2002, Cipla isolated a hydrated form (monohydrate) of perindopril erbumine API and applied for several patents as of 18 November 2002 (the priority date of EP1565485B1, granted on 24 January 2007).

(2699) In July 2003, Cipla revived cooperation with Sochinaz as Cipla agreed to manufacture and sell perindopril API to Sochinaz. Subsequently, Cipla would transfer the complete technology and industrial process to Sochinaz, allowing the latter to manufacture the product. It supplied Sochinaz with around 200 g of API in 2003 to support its development of formulations.

(2700) However, Cipla experienced difficulties in scaling up API production. Owing to these delays, Sochinaz (which was, according to Cipla, looking for an early supply of Cipla perindopril API on an industrial scale) reportedly terminated the agreement with Cipla in or around July 2004.[3470] According to Sochinaz, "*[Company name]* didn't manage to obtain the right product and we decided to cease the*

[3466] ID1571, p. 17.
[3467] ID3153, p. 7.
[3468] ID5612, p. 8 (paragraph 5.9).
[3469] ID2481, p. 3.
[3470] ID3924, p. 8 - 9.

collaboration".[3471] Consequently, Cipla decided to pursue development on its own.[3472]

(2701) Cipla continued its scaling-up efforts which were eventually successful for both the API and the process in March 2005. Together with the studies relating to both the process (optimisation, validation) and the API (impurities, identification, synthesis and characterisation), this took aproximately two years. The DMF for the Union was completed in July 2006 and then submitted to marketing authorisation bodies.[3473]

(2702) In parallel to the development of the API, Cipla was developing perindopril formulations. To this effect, it entered into a strategic alliance agreement with Neolab,[3474] a UK company with no internal R&D, manufacturing or distribution facilities. "*In essence, Cipla develops the target products selected by Neolab whilst Neolab organises registration in the UK and distribution/marketing, mainly through wholesalers"*.[3475]

(2703) Formulation development work on Cipla's tablets began in 2002 and continued until 2005. In March/April 2005, validation batches were taken and formal stability studies were initiated. On this basis, the bioequivalence study started in October 2005 and was completed in December 2005.

(2704) In July 2004, Servier received a report from the University of Rouen concerning Cipla's patent application for perindopril erbumine monohydrate. The report finds that the form claimed by Cipla was a priori original, but found it remarkable that the application disclosed little information on the monohydrate. Thus, the patent application provided no information to answer, amongst others, the "fundamental questions" such as (i) the form of perindopril (for example, alpha, beta etc.) to which a desolvation[3476] of the monohydrate would lead, or (ii) the temperature at which the hydrate would desolvate.[3477]

(2705) By letter to Servier of 3 December 2004, Neolab attempted to clear the way for Cipla's perindopril.[3478] In the letter, Neolab referred to Cipla's patent applications, claiming that no process or formulation patents of Servier would be infringed. The letter also announced the readiness to launch a declaratory court action in case "*an alternative solution acceptable to both parties*" was not found. In its reply of 10 January 2005, Servier did not take a position on Neolab's claims but expressed an interest in receiving further information and materials (API samples, full process details, and a list of Member States for launch) and explicitly pointed to the existence of crystalline form patents.[3479] Cipla reportedly was never in direct contact with Servier, but submitted samples of its perindopril tablets and API to Neolab's lawyer

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3471 ID3575, p. 4.

3472 ID3924, p. 8.

3473 ID3924, p. 9, ID4796, p. 1.

3474 ID3924, p. 9.

3475 ID2394, p. 2.

3476 Desolvation is understood in this case to mean the removal of a solvent, in this case water, from the perindopril salt in the solution.

3477 Servier's reply to the Statement of Objections, paragraphs 1827 and 1828, ID10114, p. 530 and Annex 12-06 (ID9065, p. 45-47 (Accessible version ID10092, p. 1-2)). See also Servier's reply to the Letter of Facts, ID10289, p. 65-66.

3478 ID0033, p. 105.

3479 ID0033, p. 102 - 104.

in 2005, in view of Neolab's attempt to clear the way.[3480] According to Neolab, these samples were dispatched to Servier for testing.[3481]

(2706) Servier confirmed having received the API samples from Cipla/Neolab at the beginning of 2005. It appears that Servier analysed the samples and considered that this API infringed its patents.[3482] This is corroborated by Servier's observations in an internal document, the aforementioned "**Monitoring of Perindopril*", observing that the crystalline form in Cipla's tablets/API could correspond to a hydrated beta polymorph[3483] (also protected by Servier's patent).

(2707) Partners for perindopril were sought by Neolab/Cipla at least from February 2004 onwards, which resulted in discussions with other generic companies, such as Ratiopharm and Sandoz.

(2708) In an email to Ratiopharm of 5 March 2004, Neolab stated that they "*have confirmed the excellent position in terms of non-infringement*", with a dossier being ready by 1st quarter 2005.[3484] Ratiopharm replied that they were interested in the API as a second API in a dossier with already running procedures for France as primary country of interest. Ratiopharm requested further information,[3485] and was eager to finalise the patent check of the API.[3486] It gave estimates of API needed for France, and mentioned that API supply would also be necessary for the Netherlands, Portugal, Denmark, the Czech Republic and the UK. In the end, no agreement was reached with Ratiopharm.

(2709) As for Sandoz, it stated that *"[d]iscussions in 2004 to license in Cipla's technology for use on the European market did not lead to any agreement as Sandoz determined it could achieve superior contractual terms and timing by reaching an agreement with [another supplier]"*.[3487]

(2710) In August 2006, Neolab Limited applied for marketing authorisations in the UK. In October 2007, authorisations were granted to Neolab Limited for 2 mg, 4 mg and 8 mg tablets of perindopril erbumine monohydrate.[3488] The dossier was also submitted as part of the applications for marketing authorisations by Cipla's other customers in several Member States.[3489]

3480 ID3924, p. 12.

3481 ID3153, p. 10.

3482 ID5064, p. 8. Reply to the RFI of 1 July 2011. This is in the Commission's view not contested by the report described in paragraph (2704) analysing Cipla's patent application, as claimed in Servier's reply to the Statement of Objections, Annex 12-06, ID10092 and the reply to the Letter of Facts, ID10289, p. 65-67. The report found that, while the claimed form was "a priori original", the patent application remarkably omitted certain information on the monohydrate, and left unanswered a number of questions, including concerning possible conversion of the monohydrate into anhydrate in the alpha, beta or gamma forms protected by Servier's patents. This document does therefore not exclude the possibility that Cipla's monohydrate could convert into forms protected by Servier, and is thus consistent with assessments by Servier and others that Cipla's product could be covered by either alpha or beta polymorph patent held by Servier.

3483 ID0113, p. 69 - 71.

3484 ID1487, p. 86.

3485 ID1487, p. 73.

3486 ID1487, p. 72.

3487 ID1480, p. 18. Reply to the RFI of 5 August 2009.

3488 See MHRA's List of Marketing Authorisations granted in October 2007, p. 7, available at: http://www.mhra.gov.uk/home/groups/l-reg/documents/licensing/con2033248.pdf

3489 ID3924, p. 9.

(2711) Although on this basis a perindopril product was launched by Neolab on 28 February 2008 in the UK and achieved turnover falling just below GBP 1 million in that year, only a fraction of this was sold in 2009 and there was no plan to market the product in 2010/11. According to Neolab, this was due to very low prices in the UK.[3490] Cipla sub-licensed its perindopril dossier to a number of smaller generic companies with a view to supplying them under marketing authorisation acquired by these companies on the basis of Cipla's dossier. However, only two companies launched Cipla's perindopril. They had very limited sales, totalling around EUR [500,000-750,000] in the period 2008-2010.[3491]

(2712) There is a degree of uncertainty as to the quality and cost-effectiveness of [company name]*'s monohydrate API. Teva analysed a perindopril sample it received from [company name]* in October 2005. However, the product was considered not to meet [company name]*'s claims, in particular concerning the non-infringement of Servier's patents as Teva (like Servier, see above) found that the crystalline form matched the beta form protected by Servier's patent. Consequently, Teva decided not to cooperate with [company name]*.[3492]

(2713) Likewise, concerning a company that was believed to use Cipla's perindopril, Lupin took the following view in July 2008: *"I believe they have Cipla hemi-hydrate Perindopril which we have proven to have alpha polymorph in. If that is the source they will get slaughtered by Servier"*.[3493]

(2714) According to Krka's reply to the RFI of 5 August 2009, Cipla was "*the only source which has claimed non-infringing crystalline form after July 2006. The sample of API as well as the tablets have been analysed [by Krka]. Technical evaluation was negative. API should have been stored and transported under special conditions, the API as well as the tablets were not stable. Also this source has been declared non viable"*.[3494]

(2715) In the abovementioned reply, Krka also commented that *"companies have been trying to develop non infringing crystalline forms, like Cipla, but the technical solution was not practical from industrial point of view – there were only proposals developed on a laboratory scale, with no realistic perspective to scale up an economical manufacturing technology; consequently, event if MAs could have been obtained, the product could not have been launched"*.[3495]

(2716) On the other hand, Neolab had no recollection of any specific issue in terms of product stability or the need for specific storage or transport conditions for the final finished dosage form.[3496]

Sources of perindopril API technology covered by the '947 patent which emerged in the period 2002-2004

Apotex

[3490] ID2394, p. 3.
[3491] ID3950, p. 21.
[3492] ID5055, p. 3.
[3493] ID5021, p. 1166, ID7652, p. 1168.
[3494] ID1307, p. 102.
[3495] ID1307, p. 97.
[3496] ID3153, p. 8.

(2717) Apotex, a Canadian generic company, started developing its perindopril products in May 2004.[3497] Both the API and the formulation were developed in-house in Canada by members of the Apotex group.

(2718) Its perindopril tablets, which contained the alpha polymorph, received the first EU marketing authorisation in the UK on 24 July 2006. The product was first launched on 28 July 2006, following which Servier obtained an interim injunction on 8 August 2006. In July 2007, Apotex successfully established in the English courts that the '947 patent was invalid. Apotex then relaunched perindopril in the UK. Apotex also filed a declaratory action for non-infringement of the '947 patent in the Netherlands, which was successfully resolved[3498] after the '947 patent was annulled in 2008.

(2719) According to Apotex, the '947 patent had a significant impact on its perindopril project: "*Apotex was delayed nearly a year as a result of the EP '947 Patent"*.[3499] In addition, Ratiopharm was one of the generic companies which terminated their respective agreements with Apotex in view of possible patent infringement issues raised by the '947 patent prior to the annulment.[3500]

(2720) However, in parallel to Servier's action for infringement of the '947 patent,[3501] in August 2006 Servier also filed proceedings in Canada for infringement of a Canadian perindopril compound patent. Apotex was in July 2008 found to infringe the patent with the production of perindopril API in Canada, where the perindopril compound patent was "*filed in 1981, but because of the peculiarities of the Canadian Patent System, only issued in 2001 and [was] set to expire in 2018*".[3502] In the period 2006-2008, Apotex transferred the manufacture of both API and formulations from Canada to related companies in India.[3503]

(2721) Apotex has been distributing perindopril itself in the UK (1st launch in July 2006, 2nd launch in July 2007), the Netherlands (launch in December 2007) and Poland (launch in March 2009). Apotex reported to market perindopril through distributors in Hungary (launch in October 2008) and Italy (launch in March 2009).

Glenmark

(2722) Glenmark Pharmaceuticals Limited ("Glenmark") is an Indian pharmaceutical company active both in the discovery of new molecules and in the generic business. Glenmark, which is active both in APIs and final formulations,[3504] developed a perindopril product with its own resources.[3505] Although Glenmark did not report it itself, information submitted by its former cooperation partners shows that its perindopril erbumine API was in alpha form and covered by the '947 patent (see below). Glenmark was amongst the companies which launched opposition proceedings against the '947 patent in 2004.[3506]

3497 ID1591, p. 11 - 12.
3498 ID1591, p. 13.
3499 ID1591, p. 22.
3500 ID1487, p. 12.
3501 See section 4.1.2.4.2.2.1.
3502 ID1591, p. 15.
3503 ID5036, p. 8.
3504 ID1045, p. 3.
3505 ID1622, p. 5-6.
3506 See section 4.1.2.4.2.1.

(2723) Glenmark first applied for a MA for its perindopril in February 2006 in the UK and the Netherlands, and the first MAs were granted in the period from November 2007 to February 2008.[3507] The first launch of Glenmark's perindopril product was in the UK in August 2008, with both direct sales and supply to a distributor.[3508] Glenmark also concluded licensing and supply agreements for its perindopril formulations with other generic companies.[3509]

(2724) According to a Servier internal assessment of June 2006, the Glenmark *"product [was] infringing 1988/2008 and α-patents"* (the 1988-2008 patents being understood as '339, '340 and '341 patents). Servier evaluated Glenmark's product as characterised by *"poor stability, residual solvents, no 8mg bioequivalence"*.[3510]

(2725) Glenmark also offered supplies of perindopril erbumine API. In May 2005, Ratiopharm informed Glenmark that it was planning to switch its source of API from the one produced by Matrix to Glenmark's.[3511] When it found out that Glenmark's API was patent-infringing, the technical transfer was cancelled.[3512] Then, according to Ratiopharm, Glenmark started the development of an API with a non infringing route of synthesis, which was expected to be available not earlier than June 2006.[3513]

(2726) Specifar stated in its reply to the RFI of 9 July 2010[3514] that it started using Glenmark's API for the development of both perindopril and perindopril combination in 2005, even though it knew that Glenmark's API infringed the '947 patent. After Servier's patent '947 was upheld in 2006 by the EPO Opposition Division, the project was discontinued even though MAs were received in certain Member States.

(2727) Glenmark was nonetheless used as a source of perindopril API by other generic companies. The companies which based their development of generic perindopril on Glenmark's API in the period 2002-2004 included Gedeon Richter,[3515] and Ranbaxy.[3516] Other companies developing perindopril formulations after 2005, such as Polpharma, Galex and Pol-Nil, also sourced Glenmark's API. That said, these companies were only developing perindopril formulations and were, as far as the API was concerned, dependent on Glenmark's API development. Thus they did not

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3507 ID1045, p. 9.

3508 ID1622, p. 7.

3509 ID1622, p. 8.

3510 ID0105, p. 178.

3511 ID1487, p. 98.

3512 ID1491, p. 55. See also ID5656, p. 18. Concerning the latter document, Servier claims that patent assessments of the Glenmark process commissioned by Krka in 2005 revealed that *"there were realistic chances"* that there was no patent infringement in Germany. Servier also complained that the Commission engaged in selective reading, and disregarded similar elements suggesting that also Niche and Lupin processes were infringing (Servier's reply to the Letter of Facts, ID10289, p. 67-69). The Commission notes that the documents referred to by Servier only relate to intermediates and patents for intermediates and not to the synthesis of the intermediates into perindopril API. Therefore, these documents do not exclude the possibility of infringement of other process patents, as documented in the Ratiopharm email, which is moreover corroborated by Servier's later assessment set out in paragraph (2724). Servier's claims pertaining to the Niche and Lupin processes are respectively addressed in sections 5.2.1.2 and 5.6.1.2.

3513 ID1491, p. 55.

3514 ID2428, p. 3.

3515 ID2119, ID3056, p.1.

3516 ID3347, ID3071, p.1. Ranbaxy was initially developing API itself in 2005 but the project was dropped from the development grid for technical reasons. Subsequently, Ranbaxy entered into discussions over perindopril API supply with Glenmark.

represent a separate source of perindopril API and are therefore irrelevant for the purpose of the assessment of independent sources of perindopril API technology.

(2728) In 2009, Glenmark supplied perindopril API and intermediates to 10 generic companies including Sandoz, Arrow, Gedeon Richter and Ranbaxy.[3517]

Hetero/Teva

(2729) The cooperation between Ivax (acquired by Teva in January 2006) and Hetero for the development of API, which was in the alpha crystalline form, started in December 2003. The MA applications were filed in November 2004, and granted to Teva in the UK in December 2006.[3518] Although Teva/Ivax did not develop API on its own, it had exclusive access to the Hetero API technology. For more details on Teva's perindopril API technology, reference is made to section 4.3.2.2 above.

Krka

(2730) Krka initiated its own development of perindopril (both API and formulation) in 2003. The API was in the alpha crystalline form. In August 2005, Krka received the first MA in Hungary, as the basis for the MRP. Krka actually launched perindopril in several CEE Member States, including Poland, in late 2005-2006 and was preparing to launch in other Member States, including France, the UK and Netherlands either alone or in cooperation with other companies. For more details on Krka's perindopril API technology, reference is made to sections 4.3.3.1 - 4.3.3.3 above.

Lupin

(2731) Lupin started developing generic perindopril API and formulations in 2002. For this purpose, Lupin developed its own processes for the manufacture of perindopril[3519] for which it filed three patent applications between February 2003 and June 2005. The API was likely covered by the '947 patent.[3520] Lupin applied for MA in January 2006. MA in the UK was granted on 22 July 2008.[3521] For more details on Lupin's perindopril API technology, reference is made to sections 4.3.4.1 - 4.3.4.4 above.

7.3.3.1.3 Companies emerging as a possible alternative source of perindopril API after 2005

(2732) New sources of API emerging after 2005 are far less relevant to the investigated practices and their possible effects, as they would only be expected to allow product as of approximately 2009 - 2010 onwards, i.e. mostly after the time period examined for the purposes of this Decision. Therefore, certain perindopril projects which have been identified as possible sources of perindopril competition are summarily presented in Table 49 below in particular concerning their timing.

(2733) Based on the above information, Table 49 below summarises key facts for each of the perindopril development projects examined above.

3517 ID1622, p. 8.
3518 See section 4.3.2.2.2.
3519 ID1039, p. 23.
3520 ID1080, p. 1 - 2; ID1081, p 1 - 14.
3521 For more detail, see section 4.3.4.9.3.1.

Table 49: Overview of independent sources of generic perindopril API

Company / project	Time period	Patent issues	Comment / Outcome of development
Period until end of 2001			
[Company name]*	1999-2001	Non-infringing (no '947 yet)	API patent application purchase by Servier, API supplies to Servier
Matrix / Medicorp	2000-2005	'947, process patents	Matrix and Niche/Unichem Settlement Agreement with Servier
Period 2002-2004			
Potentially not infringing the '947 patent			
Azad	2002-2004	Non-infringing	API patent application purchase by Servier, discontinuation of development
Cipla	11/2002 – end of 2009	Non-infringing / infringing	1st launch in the UK in 2008 but marketing terminated at the end of 2009
Sandoz	2003 – MA Q1&2 2008	Non-infringing	Attempted technology acquisition by Servier in 2007-2008; launched in various markets from 5/2008 on
Potentially infringing the '947 patent			
Apotex	5/2004 – MA 7/2006	'947	1st launch in the UK in July 2006; 2nd launch in July 2007
Glenmark	2004 – MA as of end 2007	'947	1st launch in the UK in 8/2008; supplier of API and formulations to other generics
Hetero/Teva	MA end 2006	'947	Launch in 5/2008 (NL), Teva Settlement Agreement
Krka alpha	MA as of end 2005	'947	1st launch Dec 2005 (HU), settlement agreement
Lupin	MA 7/2008	'947	Lupin Settlement Agreement
Period 2005 and after			
Potentially not infringing the '947 patent[3522]			
Arch Pharmalabs[3523]	02/2007 – 2nd Q 2007	Non-infringing	DMF filed in October 2008
Dr Reddy's[3524]	2007	Non-infringing	Discontinued immediately for commercial reasons.
Galex[3525]	07/2007 – MAs 2010	Non- infringing	Not commercialised by 2010
Ipca[3526]	2003-DMF in 9/2009	Non-infringing / alpha	[…]*
Krka CET[3527]	MA in 2010	Non-infringing	Not launched in the EU due to annulment of the '947
Potentially infringing the '947 patent			
Sochinaz[3528]	CEP in May 2009	alpha	No launch
Chemo[3529]	2002 –DMF in June 2006	alpha	MA granted but no launch
Aurobindo[3530]	DMF in 2007	alpha	MA applied in 2009, granted in NL but no launch yet

3522 Servier claims that these sources, in particular Dr Reddy's and Arch Pharmalabs, were at a comparably advanced stage of development as Sandoz and Cipla already in 2006 (reply to the Statement of Objections, paragraph 853, ID10114, p. 309). Servier fails to acknowledge that in the period of the investigated transactions (from November 2004 to January 2007), these development projects were at very preliminary stages and lagging significantly behind either Cipla or Sandoz. Both Cipla and Sandoz filed the DMF dossier for the API in July/August 2006, while Arch only did this in October 2008. Dr Reddy's only started the development in 2006/2007, and discontinued it shortly thereafter.

3523 ID3195, p. 2 - 5, ID3198, ID2428, p. 3 - 6.

3524 ID4605.

3525 ID1486, p. 3 - 17, 21 - 22, 60 - 61, ID3165, ID3167, ID3169, p. 2-4, ID4746, p. 1.

3526 ID4699.

3527 ID0046, p. 34 - 35, ID1307, p. 91 - 92, ID2301, p. 2.

3528 ID3575, p. 4 - 8.

3529 ID1487, p. 135, ID3045, p. 1, ID3216, p. 3 and subsequent., ID3613, p. 1 - 2, ID4716, p. 1.

(2734) In its reply to the Statement of Objections, Servier makes a reference to multiple alternative sources of potential supplies of perindopril API and of perindopril technologies by third parties. However, Servier's own review of those sources[3531] shows that most of the development projects did not lead to technologies established as viable within the concerned period, i.e. prior to July 2007. Despite listing 43 projects, Servier's review, for example, contains only three cases in which the generic developers were eventually successful in obtaining MAs (Sandoz, Cipla, Chemo/Quimec) and one case of the development project that allowed for market entry outside the EU (Glenmark in India). All the leading projects for potentially viable technologies are taken into account in the technology market analysis contained in the present Decision. The Commission's analysis shows that none of those projects actually led to the perindopril API technology being established as viable until at least 2008 (see section 4.2.2.8.4, paragraphs (2693) – (2716) and (2722) - (2728) and Table 49).[3532] Nor were these sources identified as relevant by the parties most directly concerned, namely the generic undertakings.

7.3.4 Assessment of Servier's position on the perindopril API technology market

(2735) Market shares provide a useful first indication for the Commission of the market structure and of the relative importance of the various undertakings active on the market.

(2736) Also in the context of a technology market, market shares can be informative of the technology holder's market power. This is acknowledged in the Technology Transfer Guidelines,[3533] which provide useful guidance on how to measure the market power, and endorse three methods: (i) calculation of market shares on the basis of each technology's share of total licensing income from royalties; (ii) calculation of market shares on the basis of sales of products incorporating the transferred technology on down-stream product markets; and (iii) identification of the number of independently controlled technologies in addition to the technologies controlled by the parties to the transfer, which may be substitutable for the licensed technology at a comparable cost.

(2737) The first method is in the present case not practicable. Although there was a considerable number of actual or attempted transfers of perindopril API technology, these transfers were not comparable as to the content of the transfer or the circumstances of the transfer, and the payments would thus not necessarily be comparable. Moreover, this method, as well as the third one, would not allow capturing the strength of the non-licensed technologies and thus misjudge Servier's market strength flowing from these technologies both in the technology market and

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3530 ID0105, p. 173, ID4499, p. 2, ID4933.

3531 Annex 12- 01 to Servier's reply to the Statement of Objections, ID9065.

3532 In its reply to the Statement of Objections, Servier simplifies the analysis by making an unrealistic assumption that any undertaking claiming to be in a position to develop perindopril API technology and to supply perindopril (i.e. putative suppliers) could constrain Servier's position (see Servier's reply to the Statement of Objections, paragraphs 1774-1890, ID10114, p. 522-542). In fact, the potential suppliers differed a lot as to their ability to develop viable technologies. The Commission's analysis in the present section focuses on those technologies that could realistically lead to market entry with perindopril final formulations. This being said, during the period for which Servier was found dominant (see paragraphs (2749) and (2757)), Servier was the only company in control of an API technology viably used on a commercial scale.

3533 *Commission Notice - Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*, OJ C 101, 27.04.2004, p. 2-42, points 23-24.

the downstream markets. The Technology Transfer Guidelines recognise that the method may be often only theoretical.

(2738) Second, the main way to commercialise perindopril API technology was where the producer of the API acted as a supplier of the API (incorporating the technology) for the generic company and as a supplier of know-how regarding the technology. Thus the price paid for the supply of perindopril API and the related technology is a useful proxy showing the demand for perindopril technology itself.[3534] The "*product market shares method*" will consider the actual commercial dimension of the technology on the downstream market. Under this approach, all sales on the relevant final product market are taken into account, irrespective of whether the underlying technology is licensed or not. This is an important indication in any API technology market with sustained patent and regulatory barriers, on which the ability of a technology to represent an effective substitute, and thus an actual competitor, will depend. Until the very launch, and even after that, it is not clear whether an alternative (generic) technology can establish itself as an actual source of competition. This is not only dependent on the ability to enter (obtaining a marketing authorisation, pricing and reimbursement status, etc.) but also on its patent status and the way the incumbent originator enforces its patents. Thus, the market position of a given API technology will crucially depend on whether the final pharmaceutical product can be viably marketed or not. By analogy to Article 3(3) of the TTBER, a new technology which has not yet generated any turnover on the product market will be assigned a market share of zero.

(2739) To calculate market shares on the basis of sales of products incorporating the licensed technology on down-stream product markets, it is justified also "*to take into account technologies that are (only) being used in-house […]*". According to the Technology Transfer Guidelines, such an approach is a good indicator of the strength of the technology as it, amongst others, reflects the connection between the market position on the product market and the position on the technology market.

(2740) The third method, considering the remaining number of independent sources of API technology may be a useful complement to the second method: such "independent sources method" may capture constraints from certain sources of technology which could be insufficiently taken into account following the product market shares method, in particular because such sources might constrain the incumbent for the future. However, in such an ex ante assessment of substitutes, particular attention needs to be given to the question whether these sources were an effective substitute from the point of view of the technology user, and the consumer.

(2741) The subsequent assessment considers whether Servier was dominant on the API technology market in the period 2001-2007, relevant for the assessment of investigated practices. Particular emphasis will be given to two time periods, the period until 2004, when Servier acquired the Azad technology, and the period from 2005 until 2007, during which Servier concluded five settlement agreements with generic challengers. These periods do not coincide with any sudden changes in the

[3534] Despite Servier's suggestions to the contrary (see Servier's reply to the Statement of Objections, paragraph 1685, ID10114, p. 507), the quantification of the sales of products incorporating a given technology has been traditionally recognized as one of the methods to assess the demand for that given technology, e.g. *Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*, OJ C 101/4, 27/4/2004, points 22 and 23.

market structure, therefore a certain degree of overlap between the different periods could not be avoided.

7.3.4.1 Dominance in the period until 2004

(2742) In the first part of that period (i.e., until the end of 2001), Servier was still enjoying protection of the perindopril compound patent (running until October 2001, followed by an SPC extension for two to seven years, except Greece, Portugal and Spain). In addition, its synthesis of perindopril API was protected by three key process patents (the '339, '340 and '341 patents), and Servier's applications for a "*maze of patents*", to use Servier's own words, were being filed.

(2743) Servier was the holder of all and any technology used for the commercial production of perindopril, and was actually the only one to commercialise perindopril. Accordingly, no other company had any market share in the technology to produce viable API or in the sales of perindopril formulations incorporating perindopril API technology.

(2744) As Servier was not licensing out its patents, a generic company seeking a source of potentially viable perindopril API supplies in this first period had limited possibilities.[3535] In addition to the transferred [company name]* technology, the only remaining independent technology was that of Matrix,[3536] which had however not completed the development of the API technology following the settlement with Servier in 2005. Therefore, while Matrix API technology was potentially viable in 2001, it cannot be considered a sufficiently substitutable source of technology to Servier's viable API technology, let alone an actual constraint.

(2745) In the second part of the period (i.e., from 2002 until 2004), Servier had lost the protection of the perindopril compound patent by 2004 (with the exception of France and Italy, where the SPC was running until 2005 and 2009, respectively). Its three

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3535 Servier contests the fact that it did not licence its patents. To support its argument, Servier refers to a licence to Solvay in respect of the perindopril API in the US, a licence to Krka concerning the '947 patent, a proposed licence to Arrow concerning the Azad technology and a licence to Merck Génériques. Servier also argues that the finding of a dominant position on the technology market should not depend on the technology holder's decision to license out or not the technology in question (see Servier's reply to the Statement of Objections, paragraphs 1761-1773, ID10114, p. 520-522). The Commission must dismiss Servier's arguments. The licensing activity may be relevant for the assessment of dominance on the technology market, in particular if the licensing activity reflects competitive pressures from other suppliers of technology. For the analysis of dominance it is important that only Servier had an unrestrained access to the viable perindopril API technology and despite its claims, was not prepared to grant a licence that would allow for unrestricted market entry. Servier had no incentives to offer a licence at competitive conditions for the markets where it was already present with its final formulations. The Commission considers that the grant of a licence for the US territory, as in the case of Solvay, is irrelevant from the perspective of viable entry with the final formulation product on the EU markets. It is recalled that the licence obtained by Krka was limited to seven CEE countries (on most of which Krka was already present) and could not lead to unrestricted entry on the other EU markets (see section 4.3.3.6). It is also recalled that Servier offered to negotiate a licence for the Azad technology under the threat of litigation by Arrow. However, the negotiations did not lead to the licence being granted. First Arrow was not satisfied with the licensing conditions proposed by Servier and then decided that the ensuing delays were too long given its business plans (see paragraphs (386)-(389)). Finally, regarding the agreement with Merck, it was one of the distribution agreements that Servier concluded in preparation to the arrival of "hostile" generics. The distribution agreements were seen by Servier as an efficient tool to maintain a *"good income from perindopril"* and volumes if generic entry took place (see paragraph (205)). They were not meant to provide for independent generic entries.

3536 See Table 49.

key process patents (the '339, '340 and '341 patents) were still in force (and enforced against advanced generics challengers, such as Niche), a number of Servier's applications for a "*maze of patents*" had been granted or were about to be granted. In particular, Servier was granted the '947 patent, protecting the most stable (and thus the most common) crystalline form of perindopril erbumine (until its invalidation in the period 2007-2009).

(2746) Servier was still the holder of all and any technology used for the commercial production of perindopril, and was actually the only one to commercialise perindopril. Accordingly, no other company had any market share in the technology to produce viable API or in the sales of perindopril formulations incorporating perindopril API technology.

(2747) As Servier was not licensing out its patents, a generic company seeking a source of potentially viable perindopril API supplies had limited possibilities. In addition to the transferred Azad technology, there were only two potentially enabling technologies for production of perindopril API which would not be covered by the '947 patent. While these technologies were potentially viable in 2004, they cannot be considered as a source of technology sufficiently substitutable to Servier's viable API technology, let alone as an actual constraint.

(2748) In addition to Azad, Cipla and Sandoz, there was also a limited number of technologies in development for the alpha crystalline form of perindopril API covered by Servier's '947 patent. Given that these technologies were not yet completed (development timeline similar to that of Azad technology – launch in around 2006/2007), they could not be considered a sufficiently substitutable source of technology to Servier's viable API technology in 2004. Moreover, these technologies would have also needed to overcome the '947 patent, either by launching at risk or by an invalidity action. Therefore, these sources can only be considered as potential sources of viable technology which by 2004 were not sufficiently comparable to Servier's viable API technology.

(2749) For the above reasons, Servier can be considered to have held a dominant position at the time of acquisition of Azad technology, on 9 November 2004.

7.3.4.2 Dominance in the period 2005 - July 2007

(2750) The facts pertaining to the period 2005 – July 2007, during which Servier concluded five reverse payment patent settlement agreements with generic challengers, are by and large similar to the ones for 2004, both as concerns Servier's technology portfolio and sources of potentially viable competition. The situation however changed as of July 2007, when the '947 patent was annulled in the UK (and later also in the Netherlands and by the EPO).

(2751) While the potentially viable sources of technology were at more advanced stages of development, Servier was still the holder of the technology used for the commercial production of perindopril, and was actually the only one to commercialise perindopril, with two limited exceptions.

(2752) First, Krka launched its own perindopril formulations (in alpha crystalline form) in a number of CEE Member States, for which it received a licence in the framework of the settlement. As Krka marketed its perindopril based on the transfer of Servier's

technology, this does not affect the assessment that Servier controlled all technology for viable, commercial production of perindopril API.[3537]

(2753) Second, Apotex launched perindopril based on its own API technology (alpha crystalline form) in the UK in August 2006. Servier promptly obtained an interim injunction and stopped the marketing of Apotex' perindopril pending the main proceedings on the infringement / validity of the '947 patent.[3538]

(2754) This is yet another example that, at the time of Apotex' launch at risk, Servier had, through patent enforcement, a degree of control over the barriers to generic entry. The '947 patent was consistently invoked by Servier, and a potential confirmation of the patent validity would establish these sources as non-viable. The threat was concisely described by Teva in June 2006: *"If Servier wins the Alpha Polymorph patent, it would effectively shut everyone out of the market"*.[3539] After the intermediate decision of the EPO Opposition Division upholding the '947 patent in July 2006, this threat became even more acute. In a number of cases, generic companies withdrew from cooperation with suppliers with technology for alpha crystalline form perindopril API (for example, Specifar concerning supplies from Glenmark,[3540] and Sandoz concerning supplies from Apotex[3541]), while others initiated appeals before the EPO, and/or challenged the validity of the '947 patent before English and Dutch courts.

(2755) Accordingly, no other company had until July 2007 any market share either in the production of perindopril formulations independent of Servier's technology or in the market for technology to produce perindopril API.

(2756) Therefore, no technology could be considered as an actually viable source of competition sufficiently substitutable to Servier's own perindopril API technology at least until July 2007.

(2757) For the above reasons, Servier can be considered to have held a dominant position at the time of concluding the five respective settlement agreements in the period from 8 February 2005 to 30 January 2007.

7.3.5 Conclusion on dominance

(2758) In view of the foregoing, it is concluded that Servier held a dominant position within the meaning of Article 102 of the Treaty on the market for perindopril API technology, which is at least EU-wide, in the entire period from 2001 to July 2007. For the avoidance of doubt, any perindopril API technologies that became available after July 2007 as potentially or actually viable options to pursue market entries with the perindopril formulation products on the EU markets have no bearing on the Commission's finding with respect to the period prior to July 2007.

3537 See paragraph (965).
3538 See section 4.1.2.4.2.2.1.
3539 ID0078, p. 192.
3540 ID2428, p. 3.
3541 ID1480, p. 18.

8 ECONOMIC AND LEGAL ASSESSMENT OF SERVIER'S ACQUISITION OF TECHNOLOGY AND PATENT SETTLEMENTS CONCLUDED BY SERVIER UNDER ARTICLE 102 OF THE TREATY

(2759) Article 102 of the Treaty prohibits as incompatible with the internal market "[a]*ny abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it […] in so far as it may affect trade between Member States"*. Such abuse may, in particular, consist in: *"[…] (b) limiting production, markets or technical development to the prejudice of consumers; […]*".

(2760) In *AstraZeneca*, the Court reiterated the settled principle that: "*the concept of 'abuse' is an objective concept referring to the conduct of a dominant undertaking which is such as to influence the structure of a market where the degree of competition is already weakened precisely because of the presence of the undertaking concerned, and which, through recourse to methods different from those governing normal competition […], has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition*",[3542] from which "*[i]t follows that Article 82 EC prohibits a dominant undertaking from eliminating a competitor and thereby strengthening its position by using methods other than those which come within the scope of competition on the merits*".[3543]

(2761) Moreover, it has been consistently held that Article 102 of the Treaty imposes on an undertaking in a dominant position, irrespective of the reasons for which it has such a dominant position, a special responsibility not to allow its conduct to impair genuine undistorted competition on the internal market.[3544]

(2762) Whilst the fact that an undertaking is in a dominant position cannot deprive it of its entitlement to protect its own commercial interests when they are attacked, and whilst such an undertaking must be allowed the right to take such reasonable steps as it deems appropriate to protect those interests, such behaviour cannot be allowed if its purpose is to strengthen this dominant position and to abuse it.[3545]

(2763) In this section, the Commission assesses the compatibility of Servier's behaviour with Article 102 of the Treaty. This section focuses not only on Servier's behaviour as a party to the five settlement agreements, but also on its behaviour as an acquirer of API technology. The Commission will, therefore, consider whether the means used by Servier constituted competition on the merits or not, and whether or not these were capable of producing foreclosure effects on the market.

(2764) The Commission explains in the present section why these practices deviate from competition on the merits since Servier used its dominant market position on the four

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3542 Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 74. See also Judgment in *Hoffman-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraph 91; Judgment in *AKZO v Commission*, C-62/86, EU:C:1991:286, paragraph 69; Judgment of 7 October 1999, *Irish Sugar v Commission*, T-228/97, EU:T:1999:246, paragraph 111; and Judgment in *Michelin v Commission*, C-322/81, EU:C:1983:313, paragraph 54.

3543 Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 75. See also Judgment of 7 October 1999, *Irish Sugar v Commission*, T-228/97, EU:T:1999:246, paragraph 111; see also Judgment in *AKZO v Commission*, C-62/86, EU:C:1991:286, paragraph 70.

3544 Judgment in *Michelin v Commission*, C-322/81, EU:C:1983:313, paragraph 57; Judgment in *Post Danmark*, C‑209/10, EU:C:2012:172, paragraph 23.

3545 Judgment of 1 April 1993, *BPB Industries and British Gypsum v Commission*, T-65/89, EU:T:1993:31, paragraph 69.

national markets for perindopril formulations in France, Poland, the United Kingdom and the Netherlands and on the perindopril API technology market to delay generic entry by removing close sources of competitive threats. First, section 8.1 will set out the general strategy, including the practices assessed in the subsequent chapters, implemented by Servier to delay generic entry. Subsequently, in order to follow the chronology of events, this chapter will address the technology acquisition (section 8.2) and then the settlements (section 8.3). Both sets of behaviour jointly constitute an abuse of dominance under Article 102 of the Treaty (section 8.4). They are without prejudice, however, to the legality of the other sets of behaviour described as part of Servier's general strategy. Indeed, none of the elements in the strategy can *per se* be qualified as problematic under Union competition law.

8.1 Servier's general strategy to delay generic entry

(2765) In section 4.1.2, it has been shown that Servier followed a plan to protect its perindopril market position against generic entry. At least for the period from 2005 to 2008, Servier wanted to preserve earnings from perindopril.[3546] Although Servier was aware that it would no longer be possible to completely block generic entry during that period, it wanted to at least delay generic entry.[3547]

(2766) Such a strategy is generally legitimate to the extent it resorts to measures representing competition on the merits (competition on product quality, strength of the patented technologies and similar). Consequently, Servier can have a strategy to protect its commercial interests without infringing Article 102 of the Treaty, which may particularly include the strategic use of IPRs and the patent system. However, the implementation of a narrower strategy to use certain measures, which, in the context of Servier's special responsibility as a dominant undertaking, deviate from competition on the merits and are capable of producing foreclosure effects will not be immune to antitrust scrutiny merely because the goals it seeks to achieve could also be achieved by legitimate means. In addition, the assessment of this behaviour will take into account the full factual setting, including other practices flowing from the strategy for which the contribution to foreclosure effects is not established in this Decision.

8.1.1 Market context of the strategy and stakes for Servier

(2767) Sections 6 and 7 concluded, regarding the definition of the relevant markets (the EU-wide market for perindopril API technology, and the four national markets for perindopril formulations in France, Poland, the UK and the Netherlands), that Servier's perindopril was effectively only constrained by its own generics. Servier had been defining its anti-generic strategy as from 1999. Although generic entry had not yet occurred in 1999 and could potentially start in 2001 when the compound patent expired in some Member States, the constraint represented by generic companies already constituted a very important threat for Servier.

(2768) Indeed, perindopril was Servier's "*dairy-cow product*", and generic entry would have jeopardised this large revenue stream: for instance, when generic entry finally occurred in the UK, prices for perindopril decreased by up to 90% from the original branded price. Servier itself acknowledged that the stakes were high in the

3546 See paragraph (105).

3547 See section 4.1.2. For further evidence of the strategy found in Servier documents, see paragraphs (107)-(108), (110), (115)-(116), (219)-(220),(234)-(235).

"*Coversyl: Defense against generics*" document of 19 June 2006, where, in asking "*What is at stake?*", it indicated the sum of EUR 940 million (corresponding to Servier's yearly perindopril turnover).[3548] Confronted with the risk of an irreversible collapse of prices following generic entry, Servier devised a strategy of resorting to measures deviating from competition on the merits to prevent, or at least considerably delay, generic entry. This strategy contributed to keeping high prices and, thus, shielded Servier's rents from its branded product. Those rents were in turn used to eliminate or delay entry of further potential sources of competition by either acquiring them or paying (or otherwise inducing) them to stay off the market.

8.1.2 Elements of the strategy implementing the overall anticompetitive objective

8.1.2.1 Factual context: Servier's broader strategy to confront generic entry

(2769) Servier's strategy was to curb generic entry with perindopril as much as possible by strengthening barriers to generic entry. Section 4.1.2 has already described Servier's anti-generic strategy as having several aspects.

(2770) Such measures included the implementation of a patenting strategy, which itself rested mainly on the creation of a "**patent thicket*" containing process and crystalline form patents.[3549] As early as 8 October 1999, Servier documents mentioned the creation of a patent thicket as a solution to delay the threat of generic entry in certain countries as of 2001: *"*[…] As we already considered, it would be quite effective to apply for blocking patents on other production processes using alternative paths in order to create a process patent thicket around the molecule. Patent applications being published only 18 months after their filing, the best would be for the publication of these new process patents to occur before October2001, so that third parties become aware of them".*[3550] These patent applications and ensuing patents made it more difficult, costly and lengthy for potential entrants to identify the scope of Servier's valid patent protection and thus develop a viable product for potential entry.

(2771) The strategy also involved raising regulatory standards by strengthening quality standards under the European Pharmacopoeia:[3551] "**It would be ideal if the standards announced led to the use of protected processes".*[3552] As a consequence, potential entrants had to meet stricter product specifications, in accordance with standards influenced by Servier itself as the originator. According to Krka, "*There were not many industrial processes which enabled manufacturing of perindopril having the required purity. Krka was one of rare companies at that time which achieved to develop* [sic]*, and has also patented, a processes* [sic] *for synthesis of perindopril of the required purity*".[3553]

(2772) These practices are considered as important factual elements which help to explain, for example in assessing the anti-competitive foreclosure effects of Servier's conduct,

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3548 ID00105, p. 160.

3549 See section 4.1.2.1.

3550 See paragraph (116). It is also noted that Servier seems to recognise that some of the patents applied for as part of the strategy did not involve any inventive activity (see paragraph (122)).

3551 See section 4.1.2.2.

3552 See paragraph (132). This quote equally shows the complementary and cumulative dimension of the various aspects of the strategy, combining regulatory interventions with patenting measures to strive for maximum effect.

3553 See paragraph (138).

why the degree of (potential) competition for the supply of generic perindopril was particularly limited.

8.1.2.2 Servier's exclusionary strategy to buy out close competitive threats

(2773) Notwithstanding the higher regulatory and patent hurdles, some companies developed perindopril technology with the potential to overcome these hurdles and allow a viable generic entry. In reaction to this, Servier developed a more specific strategy targeting each such advanced source of competition to prevent generic launch by circumventing the "**blocking patents*", either by developing forms not covered by the patents or by a patent revocation action. In this context, Servier went beyond the mere defence of its IP rights. Servier not only attempted to enforce its patents, but attempted systematically and continuously to prevent generic entry when its patents could fail to block the generic companies' market access. As a rule, Servier induced these potential sources of generic competition into withdrawing from competing with it by means of significant value transfers.

(2774) The pattern of Servier's conduct combined a technology acquisition and five consecutive settlement agreements and served principally to remove close sources of competition. That this formed a single and continuous exclusionary strategy is confirmed by a number of contemporaneous elements.[3554]

(2775) In 1999, an internal note to top management of Servier advised that "**Generics of Coversyl may be launched, provided that Perindopril is synthesised by a synthesis route which is different from that described in our process patents".* and stressed the need to file "**blocking patents*" to create a "**a cluster of process patents around the molecule*".[3555] Other documents from the same period clearly identify the strategic objective of neutralising the arrival of generics ("**Develop a strategy to neutralise the arrival of generics*"), and specify how this is to be achieved ("**All synthesis routes that can potentially be industrialised should be blocked by blocking patents".*).[3556] Admittedly, this statement, drafted at a time when there was no advanced generic technology capable of overcoming these patent barriers, explicitly relates to Servier's patenting activity only. But, as it emerged subsequently, its own patenting activity was complemented by Servier's endeavours to acquire substitute technology from competing operators. For all practical purposes, this was just another, complementary, way to block "*[a]*ll synthesis routes that can potentially be industrialised "*, fully consistent with the aforementioned strategic orientation. In Servier's own words, *"[a]ll complementary means to forbid them to reach the market will have to be used"*.[3557] Servier seems to have fully implemented this command. Servier internally reported that the first threat of generic entry occurred in 2001.[3558] This coincided with its first perindopril API technology acquisition from [company name]* in […]* 2001.

(2776) Also, as will be explained further in section 8.2, with regard to the technology acquisition specifically, there is documentary evidence showing that Servier

3554 Servier's position as to this anti-generic strategy is inconsistent. Servier simultaneously denies the existence of a strategy and claims that such a strategy is, in itself, entirely legitimate and lawful (reply to the Statement of Objections, paragraphs 1966-1969, 1975-1980 and 2346, ID10114, p. 556-557 and 617).

3555 See paragraph (115).

3556 See paragraph (117).

3557 See paragraph (219).

3558 See paragraph (266).

purchased the Azad technology (which successfully avoided the '947 patent for the alpha form) in order to hamper generic entry rather than to pursue efficiencies from the acquired technology. Indeed, the preamble to the Azad Agreement of 9 November 2004 contains an explicit statement of Servier's intentions:[3559] "*SERVIER is interested to strengthen the defense mechanism for its own alpha, betha* [sic] *and gamma forms of Perindopril and has decided to purchase the Patent Application and its know how*". This confirms that Servier's interest in the acquisition of the Azad technology was not to improve its production processes (as stated *ex post facto* in the context of the present investigation),[3560] but to add the Azad patent application to its "defense mechanism" which can only have been designed to defend against generic entry.[3561] There is also evidence that Servier did not put to use the purchased technology (see paragraphs (380)-(381)). In addition, Servier's list of patents qualified as protective measures against generics later contained an explicit reference to the patent application for delta and epsilon polymorphs acquired from Azad.[3562] This again confirmed that the Azad technology was effectively added to the "**blocking patents*".

(2777) The combined sequence of these practices further emphasises the degree to which they were complementary elements intended to implement a broader strategy to delay generic entry. Discussions with Azad on the acquisition started in late June 2004, and the due diligence began in September 2004.[3563] In parallel, Servier made an offer to acquire Niche (which was in litigation with Servier concerning an alleged infringement of Servier's process patents), and later sent a draft non-disclosure agreement in that regard on 28 October 2004 while already listing the information to be provided in the upcoming due diligence on 3 November 2004. The Azad acquisition was then finalised on 9 November 2004. A week later, on 16 November, the Niche due diligence started,[3564] but, instead of an acquisition, Servier eventually opted in early 2005 for a patent settlement ("*[Servier] expressed preference to pay a 'patent settlement' rather than acquire shares".*[3565]), to which Niche agreed. The settlement was signed on 8 February 2005. At the very last moment, Matrix also had to be informed and brought in from India to sign its own settlement on the same day. Servier had succeeded in discontinuing yet another project to launch generic perindopril.

(2778) In 2005, Teva (through Ivax) was the first operator to contest the validity ot the '947 patent in court proceedings. In return for its agreement to stay the proceedings and wait until the final EPO decision, Servier allowed Teva to launch a product covered by the '947 patent, provided other Servier patents were not infringed. When Teva was in advance preparations to launch either its own or Krka's perindopril, settlement negotiations with Servier started and the Teva Settlement Agreement was concluded

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3559 See paragraph (369).

3560 See Servier's reply to the Statement of Objections, paragraphs 2154-2171 and 2274-2303, ID10114, p. 584-586 and 603-607. In a footnote to paragraph 2281, Servier explained that this objective of complementing its crystalline forms in order to improve its production process was the meaning of the quoted preamble.

3561 As described in paragraph (2782) and footnote 2421, the draft terms of agreement between Sandoz and Servier suggest that Servier's unsuccessful attempt to acquire technology from Sandoz were […]*.

3562 See paragraph (141).

3563 See paragraph (358) and subsequent.

3564 See paragraphs (528)-(535).

3565 See paragraph (533).

in June 2006. This settlement essentially turned Teva from a competitor into a distributor of Servier products.

(2779) Servier's internal document entitled "*Coversyl: defense against generics*", prepared only days after the Teva Settlement Agreement, lists a number of "*protective measures against generics*", including in particular patent protection.[3566]

(2780) Under the title "*Did it work*?", the presentation mentions that the first generic threat emerged in early 2001. Subsequently, it lists a number of other indications suggesting that the strategy to delay generic entry was successful. This includes a reference to the Niche litigation in the United Kingdom, and the patent settlements with Niche/Unichem and Matrix and the "partnership" with Teva. The presentation also reveals that, at the time when it was prepared, Servier was still closely following the development of two advanced sources of perindopril, which obtained or were close to obtaining a marketing authorisation: Apotex and Krka.

(2781) Only a few months later, in October 2006, after the Opposition Decision upholding the '947 patent and its litigation with Krka in the United Kingdom concerning both the infringement and validity of Servier's patents, Servier then concluded a patent settlement agreement with Krka, which also transferred its technology to Servier in January 2007. In the same period, October 2006, Lupin launched a revocation action against the '947 patent. In January 2007, Servier concluded the Lupin Settlement Agreement, which also comprised an acquisition of the relevant Lupin technology by Servier. Generic entry then only occurred in the UK in July 2007, after the local annulment of the '947 patent, and in December 2007 in the Netherlands, when Apotex entered at risk.

(2782) Meanwhile, in October 2007, Servier signed Heads of Agreement for the possible acquisition of a number of patent applications from Sandoz, one of the very rare companies which had developed a form of perindopril not covered by the Servier patents (amorphous perindopril erbumine).[3567] The terms of the Heads of Agreement contain a clear indication that Servier was only interested in purchasing the Sandoz technology to the extent it could not reasonably attempt to block Sandoz with its perindopril patent portfolio. Thus, the purchase by Servier for the total of USD [40–55]* million would only ensue if, following Servier's assessment, Sandoz's perindopril product was found as (cumulatively)[3568] not infringing Servier patents, stable, and capable of being manufactured on an industrial scale. […]*. Nevertheless, Sandoz ultimately decided not to finalise the agreement, but only after it had already entered some markets with its generic product.[3569] In particular, it entered the French market in September 2008.

(2783) This short chronological description of how the investigated transactions unfolded shows to what degree they were intertwined. Furthermore, it highlights that, whatever the legal tool ultimately used in each particular case, Servier used all available means to eliminate close threats one after the other as the only way and with the single objective of preventing and/or delaying generic entry on the market and the ensuing collapse of its revenues. These investigated practices, which strayed from competition on the merits, are fully assessed in the following sections.

3566 See paragraph (111)

3567 See section 4.2.2.8.4.

3568 See paragraph (407).

3569 See paragraphs (406)-(410), (2327), and footnote 2421.

(2784) Consequently, only one set of legal proceedings challenging Servier's patents survived the series of settlements. This was the Apotex litigation in the United Kingdom, and Servier considered various options to prevent the Apotex launch (other than prevailing in the said litigation). Thus, Servier not only considered the option to settle,[3570] but also tried to block Apotex's launch through an action for the infringement of the perindopril compound patent in Canada, where Apotex produced perindopril at the time.[3571] Although Servier did prevail in Canadian proceedings, this came too late to prevent Apotex from launching in the United Kingdom, where it continued litigation and had the '947 patent annulled.

8.1.3 Servier's strategy was broadly recognised by the generic industry

(2785) Servier's exclusionary strategy of buying out close sources of competitive threats, as depicted in section 8.1.2.2 was promptly recognised as such by generic companies.[3572] This awareness is illustrated by the contemporaneous statements of several generic companies.

(2786) As early as 7 February 2005, an internal Teva email stated that "*Teva development [was] delayed as cannot acquire any API (Servier keep buying up API companies)*".[3573] This remark was made only three months after Servier's acquisition of IPRs from Azad, and on the eve of the conclusion of the settlement agreements between Servier, and Matrix / Niche, respectively. It is also recalled that Servier attempted to acquire Niche.[3574]

(2787) Just a few months later, on 17 June 2005, an internal Ivax/Teva email indicated, after a meeting with Krka, their perceptions that: *"KRKA feel there is a strong likelihood that Servier will attempt to buyout all API manufacturers, (I have not advised them of our source except to say it is not Matrix, who were bought out with Niche)".*[3575] This was a year before Teva concluded an agreement with Servier, and almost a year and a half before Krka also did so.

(2788) Similarly, on 10 August 2005, an internal Ivax/Teva email emphasised the general understanding among generic companies that Servier was eliminating potential sources of competition and that the names of these potential sources should be kept from it: *"In any conversations with Servier, it is important that they are not given the name of our APIs supplier. The general industry consensus is that Servier will attempt to take out API sources".*[3576]

(2789) On 3 October 2005, Ivax/Teva reported in an internal communication that: *"The position with Perindopril is very complicated in terms of patents- particularly process patents which affect API manufacturers. This is partly why everyone is late (once an API manufacturer has got round the process patents Servier has bought the company, sourcing API has been very difficult".*[3577] This confirms that eliminating potential sources of competition was already perceived as a continuous course of

3570 See paragraphs (179) and (191).
3571 See paragraphs (886) and (2720).
3572 See paragraph (142).
3573 See paragraph (413).
3574 See section 4.3.1.3.
3575 See paragraph (414).
3576 See paragraph (142).
3577 See paragraph (416).

conduct, in the further context of heightened barriers to entry, which was also part of Servier's strategy in order to limit the number of these potential sources.

(2790) Then, shortly after the Krka settlement but two months before the Lupin agreement, Lupin showed, in an internal document of 14 November 2006, its awareness of Servier's previous settlements and painted the overall picture of Servier's implementation of its anti-generic strategy.[3578] Because Lupin was aware of these settlements, it was also aware of the fact that settling with Servier was an option for itself. In addition, this possibility and the picture Lupin paints clearly show how Servier fettered with the incentives of generic companies to engage in competition by instead concluding settlements with them.

(2791) The pattern of Servier's settlements became so obvious that, even after the Lupin settlement, generics anticipated further settlements. An internal Teva communication of 27 February 2007 commented on the litigation between Servier and Apotex, the last "*hostile player*" after all the investigated transactions had taken place, that: *"[a settlement between Servier and Apotex] would be a good result for us (...)? If the settlement keeps other generics off the market in the UK then we keep our present arrangement with Servier. (...) I have asked Alia to keep an eye on the court lists to see if this case gets withdrawn"*.[3579]

(2792) Finally, in an internal email from 22 November 2007, Sandoz, at the time in discussions with Servier on a potential agreement, reported that: *"[a generic company] also informed about the fact that Servier is closing deals with developers to cancel their development"*.[3580]

8.1.4 Conclusion on Servier's overall strategy

(2793) Faced with the expiry of the compound patent protection after up to 15 years of product exclusivity, Servier put in place and rigorously pursued a comprehensive strategy using all complementary means to protect perindopril. This broader strategy relied on the creation of a "*maze of patents*", and influencing regulatory standards so that they would, for example, "*lead to the use of* [Servier's] *protected processes"* and thus influenced the parameters for viable market entry by generic perindopril. Within that broader context, Servier pursued a targeted exclusionary strategy, as assessed in this Decision, to remove, before market entry, all close sources of competitive threats on the up- and down-stream markets for perindopril with the potential to overcome notably the patent and regulatory barriers. By and large, these threats were not ousted from competition based on the merit of Servier's patent portfolio, its superior efficiency, or better quality of its products, but by a string of technology acquisitions (Azad in 2004, Sandoz (failed) in 2008) and rent sharing in the form of a series of reverse payment patent settlements with generic companies (Niche/Unichem and Matrix in 2005, Teva and Krka in 2006, Lupin in 2007).

(2794) As will be further developed in the subsequent sections, considering the clear pattern of Servier's conduct and based on contemporaneous evidence, the acquisition of Azad's patent application and related know-how by Servier ("Azad Technology Acquisition") and the reverse payment patent settlements can be seen to form a single and continuous exclusionary strategy by Servier. There are essentially two ways to

3578 See paragraph (1023).

3579 See paragraphs (773) and (1265).

3580 See paragraph (420).

viably launch a generic product where the market is still protected by patent barriers. The first one is to invent around the remaining patents and develop a non-infringing product. The second one is to challenge the relevant patent situation, either by directly seeking a finding of invalidity or non-infringement of the patents or by entering at risk. Any strategy to successfully delay generic entry, would have to address both types of generic threats, as illustrated by the above-mentioned documents from Servier and generic companies, which advocate the use of both acquisition of novel, non-infringing, technology and settlements to end litigation on the relevant patents.[3581]

(2795) This is why the Azad Technology Acquisition, targeting an independent non-infringing technology to produce perindopril API, was a necessary complement to the patent settlement agreements with generic companies which threatened to invalidate the '947 patent in legal proceedings.[3582]

(2796) In its reply to the Statement of Objections,[3583] Servier contends that the practices assessed under Article 102 of the Treaty constituted competition on the merits. It explained that technology acquisitions are lawful except in very specific circumstances which are not present in this case, where the acquisition had the purpose of improving Servier's production process.[3584] It also explained that patent settlement agreements were concluded not with an illegitimate purpose but because of the asymmetry of risks which the originator faces, that they were reached on the basis of the respective assessments of the situation by the parties and not on that of an alleged inducement in the form of a payment, and that in any event generic entry was prevented by the patents and not the settlement agreements.[3585] Sections 8.2 and 8.3 will show that, on the contrary, these practices deviated from competition on the merits.

(2797) The respective contributions to the overall foreclosure effects that these transactions, which implemented Servier's anti-generic strategy, were capable of producing, will be assessed in sections 8.2 to 8.4. It will be considered whether, under Article 102 of the Treaty and in the full context taking into account the implementation of other elements of the strategy, each practice was capable of contributing to the overall foreclosure effects on the four national markets for perindopril formulations in France, Poland, the United Kingdom and the Netherlands and on the market for perindopril API technology.

8.2 Assessment of the Azad Technology Acquisition

(2798) Servier's acquisition of the Azad Technology was chronologically the first transaction covered by this Decision implementing Servier's investigated exclusionary strategy. This section will assess whether this acquisition deviated from competition on the merits and was capable of contributing to the foreclosure effects of the overall strategy, that is to say rendering generic entry more difficult and/or delaying it.

3581 See, for example, paragraphs (2776)-(2782).

3582 To illustrate the complementarity of these practices, see Table 49.

3583 Servier reply to the Statement of Objections, paragraphs 1922, 2344-2346, ID10114, p. 548 and 617.

3584 Servier reply to the Statement of Objections, paragraphs 1928 and 1966-1980, ID10114, p. 549 and 556-557.

3585 Servier reply to the Statement of Objections, paragraphs 2329-2342, ID10114, p. 612-616.

8.2.1 Applicable legal framework

(2799) Technology transfers whereby one firm acquires technology from another firm are usually pro-competitive in that they can help to diffuse the use of that technology. This diffusion can lead, for example, to more efficacious active substances or lower production costs.

(2800) The Commission takes into consideration three elements for the purpose of assessing whether the technology acquisition in the present case deviates from competition on the merits and, consequently, is capable of producing foreclosure effects contributing to an overall single infringement of Article 102 of the Treaty. The three elements of analysis in this case are:

- whether the technology that Servier purchased was potentially enabling[3586] and thus a source of competition to Servier, i.e. whether it was sufficiently advanced (as opposed to merely embryonic and distant from possible commercial exploitation by the extent of the development work still needed), and had the potential to overcome barriers to entry;[3587]
- whether the purchased technology was effectively removed from the market as a potentially enabling source of competition, i.e. whether the transferor remained free to use and/or license the technology or parts thereof and whether the transferee was willing and able to license it out on terms that would be attractive to competitors; and
- whether the acquisition was "*capable of making more difficult, or impossible the entry*"[3588] and thus to significantly delay[3589] generic competitors trying to enter the perindopril market, namely to what extent the purchased technology was necessary for timely entry, and, conversely, to what extent there existed alternative technologies capable of offsetting the loss of one source of technology (in particular, whether such alternative sources of API technology were scarce or inferior in quality).

(2801) In conducting this multi-pronged assessment, the Commission takes account of the specific nature of pharmaceutical markets, where (a) API is an indispensable input into final formulation; (b) generic entry requires several years of multifaceted development work (vertically integrated, or in cooperation on one or more levels) on the API, the formulation, distribution, taking into account regulatory and patent law requirements; and any disruption of this process is liable to cause significant delays (for example because both the work on the API and the formulation may need to be restarted if a source of API is lost); (c) any delay in generic entry,[3590] from the end of

3586 Also referred to as "potentially viable" in this decision.

3587 To the extent that an alternative API source is removed before the end of the product development and marketing, there is no certainty at the time of the acquisition that the API, as an input, would be an actual source of competition on the API and final product market. Therefore, the Azad technology will be examined as a potential source of competition in view of the barriers to entry.

3588 See judgment in *TeliaSonera Sverige*, C-52/09, EU:C:2011:83, paragraph 63, referring to Judgment in *Deutsche Telekom v Commission*, C-280/08 *P*, EU:C:2010:603, paragraph 253.

3589 This condition appears to be recognised in principle in Servier's reply to the Statement of Objections, paragraphs 1933-1942 and 1950-1954, ID10114, p. 550-554.

3590 The extent of the delay depends on the time needed to develop another new alternative technology (not to mention the risk that such new development eventually fails to overcome the high barriers to entry), or, in the case a switch to an existing alternative source is possible, the time needed for additional

the patent term, causes significant consumer harm both for patients and for social security systems; (d) the demand is fairly price-inelastic prior to generic entry;[3591] (e) the price difference between a monopolised market and a market with just two (or more) competitors is often very large – sometimes a factor of ten to one.

(2802) The elements of analysis set out in paragraph (2799) draw on previous case-law on abusive patent acquisition. In particular, the *Tetra Pak* case-law holds that an acquisition of exclusive rights can, in specific circumstances where this acquisition strengthens the dominant position and prevents or considerably delays the entry of competitors on the market, constitute an abuse under Article 102 of the Treaty. In the present case, the acquisition of a technology is held to contribute to the foreclosure effect of the overall single infringement of Article 102 of the Treaty. Indeed, the effects of the technology acquisition cannot be isolated from those of the reverse patent settlement agreements pursuing the same objective, namely delaying generic entry.[3592]

8.2.1.1 Commission practice and case-law

(2803) The *Tetra Pak I* case concerned the question whether the acquisition of an exclusive license could constitute an abuse of a dominant position under Article 102 of the Treaty.[3593] Because the competitive effects of an outright transfer of technology can be similar to the grant of an exclusive license, *Tetra Pak I* may provide useful guidance for the Azad Technology Acquisition.

(2804) The Commission's *Tetra Pak I* decision found that, concerning the abuse, "*in the specific circumstances of this case*", Tetra Pak's acquisition of the exclusive license had two consequences. First, it "*strengthened Tetra's very considerable dominance*" compared to its actual competitor in the relevant market, PKL, "*by reinforcing its technical advantages vis-à-vis the minimal competition that remains*". Second, the exclusive license "*had the effect of preventing, or at the very least considerably delaying, the entry of a new competitor into a market where very little if any competition is found*". With regard to this second point, "*The impact of this acquisition on the market was not hypothetical but very real. The effect in the circumstances of this case was to preclude the possibility of any new competition (in particular from Elopak, which was on the verge of trying to enter the market)*". The Commission thus concluded that the exclusive license had "*The effect of blocking or delaying the entry of a new competitor*". The overall effect is that "*any competition remaining is substantially fettered or practically rendered impossible*". This does not require competition to be eliminated; "*substantially fettered*" is sufficient.

(2805) The *Tetra Pak* I decision does mention that "*only Liquipak*" held the "*vital*" technology at issue in this case, which suggests that access to that particular technology was necessary for a third party to bring about competition in the market in the short term, as other technologies required "*further technological development*". But as the decision refers to the condition to "*delay the entry of a new competitor*", it does not preclude the possibility of a scenario where a dominant undertaking also

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development, including restarting or updating regulatory procedures. It may also reflect the additional time needed for invalidation or expiry of the blocking patents.

3591 See paragraph (2532).

3592 For more details on the combined effects, see sections 8.4.1. and 8.4.2.

3593 88/501/EEC: Commission Decision of 26 July 1988 relating to a proceeding under Articles 85 and 86 of the EEC Treaty (IV/31.043 - Tetra Pak I (BTG licence), OJ L 272 , 04/10/1988 p. 27 - 46.

delays the entry of a new competitor in a somewhat different setting. This interpretation was later confirmed by the Courts of the European Union, as explained in paragraph (2810).

(2806) The General Court discussed the *Tetra Pak* case twice, first in connection with Tetra Pak's action for annulment of the decision, and then again twenty years later, in *AstraZeneca*.

(2807) In the *Tetra Pak* judgment, the General Court only needed to address Tetra Pak's argument that the Commission erred by applying Article 102 of the Treaty to an agreement which was exempted under Article 101(3) of the Treaty.[3594] The judgment nevertheless contains a number of relevant findings concerning the abuse.

(2808) First, the Court ruled that "*the mere fact that an undertaking in a dominant position acquires an exclusive licence does not per se constitute abuse within the meaning of Article [102]*". The Court emphasised the circumstances surrounding the acquisition and the effects of such acquisition on the structure of competition in the market.[3595]

(2809) In that regard, according to the Court, the specific context of the case was "*the fact that acquisition of the exclusivity of the licence not only 'strengthened Tetra's very considerable dominance but also had the effect of preventing, or at the very least considerably delaying, the entry of a new competitor into a market where very little if any competition is found*'".[3596] The Court thus concurred with the Commission that abuse may take place not only where competitive entry is prevented altogether, but also in cases where it is considerably delayed. The Court went on to note that the "*decisive factor*" was that "***at the material time*** *the right to use the process protected by the […] licence was alone capable of giving an undertaking the means of competing* ***effectively*** *with the applicant*" (emphasis added).

(2810) In the *AstraZeneca* case, the General Court made the same two points about *Tetra Pak*, though not in the same order. The General Court was assessing whether the undue acquisition of an exclusive right – in that case, an SPC obtained through false representations to the patent office – could constitute an abuse of a dominant position. AstraZeneca had argued that, on the basis of the *Tetra Pak I* judgment, the undue acquisition of an exclusive right could only constitute an abuse if it eliminated all competition. The Court rejected the argument, thereby providing useful guidance on *Tetra Pak I* and Article 102 of the Treaty. The Court first noted that the technology at issue in *Tetra Pak I* was "*the only means of competing effectively*" with Tetra Pak. It then moved on to what it viewed as the decisive point in *Tetra Pak I*. According to the Court, the *Tetra Pak I* judgment stands for the proposition that a dominant undertaking cannot acquire an exclusive license to "*strengthen its*

3594 Judgment of 6 October 1994, *Tetra Pak v Commission*, T-83/91, ECR, EU:T:1994:246.

3595 Judgment in *Hoffman-La Roche v Commission*, C-85/76, EU:C:1979:36.

3596 The seriousness of these concerns is illustrated by the fact that they can also arise under Article 101 of the Treaty and the Merger Regulation. Under Article 101, "*where a dominant licensee obtains an exclusive licence to one or more competing technologies, [...] entry into the technology market is difficult and the licensed technology constitutes a real source of competition on the market*" the license agreement may raise concerns (see *Commission Notice - Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements*, OJ C 101, 27.04.2004, p. 2-42, point 166). Under the Merger Regulation, buying a substitute technology can be a problematic horizontal merger, while buying a key input into a rival product can also raise concerns under an input foreclosure theory of harm (see the *Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings*, OJ C 265, 18.10.2008, p. 6–25).

[already] very considerable dominance and to prevent or considerably delay the entry of a new competitor" (internal quotation marks omitted). The Court thus ultimately did not base its findings on the notion of indispensability of the technology,[3597] but on the considerable delay to the entry of competitors.

(2811) The *AstraZeneca* judgments also contain two additional points that are relevant for present purposes.

- First, the General Court held that "*although proof of the deliberate nature of conduct […] is not necessary for the purposes of identifying an abuse of a dominant position, intention none the less also constitutes a relevant factor which may, should the case arise, be taken into consideration by the Commission*".[3598]
- Second, on appeal, the Court of Justice held that "*the anti-competitive nature of its acts must be evaluated at the time when those acts were committed*".[3599] This is the *ex ante* perspective that the Commission applies in this case: the anti-competitive nature of the acts at issue must be assessed in the light of what the parties knew or could reasonably predict at the relevant time.

8.2.1.2 Assessment of the technology acquisition: general points

(2812) The assessment of the elements concerning the technology acquisition identified in paragraphs (2799) to (2801) is therefore based on the situation at the time of the relevant acquisition (i.e. an *ex ante* assessment), as it is not necessary to prove that the conduct succeeded in generating actual foreclosure effects.[3600] The assessment thus not only looks at what existed at the time of the acquisition but also takes into account what could reasonably be expected to constrain Servier in the future. Indications that Servier could, going forward, remove further competitive threats in implementing its overall strategy, and that thus the remaining sources of competition could become more limited, are also considered.

(2813) The capability of input foreclosure is examined on two neighbouring markets, the market for perindopril API technology and the market for perindopril formulations, the final perindopril product.

(2814) In its reply to the Statement of Objections,[3601] Servier alleged that the Commission's test would make any technology acquisition abusive and thus harm innovation and, ultimately, patients. As detailed in the present Decision, the test used by the Commission is, on the contrary, stringent and objective, and the finding of abuse is limited to the specific circumstances of the present case, where the acquisition of technology as part of a broader exclusionary strategy was clearly anticompetitive. It would normally not prohibit non-exclusive transactions, transfers of technology complementary to their own and which would in principle encourage competition rather than delay competitive entry, as is common in the industry.

3597 For Servier's arguments on the indispensability of the technology, see its reply to the Statement of Objections, paragraphs 1917 and 1929-1932, ID10114, p. 547 and 549-550 [confidential].

3598 Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 359.

3599 Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 110.

3600 See paragraphs (2810) - (2811).

3601 Servier's reply to the Statement of Objections, paragraphs 1917, 2006 and 2443, ID10114, p. 547, 561 and 648.

8.2.2 Assessment of Servier's acquisition of the Azad technology

8.2.2.1 The acquisition as part of Servier's patent related strategy to confront generic entry

(2815) Servier's initial plan to block all industrially applicable methods to synthesise perindopril[3602] failed to create an impenetrable ring of patent protection, a conclusion which is reached on the basis of the analysis of available sources of perindopril API, summarised in Table 49, overview of perindopril API sources]. Namely, there were isolated cases of companies which were able early on to find ways to produce perindopril without infringing Servier's process patents in force ([company name]* by 2001) and, later, the '947 patent (Azad by 2004, Sandoz). Servier successfully acquired exclusive rights to technology from both [company name]* and Azad, but failed in 2008 to acquire the technology from Sandoz.

(2816) As shown in section 8.1, acquiring competing technology for producing perindopril formed part of Servier's overall strategy to delay generic entry. As shown below in section 8.3, this strategy also comprised entering into a series of patent settlements to remove generic competitors which threatened to overcome Servier's patent in litigation.

8.2.2.2 Introduction

(2817) The assessment of the Azad Technology Acquisition will build on the previous findings of Servier's dominant position in the markets for the final perindopril product in France, the Netherlands, Poland and the United Kingdom and perindopril API technology at the time of the IPR acquisition by Servier, i.e. in 2004 (see section 6.5.2.6 and section 7.3.5), and will aim at establishing whether Servier's acquisition of the Azad technology differed from competition on the merits and produced foreclosure effects which, in the context of Servier's single and continuous strategy as described in section 8.1, contributed, together with the five patent settlements assessed in section 8.3, to Servier's conduct being capable of producing foreclosure effects, constituting an abuse of dominance under Article 102 of the Treaty.

(2818) This section will assess: (i) whether Azad had potentially enabling technology which could represent a source of competition to Servier, (ii) whether Azad and its technology were effectively removed as a potentially enabling source of competition, and (iii) whether this was capable of producing foreclosure effects.[3603]

8.2.2.2.1 Azad was a source of potentially enabling API technology and thus a competitive threat to Servier

(2819) At the time of Azad's development of perindopril technology, and its acquisition by Servier in November 2004, there were various barriers to entry for generic competitors. These included the strict standards of the European Pharmacopoeia monograph (purity, quality, stability etc.) required for the marketing authorisation, and the process patents already mentioned in section 8.1. However, the '947 patent represented the most important constraint for generic competition.[3604] As a patent

3602 See section 4.1.2.1.

3603 See paragraph (2799).

3604 Contrary to what Servier claims (paragraphs 2174 to 2176 of its reply to the Statement of Objections, ID10114, p. 586-587), and in view of the timeline for the launch of perindopril products as described below, the compound patent was not a significant obstacle to market entry for Azad. Indeed, since market launch was expected in early 2007, the SPCs prevented entry only in Italy (where it expired in

covering the most stable (alpha) form of perindopril erbumine, it became a major barrier to the production of perindopril by generic companies, even if using alternative, non-infringing production processes.[3605] The '947 patent was highly contested in view of alleged prior art in the form of Servier's earlier '341 process patent. Most of the known alternative processes also yielded perindopril in alpha crystalline form, or forms which carried the risk of converting into the alpha form, and would thus be covered by the '947 patent. This explains why 10 oppositions to this patent were filed before the EPO in October - November 2004.[3606] Teva's internal assessment from 2006 (i.e. after the Azad Agreement) is more than telling concerning the importance of the '947 patent for generic competition: "*If Servier wins the Alpha Polymorph patent, it would effectively shut everyone out of the market*".[3607]

(2820) The technology developed by Azad had from the outset the potential to avoid claims of infringing the '947 patent and related litigation for patent infringement and/or invalidity, and Servier later expressly recognised that Azad's delta form of perindopril did not infringe any of Servier's patents.[3608] Azad discovered new polymorphic forms of perindopril API, delta and epsilon, for which it filed a patent application in June 2003, which were distinct from Servier's patented crystalline forms.[3609] In August 2003, Azad issued a document indicating that perindopril which would be manufactured pursuant to the Azad technology did not infringe Servier's patents ("declaration of non-infringement").[3610] The declaration of non-infringement covered a number of Servier patents, including the process patents '339, '340 and '341 and Servier's patent applications for the alpha (i.e. the '947), beta and gamma polymorphs ("*We [Azad] are manufacturing a different polymorphic form of Perindopril erbumine and filed our own patent*").[3611] Servier concurred with this. In the preamble to the Azad Agreement, Servier explicitly recognised that it was "*of the opinion that the Patent Application do* [sic] *not infringe the SERVIER patents"*. The preamble also states that Servier had "*conducted a thorough due diligence of the products and information received from AZAD, has independently and fully assessed the merits and particularities of the Patent Applications (including the patentability of it) and the associated know how"*.[3612] These statements carry particular weight. Not only did Servier accept that Azad's technology was non-infringing after due diligence, but it also did so in a legally binding contract. For the purpose of the subsequent assessment, Azad's API will thus be considered as not infringing any of Servier's patents.

(2821) According to the information gathered from Azad and its cooperation partners, the development of perindopril API reached an advanced stage by the time of the Azad Technology Acquisition. The scaling up for industrial quantities (commercial

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February 2009). However, entry in the four national markets analysed in detail in this Decision was not blocked by the compound patent.

3605 See section 7.3.3.1.2.

3606 See section 4.1.2.4.2.1

3607 See paragraph (2688).

3608 See paragraph (369).

3609 See paragraph (308).

3610 See paragraph (323).

3611 ID1570, p. 12.

3612 See paragraph (369). The "*thorough due dilligence*" (in the words of the preamble to the Azad Agreement) comprised an information package by Azad, a meeting of experts of Servier and Azad, and further clarifications on the stability of the delta form (see paragraphs (361) - (365)).

batches) was on-going.[3613] In addition, according to information provided by Teva and Arrow, each of these companies was discussing with Azad a timeline for the preparation of the regulatory dossiers. Thus, Arrow reported extensive discussions with Azad on the timing for the preparation of a DMF for the purpose of marketing authorisation procedures in the United Kingdom and Portugal.[3614] Arrow understood that CCSB, the contract manufacturer to Azad, would file a DMF in February 2005 and, on this basis, Arrow planned to apply for marketing authorisations in the EU in March 2005.[3615] Likewise, Teva's cooperation with Azad reached the stage where Teva was preparing for a [non-EEA jurisdiction]* regulatory filing before the [non-EEA adminsitration]* in October 2004, and subsequently for the EU filing (more stability data was required under EU regulatory procedures). Had Azad's development continued, Teva expected to be able to apply for marketing authorisations in the EU in the first half of 2005, in the absence of any unforeseen difficulties.[3616] In Teva's words: "*Azad terminated the cooperation very late, literally before [Teva's] filing for [non-EEA jurisdiction]* approval*".[3617]

Alleged decisive development difficulties

(2822) Contemporaneous evidence shows that, while Azad was confronted with certain difficulties in the development of perindopril API, the main difficulties identified by that time had been successfully overcome. This subsection will show that Azad's technology was potentially enabling, and a competitive threat to Servier, as it was at an advanced stage of development, non-patent-infringing, met no insurmountable difficulties, and thus had the potential to be used as an efficient alternative industrial process for the production of perindopril API both from patent and regulatory perspectives.

(2823) In the course of the Commission's investigation, Azad claimed that it risked not meeting patent and/or regulatory requirements due to development difficulties, and consequently decided to transfer its perindopril technology to Servier. Specifically, Azad invoked on-going difficulties with the production of validated commercial batches and the uncertainty concerning the adequate stability data of the batches.[3618] However, Azad provided no supporting documents for these affirmations.

(2824) In keeping with this, Servier argues that certain contemporaneous documents show that Azad was facing technical problems (in particular the hygroscopic nature of the

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3613 See paragraph (312).

3614 See paragraph (327).

3615 See paragraph (392).

3616 See paragraph (343).

3617 See paragraph (396). Concerning Servier's argument (paragraph 2196 of the reply to the Statement of Objections, ID10114, p. 590-591) that Specifar stated that "product launch was not expected in the near future" (ID5609 paragraph 1, quoted in the aforementioned reply paragraph, emphasis added), which is a subjective notion, see paragraph (355) above, explaining that Specifar provides a more specific timeline (market entry in the first half of 2007) later in the same document.

3618 See section 4.2.2.2. In its reply to the Statement of Objections (ID10114, p. 588), Servier relies on these declarations. However, as explained, these declarations are unsupported by the contemporaneous documents, which on the contrary show that Azad was at an advanced stage of development, had a number of generic cooperation partners, was addressing the outstanding issues and did not foresee insurmountable difficulties (see paragraphs (2827) and (2828)). In addition, these declarations must be read in context, it being emphasised that replies to RFIs in an investigation, like Azad's, can be self-interested. It thus had an interest to claim that it was not a competitor (analogous to that described in point 32 of the Technology Transfer Guidelines). It is also noteworthy that Azad provided virtually no documents to support its statements, although it was particularly well placed to do so.

API, its purity and its stability) and therefore not a source of potentially enabling API technology. These arguments will be assessed in the following paragraphs. Servier's affirmations also fail to explain why Servier, after performing a thorough due diligence of Azad's technology, would buy such an allegedly deficient technology to improve its already efficient processes.

(2825) On the contrary, information gathered from Azad's contemporaneous partners confirms that viability of Azad's technology was never seriously put in question despite occasional development issues.

(2826) On balance, the evidence from those closely cooperating with Azad indicates that it was (i) reacting promptly to any potential problems[3619] and that (ii) there were no insurmountable problems for Azad's development at the time of Servier's acquisition,[3620] as illustrated on the two main development issues.

(2827) One issue related to the hygroscopic nature of the API, which could result in too high water content.[3621] However, Azad solved this problem, as reflected in a stability study submitted to Servier in the context of the due diligence, which concluded that "*the [Azad API] material is slightly hygroscopic and that the Delta polymorph is stable under both ambient and dry (sealed) condition"*.[3622] This was confirmed by Teva's internal analysis, which generally concluded that the Azad API complied with the European Pharmacopoeia monograph requirements, including on this issue.[3623]

(2828) With respect to the alleged difficulties with validated commercial batches, the exchanges between Teva and Azad in August 2004[3624] directly contradict allegations of serious, and possibly irremediable, difficulties: "*the last batch of intermediates caused an out-of-spec regarding an impurity […] we now know that the spec for isomeric purity for one of the key intermediates was set too wide by our development partners. […] So now we have had to order more intermediates from our supplier at the narrower spec. in order to replace the failed batches. […] This is a very unfortunate and unexpected occurrence and was out of Azads* [sic] *control. However, we have made sure that it won't happen again"*. Azad even committed to pay a premium price to one of the suppliers of the intermediates to ensure that the intermediates would be available for synthesis already in November 2004. Another generic company, Specifar, confirmed that pilot batches were successfully manufactured in October 2004.[3625]

(2829) As for the European Pharmacopoeia monograph, Teva internally certified that the Azad API conformed to the required specifications in a signed Certificate of Analysis issued only days before Servier's acquisition of Azad's technology, on 3 November 2004.[3626]

3619 See, for example, paragraph (338).

3620 In paragraphs 2204 to 2216 of its reply to the Statement of Objections, ID10114, p. 592-595.

3621 See paragraph (316) and (350).

3622 See paragraph (316), which addresses Servier's argument on the water content (reply to the Statement of Objections, paragraph 2206, ID10114, p. 592).

3623 See paragraph (337). In Teva's […]* dated 13 October 2004, the API's appearance is described as "*slightly hygroscopic*", and the result of the analysis on this point was that it "*conforms*".

3624 See paragraphs (314) - (315).

3625 See paragraph (354), which addresses Servier's argument regarding stability and purity (reply to the Statement of Objections, paragraphs 2198, 2202, 2207 and 2211, ID10114, p. 591-594).

3626 See paragraph (337).

(2830) Servier also invokes alleged stability problems.[3627] The relevant documents on which it relies however do not report any actual problems with the stability of the API, but raise the need to perform stability tests (needed for the bio-equivalence study) once the impurity problem had been overcome, and the related delays and uncertainty generally associated with such tests. Moreover, during Servier's due diligence of Azad's technology, stability was closely scrutinised. Based on two stability studies, Azad declared to Servier that "[*t*]*hese data indicate that commercial delta perindopril will be stable under routine shipping and storage conditions, and that commercial delta perindopril will not contain beta perindopril*".[3628] Upon further queries by Servier, Azad specified that "*the apparent variations in the […] data are the result in changes in the method of sample preparation protocol during the stability study, and are not an indication of instability of the δ polymorph*".[3629] Servier, which was analysing these data in the context of its "*thorough due diligence*" provided no contemporaneous data which would support its allegations. Instead, it explicitly confirmed that Azad's technology did not infringe Servier's patents, acknowledging that stability problems would not cause the API to convert to any of the forms protected by Servier's patents.

(2831) Azad did face challenges in developing its perindopril API. The main challenges consisted in the hygroscopic nature of Azad's API and the impurities. The development was not fully accomplished at the time of the acquisition, and therefore some uncertainty was still intrinsic to the project. However, contemporaneous evidence shows that the main difficulties identified by that time had been successfully overcome and generics continued to pursue their cooperation with Azad. The perceived potential of Azad's development is exemplified by the following statement by Specifar, which was also cooperating with Azad:[3630] *"To the best of our knowledge, the only operator that fits the described criteria (patent-free with regards to EP1296947, stable, industrially applicable, able to support a marketing authorization application, economically sustainable) is Azad".*

Alleged lack of commercial interest by generic companies

(2832) Irrespetive of the finding that Azad did face certain challenges in developing its perindopril API, contemporaneous evidence shows that the main difficulties identified by that time had been successfully overcome and generics continued to pursue their cooperation with Azad. This subsection shows that, in view of the potential of Azad technology, there was real and widespread interest from generic companies which wanted to base their development of perindopril formulations on the API technology from Azad.

(2833) Servier contends that the Azad Technology Acquisition did not hinder the entry of generic companies as these were not willing to offer a firm commitment to Azad. Servier bases this on Azad's claims essentially stating that "*Azad tried in vain to commercialize its product and to get firm orders for its Perindopril*".[3631]

3627 See Servier's reply to the Statement of Objections, paragraphs 2180, 2185, 2187, 2198, ID10114, p. 587, 588, 591.

3628 See paragraph (316).

3629 See paragraph (364).

3630 See paragraphs (354) - (356).

3631 See Servier's reply to the Statement of Objections, paragraphs 2217-2240, ID10114, p. 595-598.

(2834) The fact that several generic companies (notably, Teva and Arrow[3632]) had entered into serious discussions with Azad about possible cooperation shows that Azad's API had real potential to be an enabling technology and constitute a competitive threat to Servier. These discussions led to a number of projects to develop generic perindopril on the basis of Azad's API. Although no written cooperation agreements were signed, and Azad contests the fact that supply agreements had been entered into,[3633] there is ample evidence that generic companies were cooperating with Azad as a potential supplier of the API and of the necessary regulatory information (access to the DMF) in order to develop their generic versions of perindopril.

(2835) First, Azad confirmed the existence of this cooperation in the framework of the due diligence carried out by Servier in September 2004, explaining that pilot batches were produced to support the product development by Azad's customers with a view to preparing applications for marketing authorisation.[3634]

(2836) Second, both Teva and Arrow ordered significant quantities of perindopril API for the purposes of development of generic products.[3635] These companies were planning to apply for marketing authorisations in the first half of 2005, and were expecting them to be granted by the first half of 2007.[3636] According to Arrow, it expected to "*likely be the first or an early entrant into several of the markets*" on the basis of the Azad API, which was thus considered as "*the most attractive option for development*".[3637] Azad's declarations that the relationships with its generic partners were non-committal and not legally binding are not reconcilable with the fact that Azad felt obliged to compensate/reimburse both Arrow and Teva for the termination of the development (Teva claimed costs of co-development, Arrow claimed foregone profits).[3638] The absence of a formal written agreement is in itself not an indication that the parties are not contractually bound.[3639]

(2837) Third, Azad cooperated with a number of other generic companies which had expressed an interest in developing their perindopril formulations on the basis of Azad's API. Notably: (i) Specifar, a Greek company, initiated the development of perindopril formulations on the basis of Azad's perindopril API in delta form in 2004. Specifar had reportedly received a pilot batch which was "successful" (understood as complying with the specifications) before the development was terminated by Azad in "fall 2004";[3640] (ii) PharOS, another Greek company, claimed in August 2004 it had "*already made [trials] on the API and we trust we have a stable formulation. As soon as we receive the two outstanding batches we will be able to [deliver] 6 months later [due to needed stability] the dossier*";[3641] (iii) Cimex,

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3632 See section 4.2.2.3.

3633 See, for example, paragraph (317).

3634 See paragraph (311).

3635 See paragraphs (326) and (333).

3636 See paragraphs (327), (392) and (343).

3637 See paragraph (321).

3638 See section 4.2.2.7.1

3639 There are other examples of companies which supplied perindopril API without having concluded a formal agreement. For example, [company name]* supplied commercial quantities of perindopril API to Servier for eight years without a formal agreement ("*The arrangement was informal, based on purchase orders and invoices only*"). Moreover, [company name]* could continue to use the technology it transferred to Servier without receiving a formal authorisation, or licence. See paragraphs (296)-(302).

3640 See paragraphs (354) - (356).

3641 See paragraph (357).

a Swiss company, was actively offering stable perindopril formulations based on Azad's API in September 2004 ("*[Cimex] develops tablets which comprise only the non-infringing polymorph both after manufacture and during shelf life"*.) and received expressions of interest by Hexal, Sandoz and [company name]*. Azad terminated this cooperation in December 2004;[3642] and (iv) as a cooperation partner of Niche, Ratiopharm requested Niche to include Azad's API as a back-up source (to Matrix API) until cooperation with Azad was discontinued in November 2004.[3643]

(2838) Fourth, although Azad API was relatively expensive, this did not deter generic interest. Azad reported that its perindopril API would have a price of around EUR [16,000-28,000] per kg,[3644] which was […]* % higher than for example the prices discussed by Teva and [company name]*,[3645] and approximately 10 times higher than Servier's own perindopril API cost.[3646] There is, however, no evidence that Azad's API would not be considered commercially viable by generic companies. This shows that the price of Azad's API was not perceived as a real problem by its commercial partners, who were in the best position to decide on this. This can possibly be explained by the absence of generic entry and the non-infringing nature of the product. In particular, if one of the generic companies could enter the market with generic perindopril based on Azad's API, which did not seem to infringe Servier's patents (as, for example, was expected by Arrow[3647]), it could secure higher prices and therefore a higher margin to cover the API cost. Therefore, while the persisting barriers to entry (in particular the '947 patent) made it more attractive for generic companies to source Azad's perindopril API as opposed to cheaper perindopril API which carried the risk of being covered by the '947 patent, the fact that Azad's perindopril API was relatively expensive did not prevent successful commercial entry by generic companies.[3648]

(2839) In contrast to Azad's unsubstantiated statements, the above information provided by generic companies unambigously shows not only a vivid interest in Azad's development of possibly non-infringing API, but also a number of advanced co-development projects. In spite of the absence of any formal written agreement, Azad

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3642 See paragraphs (345) - (346).

3643 See paragraph (353).

3644 Corresponding to USD [20,000-35,000] quoted by Azad, at the average exchange rate for 2004 (USD/EUR 1.244). See paragraph (310).

3645 See paragraph (259).

3646 See paragraph (301).

3647 See paragraph (321).

3648 Hence, contrary to what Servier argues in paragraph 2302 of its reply to the Statement of Objections, ID10114, p. 607, these high API prices did not mean that Azad's project would not have been viable if it had not been acquired by Servier. Specifar, which Servier quotes, in fact even considered in another submission that *"[t]o the best of our knowledge, the only operator that fits the described criteria (patent-free with regards to EP1296947, stable, industrially applicable, able to support a marketing authorization application, economically sustainable) is Azad*" (see paragraph (356)). Specifar seemed to be an outlier in assessing that the API cost made the Azad project not viable (see Table 48, above), since the other companies provided viable figures. In that regard, the fact that the API price would render the product of certain companies not viable for certain territories is not informative as to the viability of this API price in general. This may be due to other factors, like lower efficiency of the company. In the particular case of Specifar, its submissions indicate that Azad was the only viable project at the time, but perhaps not so for every single national market, in particular those on which it was itself mainly active (Greece and some other small markets like Albania, Kosovo, Spain, Portugal and the Czech Republic, but not the four national markets assessed in section 8, except perhaps for the Netherlands; see ID5608, p. 1 and 7-9).

was involved in cooperation with generics over a substantial period (one to two years), geared towards a specific outcome (provision of access to DMF and, subsequently, commercial perindopril API supplies to generics). This cooperation was not terminated for technical problems but due to the acquisiton of technology by Servier.[3649]

8.2.2.2.2 The Azad Technology Acquisition by Servier removed Azad as a potentially enabling source of perindopril API technology and API supplies

(2840) The preamble to the Azad Agreement states that[3650] "*SERVIER is interested to strengthen the defense mechanism for its own alpha, betha* [sic] *and gamma forms of Perindopril and has decided to purchase the Patent Application and its know how*". This confirms that Servier's interest in the acquisition of the Azad technology was not to improve its production processes (as claimed in the context of the present investigation), but to add the Azad patent application to its "defense mechanism" which can only have been designed to defend against generic entry.

(2841) The Azad agreement notably consists in the acquisition, by Servier, of Azad's patent application (Swiss application No. 2003 1109/03 and PCT/CH 2004/000374, now under publication number EP1636185) concerning two novel polymorphic forms of perindopril API, and the related know-how. Servier paid Azad EUR 13.37 million for the transfer.[3651] This agreement eliminated Azad and its technology as a potentially enabling source of perindopril API for generic entry.

(2842) First, Azad irrevocably assigned the patent application and related know-how to Servier world-wide upon agreed payment. In addition to the know-how already disclosed/transferred (as attached to the Azad Agreement), Azad also undertook to transfer the know-how concerning 4 synthesis routes for the manufacture of perindopril and to give all reasonable technical assistance to Servier.

(2843) The transferred Azad patent application and know-how cover the core of Azad's commercial development of the apparently non-infringing delta form of perindopril erbumine. Azad stated that it had no patent applications or significant know-how related to perindopril other than that transferred to Servier. This was also confirmed by Servier, which had carried out a "*thorough due diligence*" into Azad's development.[3652]

(2844) Moreover, Azad expressly committed "*that it shall not directly or indirectly use, transfer, assign or license rights related to the Patent Applications and the Know-How any more*". And, Azad undertook that it will "*keep the transferred Know-How*

3649 Contrary to Servier's argument (paragraph 2223 of its reply to the Statement of Objections, ID10114, p. 596) and Azad's statements (see paragraph (317) above), the absence of formal agreements does not entail the absence of vivid interest or even of effective collaboration. Indeed, Servier states that it collaborated with [company name]*, for a long period of time and with a very positive outcome, without such formal agreements (see paragraph (297)). In addition, the fact that, despite the absence of such formal agreements, Azad still agreed, after the acquisition, to reimburse Arrow and Teva for the investments made in their respective collaborations with Azad (see section 4.2.2.7.1, and paragraph (2836)), shows that the companies involved considered that there was an adequate legal title for such reimbursement claims.

3650 See paragraph (369).

3651 See paragraphs (370)-(371).

3652 See paragraph (369).

secret and shall not use it for any other purpose than covered by this Agreement" for a period of ten years.[3653]

(2845) As a result, the Azad Agreement left Azad no scope to continue with the commercial development of the delta or the epsilon form. Servier not only acquired control over the existing technology of Azad, but also required Azad not to use the knowledge it had already developed for possible new development projects for perindopril.

(2846) This effectively meant that Azad would need to start any perindopril development entirely anew, if this were at all possible in view of the undertaking to Servier not to use in any way the know-how which Azad had developed on perindopril and which was acquired by Servier. And this does not seem to have been a realistic option. It is highly questionable whether Azad could discover and successfully develop yet another non-infringing form of perindopril, of which there was only a limited number which were appropriate for viable entry (as also shown by limited entry of such forms). Even if it did eventually succeed, this would imply an additional delay of up to two to three years (by comparison with Azad's original timeline),[3654] which would be much less commercially attractive to potential generic companies.

(2847) In any event, it is questionable to which extent Azad had an incentive to compete with Servier after it received, to quote Teva, "*several good millions for their process/polymorph*".[3655] Following the Azad Agreement and the subsequent settlement agreement with Arrow [3656] (and Servier), commercial relations between Servier and Azad continued, if not intensified, leading to an agreement between Les Laboratoires Servier and Azad concerning certain compounds (other than perindopril) in August 2007.[3657]

(2848) Azad has confirmed that it was involved in "*no activity with perindopril since December 2004*".[3658] After the acquisition, Azad's cooperation partners or customers (including Teva and Arrow) were informed that Azad was discontinuing the development of perindopril API. Arrow blamed Azad for having "*done a deal with the brand to stay off the market*".[3659] Azad was then confronted with a reimbursement claim from Teva (approximately USD [0.5–1.5]* million), which it honoured in February 2005.[3660] Azad also faced a compensation claim from Arrow in August 2005, which led to a dispute between Arrow, on the one side, and Azad and Servier, on the other side, claiming damages amounting to USD [low nine digit figure] for foregone profits "*during the period when [Arrow] was unable to market a generic perindopril product as a result of AZAD's failure to supply perindopril API (one and a half years in the case of the EEA)*".[3661]

(2849) While Servier fully contested Arrow's claims, in October 2005 it offered a sub-licence to Arrow "on a fair and reasonable basis" for the technology Servier acquired from Azad. It must be emphasised that, contrary to what Servier argues in its reply to the Statement of Objections, this offer of a licence can hardly be seen as

3653 See paragraph (370).
3654 See, for example, paragraph (343).
3655 See paragraph (342).
3656 See paragraph (393).
3657 See paragraph (398).
3658 See paragraph (372).
3659 See paragraphs (329) - (330).
3660 See paragraph (396) - (397).
3661 See paragraph (392).

"spontaneous" given Arrow's large compensation claim before Swiss courts, which seems to have prompted the offer.[3662]

(2850) Servier also claims that, as the licensing offer was rejected by Arrow, allegedly the only generic company interested in the Azad technology, this shows that the Azad acquisition cannot have had foreclosure effects.[3663] This is unfounded. First, Servier did not make a general offer to licence out the Azad technology to any interested generic company. The offer was limited to Arrow and was evidently prompted by Arrow's legal action. This explains why Arrow was the only company in licensing talks with Servier, and why it is appropriate to assess whether the licence was a viable option to Arrow. In this context, Servier's argument is based on the false assumption that the licence could by and large reproduce the competitive conditions absent the acquisition more than a year later. While Arrow and Servier also found no agreement on the applicable royalties, Arrow reportedly discarded the licensing option essentially due to the implied delays and uncertainty compared to the situation before the Azad Technology Acquisiton.[3664] First, resuming development based on a licence would require CCSB, the contract manufacturer, to re-activate its program to produce perindopril, for which the costs and delays were unknown. Second, the DMF would need to be finalised and filed, possibly requiring another bioequivalence study. The Commission also notes that Azad was, due to the agreement with Servier, no longer able to assist Arrow with the development, neither could its know-how be used for a period of ten years. Under these circumstances, and in view of the time lapsed from the Azad Technology Acquisition, Servier's licensing offer to Arrow did not represent a viable alternative to Arrow's (discontinued) cooperation with Azad, premised on Arrow's ambitions to "*be the first or an early entrant into several of the markets"* based on the Azad technology.[3665]

(2851) It follows from the foregoing that the Azad Technology Acquisition was implemented in a way to effectively remove the Azad technology, as a non-infringing source of API technology and supplies for generic competitors, including by removing the incentive and the capacity of Azad to continue exercising competitive pressure on Servier by developing generic perindopril API. As a consequence of the acquisition, Azad could no longer support its generic perindopril partners, which needed a viable source of perindopril API. This is clearly corroborated by Azad's liability to reimburse or compensate its cooperation partners.

(2852) The above is in line with how Servier perceived the acquired technology in 2006. As explained in paragraph (2776), Servier's strategy document made an explicit reference to the patent application for delta and epsilon polymorphs acquired from Azad in the context of listing Servier's patents which were described as "*protective measures against generics*".

3662 Servier reply to the Statement of Objections, paragraph 1767, ID10114, p. 521 [confidential] (see also paragraphs 2242 to 2244 of the reply to the Statement of Objections, ID10114, p. 599). Consequently, this offer cannot be seen as revealing that Servier's goal in the acquisition was not to defend its patents. Moreover, the control Servier acquired over the Azad technology meant that, even if it were allegedly willing to offer a licence, it was obviously in a position to decide who was going to get a licence, or not, thus resulting in, at least, potential foreclosure effects. In addition, many other generic companies were interested in the Azad technology (see paragraphs (2832) - (2839)), and not offered a licence.

3663 Reply to the Statement of Objections, paragraphs 2240 and 2252, ID10114, p. 598 and 600.

3664 See paragraph (389) Arrow finally settled for EUR [seven digit figure] payment from Azad.

3665 See paragraph (2836).

8.2.2.2.3 The Azad Technology Acquisition was capable of restricting competition by making it more difficult for generics to enter the market

(2853) The assessment of the competitive impact and implementation of the Azad Agreement on the API technology market and the supply of perindopril formulations needs to determine whether Servier's acquisition of Azad's technology was "*capable of making more difficult, or impossible, the entry of […] competitors onto the market concerned*".[3666]

(2854) The assessment of the effects of the Azad acquisition will accordingly look at the following elements: (i) the anticompetitive effects the acquisition was capable of producing in view of the alternative potentially enabling sources of API technology able to constrain Servier in the absence of Azad (*ex ante* perspective), and (ii) the consequences of the acquisition on Servier's position on the API technology market and the final product market for perindopril formulations.

8.2.2.2.3.1 Capability of foreclosure in view of the alternative potentially enabling sources of API able to constrain Servier in the absence of Azad

(2855) At the time of the Azad Technology Acquisition in 2004, potential competition was still scarce.[3667] Servier controlled the entire production of perindopril API for commercial purposes (either its own production or through supplies from [company name]*). No generic companies had managed to launch perindopril yet, although some potential competitors (in particular Niche and Matrix) were already in advanced generic product development stages and involved in patent disputes and/or litigation with Servier. All the commercial supplies of API were used for Servier's production of perindopril tablets, the final product. Servier was not offering perindopril API or the related technology to third parties.

(2856) As a result of the combination of these factors, at the time of the Azad Technology Acquisition, the supply side of the API market was still fragmented with very few generic market players. The market players which were present had highly differentiated API technologies in development. These market players can be separated into those which pursued the development of API covered by the '947 patent and which would thus need to enter at risk or challenge this patent, and those companies (including Azad) which were developing a form of perindopril not covered by the '947 patent.

(2857) Servier claims that there is a contradiction in the Statement of Objections between the Commission's assessment of potential competition under Article 101 of the Treaty – which essentially held that generic companies with products covered by Servier's '947 patent were potential competitors – and its description of the availability of alternative sources of API technology under Article 102 of the Treaty, where the Commisison describes Servier's patents as insurmountable and dissuasive for generics. In addition, this contradiction would allegedly have deprived Servier of its rights of defence.[3668] First, Servier's claims are based on a misrepresentation of the Statement of Objections, which described the '947 patent as "*significantly constrain[ing]*" (paragraph 1529 of the Statement of Objections), "*single most*

[3666] See Judgment in *TeliaSonera Sverige*, C-52/09, EU:C:2011:83, paragraph 63, referring to Judgment in *Deutsche Telekom v Commission*, C-280/08 *P*, EU:C:2010:603, paragraph 253.

[3667] See section 7.3.3.1.2.

[3668] See Servier's reply to the Statement of Objections paragraphs 1738-1741 and 1900, ID10114, p. 517-518 and 544.

constraining patent" (paragraph 1643 of the Statement of Objections) as well as a "*major limitation for the developers of API*" (paragraph 1669 of the Statement of Objections), notions which in no way rule out the possibility of entry, and thus scope for competition. In other words, although the patent was acknowledged to represent a significant barrier to entry, the Commission never qualified it as an insurmountable barrier to entry. Second, the Commission's assessment under Article 102 of the Treaty is fully consistent with the assessment under Article 101 of the Treaty, in that the generic companies which were involved in patent litigation or disputes with Servier are in both cases considered as potential competitors. The Statement of Objections and this Decision however acknowledge that not all sources of competition exerted the same type and amount of competitive pressure on the incumbent, Servier. Notably, API solutions not covered by the '947 patent presented a number of advantages over the litigation option, for example:

- no *a priori* need to clear the way by means of patent annulment. Patent annulment (save for EPO Opposition procedures) would clear the way for one Member State only, while a product not covered by the patent could allow for entry in all markets;
- reduced likelihood of infringement actions (for example, when Sandoz, as the first generic entrant, launched its non-infringing perindopril in 2008 in France, no patent infringement action was lodged by Servier, unlike in the preceding launch attempts with perindopril in alpha crystalline form);
- reduced likelihood of interim injunctions as compared to launching material covered by a contested patent;
- connected benefits: likely lower litigation costs, shorter time to launch as compared to the annulment option;
- no *erga omnes* effects: avoiding freeriding by generic companies which do not challenge the patent validity yet may benefit from an allegedly blocking patent being annulled in an action by another generic company.

(2858) At an equivalent stage of development, a non-infringing API is likely to enter the market earlier than an API for which a generic company would need to litigate its way to the market. The first option would be more profitable for the generic company, and more beneficial for the consumer. Thus, provided other compulsory requirements were met, an API source not covered by the '947 patent would under normal conditions represent the preferred route for development of generic formulations, and represent the most immediate generic threat to the originator. For example, Arrow claimed that Azad, which had a non-infringing delta form of perindopril API, was an attractive source given that other sources available to Arrow only had perindopril API which would be covered by the '947 patent.[3669] While generic perindopril covered by the '947 patent represented an important source of competition to Servier,[3670] it implied a superior legal risk for the generic companies and likely delays due to court proceedings.

(2859) In the aftermath of the Azad Technology Acquisition (and just before Servier settled with both Niche and Matrix), Teva (which had been cooperating with Azad until the

[3669] See paragraphs (321) - (322). See also Specifar's statement, paragraph (356).

[3670] See notably sections 5.1.3, 5.2.1.2, 5.3.1.2, 5.4.1.2, 5.5.2 and 5.6.1.2.

acquisition) internally complained that "*Teva development [was] delayed as cannot acquire any API (Servier keep buying up API companies)*".[3671] These problems were again raised by Teva in October 2005: "*The position with Perindopril is very complicated in terms of patents - particularly process patents which affect API manufacturers. This is partly why everyone is late (once an API manufacturer has got round the process patents Servier has bought the company, sourcing API has been very difficult)*". [3672]

(2860) This evidence suggests that Teva, a sophisticated multinational generic company, considered that alternatives to the Azad technology were very limited, and in any event implied development delays due to Servier's practices. Together with the extensive overview carried-out by the Commission and developed in section 7.3.3.1, it rebuts Servier's claims that there were many other sources of potentially viable perindopril API technology, or that such technology could quickly be developed.[3673]

(2861) This section will complement the anecdotal evidence by analysing the competitive landscape to determine whether other independent operators offered, or were developing, potentially enabling perindopril API capable of effectively constraining Servier and avoiding a delay in generic entry.

8.2.2.2.3.1.1 Alternative potentially non-infringing sources of perindopril API

(2862) The operators which had reached an advanced stage of development of perindopril API technology potentially not covered by the '947 patent at the time of the Azad Technology Acquisition were essentially limited to Cipla and Sandoz. In particular, there is no evidence, not least by the parties most concerned, namely the generic companies, that the other sources mentioned by Servier were potentially viable for entry in a manner and time frame that would avoid significant delays to generic entry.[3674] However, even Cipla and Sandoz appeared to have been roughly a year behind Azad's timeline for perindopril development, judging from the status of these projects at the time of the acquisition. In addition, the Azad API was used for a number of different independent developments of generic perindopril formulations already, which was not the case for Cipla and Sandoz.

a. Cipla

(2863) As described in section 6.1.2.2.2., Cipla had an advanced project for the development of perindopril monohydrate, which it claimed was not covered by Servier's crystalline form patents. However, several indications suggest that Azad posed a more immediate competitive threat to Servier than Cipla.

(2864) First, it appears that Cipla's development timeline was roughly a year behind Azad's. Bioequivalence studies on Azad's API were planned for 2004 or early 2005 (by Arrow and Teva), while Cipla only conducted such studies at the end of 2005. Had Azad continued with the API development (and absent any unforeseen difficulties), the filing of the first marketing authorisation applications by both Arrow and Teva was expected for the first half of 2005, while Cipla only applied for marketing authorisations in August 2006. Accordingly, there was an approximate one-year lag

3671 See paragraph (413).

3672 See paragraph (416). See also section 4.2.3.

3673 See, for example, [confidential].

3674 Servier reply to the Statement of Objections, paragraphs 2272-2273, ID10114, p. 603. See also paragraph (2734).

between the planned launch of Arrow in April 2007[3675] and Cipla's first launch in February 2008.

(2865) Second, it was possible that Cipla's monohydrate would raise issues of infringement of Servier's crystalline form patents, with the risk of further delaying market entry. In an attempt to clear the way, Cipla submitted samples of its API to Servier for testing. Servier's statements and internal documents show that Cipla's API was considered as potentially infringing the beta polymorph patent held by Servier.[3676] This is mirrored by patent analysis of Cipla's API by certain generic companies, which suggested that the API would infringe either the alpha or the beta polymorph patent, both held by Servier.[3677] By contrast, Servier ultimately recognised that Azad's technology did not infringe its patents.[3678]

(2866) Third, despite efforts e.g. by Neolab (Cipla's United Kingdom partner), Cipla did not have any major generic partners developing formulations on the basis of the Cipla API (e.g. Teva, Arrow). Therefore, even a successful development of the Cipla API would lead (and actually led) to a more limited uptake by generic companies and thus a lesser overall impact on Servier than was likely if Azad's perindopril technology had remained in independent hands.

(2867) For the above reasons, Azad's API development at the time of the acquisition should be understood to have posed a more immediate competitive threat to Servier than Cipla's development, in particular as concerns the expected entry date and exposure to patent litigation and related delays.

b. Sandoz

(2868) Sandoz developed amorphous perindopril erbumine API, which it claimed did not infringe the '947 patent (see section 4.2.2.8.4). Several indications suggest that, at the time of the acquisition, Azad posed a more immediate competitive threat than Sandoz.

(2869) First, it appears that Sandoz's development timeline was roughly a year behind Azad's. Although there is little or no information on Sandoz' development timeline at the time of the Azad transaction, later evidence confirms a time lag of about one year. The first pilot batches were produced by Sandoz in July 2005[3679] more than a year after Azad had supplied such batches to Teva and Arrow.[3680] Sandoz only finished the completion of the API regulatory dossier (chemistry, manufacturing, controls) in July 2006,[3681] while Azad's DMF was due to be completed in the months following the acquisition in November 2004.[3682] The filing of the first marketing authorisation based on Azad's API was expected for the first half of 2005,[3683] while

3675 See paragraph (392).
3676 See paragraph (2706). Contrary to Servier's claims (for example, reply to the Letter of Facts, ID10289, p. 65-67), the report from the University of Rouen did not dispell, but possibly even reinforced the suspicion that Cipla's API may convert to patent protected forms of perindopril, as explained in paragraph (2704).
3677 See paragraphs (2712)-(2715).
3678 See paragraph (369).
3679 See paragraph (404).
3680 See paragraphs (326) and (333).
3681 See paragraph (404).
3682 See paragraph (327).
3683 See paragraphs (343) and (392).

Sandoz only applied for marketing authorisations in September 2006,[3684] a month after Cipla. Accordingly, there was also an approximate one-year lag between the planned launch of Arrow and Teva in the first half of 2007[3685] and Sandoz's first launch in May 2008.[3686] Under such a timeline, Sandoz's launch could not prevent a delay in generic entry with a perindopril not covered by the '947 patent.

(2870) Second, Sandoz's development of the amorphous perindopril erbumine API was vertically integrated into its in-house development of perindopril formulations not covered by the '947 patent. Thus, Sandoz was not minded to offer API for development by its generic competitors, and no such cooperation ever took place.[3687] Contrary to what Servier seems to imply, Sandoz was for example not itself seeking generic licensing partners.[3688] As the Glenmark example shows,[3689] a single source of API may support a high number of formulations from different generic companies, which will, on the whole, normally accelerate erosion of prices and volumes and represent a bigger generic threat to the originator as compared to a single generic formulation, even if by the first entrant. While Sandoz's vertically integrated development was geared to Sandoz's own perindopril formulation, Azad was essentially an API company supporting the development of many independent perindopril formulations by important generic companies, which would have likely exerted more competitive pressure on Servier than a single source of generic perindopril.[3690]

(2871) For the above reasons, Azad's API development at the time of the acquisition should be understood to pose a more immediate and significant competitive threat to Servier than Sandoz's development.

c. Conclusion on the potentially non-infringing sources of perindopril API

(2872) As shown in section 8.1.2.2, the Azad Technology Acquisition formed part of Servier's strategy to remove the close competitive threats - it was not an isolated event, but followed a consistent line of activities on the part of Servier. From Servier's perspective, removing further competitive threats by means of patent settlements or technology acquisitions was prospectively a realistic option. As each period of generic delay equalled significant additional revenues for Servier, a forward looking assessment, based on the conduct established at the time of the Azad Technology Acquisition, needs also to consider the possibility that Servier would continue in its endeavours to buy-out competitive threats. This is corroborated by the actual course of events – in addition to the five settlement agreements further examined in section 8.3, […]*. Ultimately, Servier's attempt to acquire Sandoz's

3684 See paragraph (404).

3685 See paragraphs (343) and (392).

3686 See paragraph (410).

3687 See paragraph (405).

3688 Servier reply to the Statement of Objections, paragraph 2268, ID10114, p. 602.

3689 See paragraphs (2727) - (2728).

3690 See, for example, paragraph 227 of the Final Report of the Pharmaceutical Sector Inquiry: *"The number of generic entrants appears to have a small but statistically significant effect on the price decrease that eventually emerges in the market"*. An example of this can also be seen in section 6.4.4.4 concerning the Polish market where, after a long period of stable generic perindopril prices by Krka as the only generic entrant, Krka's prices drop by 28% in the period where further generic entry was expected, and materialised.

technology failed, as Sandoz abandoned the negotiations and launched its generic perindopril (with relatively much more commercial success than Cipla).[3691]

(2873) This shows that Servier's strategy of foreclosing access to sources of API targeted most, if not all, advanced and independent sources of potentially non-infringing perindopril API.

(2874) Based on the above, Azad can therefore be considered as Servier's most immediate threat at the time of the Azad transaction in terms of possible supplies of non-infringing perindopril API for production of perindopril formulations. Azad's perindopril API was non-infringing, available to various generic partners, and would have potentially allowed generic launch in 2007 (see section 8.2.2.2.1). The development timelines of both Cipla and Sandoz meant that generic perindopril not covered by the '947 patent could not be launched in 2007, and Cipla's API was in additon fraught by possible patent infringement risks. For these reasons, the absence of Azad's perindopril API was capable of making it much harder, from an *ex ante* perspective, for generics to launch generic perindopril without incurring significant delays. This concurs with a statement by Specifar, a former customer of Azad, that "*the only operator that fits the described criteria (patent-free with regards to EP1296947, stable, industrially applicable, able to support a marketing authorization application, economically sustainable) is Azad*".[3692] A similar inference can also be drawn from Teva's concerns voiced more than 18 months after the Azad acquisition: "*If Servier wins the Alpha Polymorph patent, it would effectively shut everyone out of the market*".[3693] This suggests that generics saw no clear alternative to Azad even in 2006.

8.2.2.2.3.1.2 Evolution of competitive pressure from potentially infringing (alpha-containing) perindopril API sources

(2875) Subject to relative disadvantages in terms of risks and time to market compared to recognised non-infringing technologies as mentioned above,[3694] API/formulations which are claimed to be covered by a patent can represent an important source of potential competitive pressure for the originator company, in particular to the extent that the relevant patent is challenged on grounds of invalidity or non-infringement. This was true in the present case, as the majority of generic companies active in perindopril did not have access to perindopril API not covered by Servier's patents, and the main way for them to enter the market was to challenge the validity of the '947 patent (hence the high number of EPO oppositions).

(2876) However, the number of sources of perindopril API and/or formulations containing the alpha polymorph covered by the '947 patent was also limited, as shown in section 7.3.3.1. In addition to Niche/Matrix, which were removed by a reverse patent settlement concluded with Servier in February 2005, only months after the Azad Technology Acquisition, the remaining API sources at a comparable stage of development to the Azad API and which were potentially covered by the '947 patent were Krka, Apotex, Teva/Hetero, Lupin and Glenmark. The latter companies envisaged to enter the markets across the Union in 2006 and 2007.

3691 See, for example, paragraph (2711).
3692 See paragraph (356).
3693 See paragraph (2688).
3694 See paragraph (2857).

(2877) The presence of these sources of perindopril API does not mitigate the foreclosure effects the Azad Technology Acquisition was capable of producing. Azad's API was non-infringing and therefore presented an advantageous route to market entry, as the likelihood of litigation and ensuing cost and delay was much lower.[3695] The existence of technologies potentially covered by Servier's patents could, under a number of plausible scenarios presented in section 8.2.2.2.3.2., not avoid the delay of generic entry compared to the expected timeline for products based on Azad API technology. As explained above, among all business considerations involved in choosing an API – and provided that all the requirements for market entry are met – the non-infringing nature of the API is key, because it provides important benefits in terms of legal risk (and the associated time delay and cost) and of avoiding the free-riding problem by not clearing the way for others as is the case with successful invalidity actions.[3696] Essentially, a product based on Azad technology had a much lower risk of infringement actions or preliminary injunctions and did not need to have the '947 patent annulled. Accordingly, it had a much lower risk of losing time in such actions. Independent market entry for formulations based on alpha API, expected in late 2005 or early 2006, only materialised, following litigation, in 2007 in the Netherlands and the United Kingdom,[3697] and later still in France and Poland, while entry based on the Azad technology was expected in 2007.

(2878) In any event, the effects of the Azad Technology Acquisition cannot be analysed in isolation from other complementary actions implementing Servier's consistent strategy to remove close sources of generic threat, as confirmed by Servier's subsequent activities targeting these remaining sources.

(2879) Servier was determined to defend the '947 patent not only from commercial challenges from alternative, non-infringing forms of perindopril, but also from legal challenges to its validity. This resulted in the settlement of litigation with Niche, with which Servier started negotiating at the time of the Azad Technology Acquisition, as well as Matrix, Teva, Krka, and Lupin in the period 2005 - 2006, notably in the United Kingdom. In fact, with the exception of the Apotex litigation, all the litigation cases were settled,[3698] and the generic companies were effectively removed as a potential source of competition by accepting non-compete and non-challenge clauses in exchange for considerable economic inducements from Servier. In the context of Servier's strategy to remove the close competitive threats, these patent settlements are also relevant for the present assessment as they were complementary to the Azad Technology Acquisition in further reducing the generic pressure on Servier's market position. In addition, in the case of Krka and Lupin, the settlements were accompanied by an acquisition of perindopril-related patent applications, including API technology.

(2880) Regarding Glenmark, its development was less advanced at the time and infringement of both the '947 and process patents was a major risk. This contrasts with Azad's technology, which was not covered by Servier's patents, and with Teva,

3695 For example, Sandoz, which was lagging about a year behind Azad in terms of development, and which also had a recognised non-infringing product, first entered in mid- 2008. Servier did not launch patent litigation against Sandoz. See paragraph (406) and subsequent.

3696 See paragraphs (2819) and (2857).

3697 See paragraphs (2821) and (2998).

3698 See section 4.1.2.4.2.2 It is recalled that Servier could also settle the Apotex litigation in the United Kingdom concerning the validity of the '947 patent. See paragraphs (179) and (191).

Krka and Lupin, which were challenging the validity of the '947 before national courts. Accordingly, Glenmark adopted a passive attitude waiting for third parties to clear the way before entering itself. Thus, it would only represent a competitive threat to the extent it could possibly enter once another generic company successfully invalidated the '947 patent.[3699] Hence, it could not be regarded as a direct threat to Servier comparable to the threat posed by Niche, Matrix, Teva, Krka, Lupin, Apotex, and Sandoz.[3700]

(2881) In sum, the perindopril API sources potentially covered by the '947 patent did appear to represent a competitive threat to Servier. However, by the loss of access to Azad and its technology, generic companies such as Teva and Arrow had to revert to sources of perindopril API possibly covered by the '947 patent, and had either to legally clear the way or launch at risk in order to enter the market, further delaying their potential entry. The acquisition deviated from competition on the merits – Azad technology was not excluded from the market because Servier's technology was superior, but because Servier, seeking to strengthen its protection against generic entry, removed this independent source of competition by means of an acquisition. This was capable of restricting competition not only because it made generic entry more remote, as a number of generic development projects needed to be discontinued, but because it was capable of delaying generic entry, as further explained in the subsequent section 8.2.2.2.3.2.. In addition, from the perspective of Servier's overall strategy, foreclosure effects from the Azad Technology Acquisition were compounded by Servier's subsequent conclusion of five patent settlements, which removed a large majority of generic challengers to Servier product exclusivity protected primarily by the '947 patent.

8.2.2.2.3.2 Servier's acquisition was liable to maintain or strenghten its dominance irrespective of the outcome of the challenges to the validity of the '947 patent

(2882) From an *ex ante* perspective, market operators were facing two main prospective possibilities in the period before a final decision on the validity of the '947 in given markets. The Azad Technology Acquisition was capable of harming consumers in either one of these two scenarios.

(2883) The first option was that the '947 patent would be eventually upheld in litigation (or a final decision on invalidity not reached, for example due to patent settlements). Under the second option, the '947 patent would be eventually annulled, following a significant delay. This is what happened in reality. Both scenarios could be affected by Servier's strategy to remove further competitive threats by means of patent settlements, as these were, as shown in sections 5 and 8.3, capable of influencing both the likelihood and the timing of a possible patent annulment.

(2884) Under both scenarios, removing the most advanced and non-infringing source of API would considerably weaken the competitive constraints on the dominant company by further delaying and increasing the cost and risks of generic entry.

(2885) In the first scenario, the '947 patent would be upheld during the investigated period. In that case, technology found to be infringing could normally be kept off the market. In that hypothesis, the non-infringing technologies would be even more important to

[3699] While Glenmark was one of the opponents before the EPO to the '947 patent, only successful national litigation on the '947 patent or a recognised non-infringing perindopril form would allow for an entry during the period of the infringement.

[3700] See paragraphs (1262), (1649) and (2037).

facilitate generic entry and the Azad technology produced the most advanced non-infringing perindopril API. In the period after the Azad Technology Acquisition, Teva saw the situation as follows: "*If Servier wins the Alpha Polymorph patent, it would effectively shut everyone out of the market*".[3701] Even allowing that Azad technology had very limited potentially viable non-infringing alternatives, the acquisition could under such circumstances delay non-infringing generic entry by around a year (as Cipla and Sandoz appeared to be one year behind Azad). In addition, it was also capable of reducing the degree of competition between the remaining operators which would have been able to viably launch during the validity of the '947 patent. If, following the Azad Technology Acquisition, Servier was successful both in defending the '947 patent and in acquiring the Sandoz technology in implementing its overall strategy, all advanced and independent sources[3702] of perindopril, whether patent-infringing or not, would be eliminated.

(2886) In the second scenario of the annulment of the '947 patent, Servier would normally be facing a constraint by the entry of generic perindopril in the alpha form. However, such annulment proceedings can take a considerable length of time (the EPO proceedings in this case took five years[3703]), during which time non-infringing API can provide the main source of competition and early generic entry (depending on the availability of injunctions in cases of entry at risk). The removal of Azad's technology as a non-infringing source of competition was capable of preventing or delaying generic entry in the time before the annulment of the '947 patent. For example, market entry based on Azad API, expected for early 2007, would have allowed early entry in France, the Netherlands and Poland, where entry eventually only occurred, respectively, at the earliest in 2008, in late 2007 and in 2009.[3704]

8.2.2.2.4 Objective justifications for the Azad Technology Acquisition

(2887) In its submissions, Servier claimed that the acquisition of the Azad process could potentially reduce the crystallisation time for perindopril erbumine.[3705]

(2888) According to the case law, "*it is for the dominant undertaking concerned, and not for the Commission, before the end of the administrative procedure, to raise any plea of objective justification and to support it with arguments and evidence*".[3706] Servier did not argue that the acquisition was objectively justified.

(2889) With respect to Servier's efficiency claims, the ECJ recently held that "*it is for the dominant undertaking to show that the efficiency gains likely to result from the conduct under consideration counteract any likely negative effects on competition and consumer welfare in the affected markets, that those gains have been, or are likely to be, brought about as a result of that conduct, that such conduct is necessary for the achievement of those gains in efficiency and that it does not eliminate*

3701 ID8281, p. 192.

3702 Taking into consideration the possible patent infringement issues with Cipla's development.

3703 Even if the EPO Opposition Division revoked the patent, an appeal by Servier would suspend the effects of such revocation pursuant to Article 106 of the European Patent Convention.

3704 See, for example, sections 6.4.3.4, 6.4.2.4 and 6.4.4.4.

3705 See paragraph (375).

3706 Judgment of 17 September 2007, *Microsoft v Commission*, T-201/04, ECR, EU:T:2007:289, paragraph 688.

effective competition, by removing all or most existing sources of actual or potential competition".[3707]

(2890) As a preliminary remark, the Commission notes that Servier submitted little or no verifiable evidence in support of its efficiency claims.[3708] For this reason alone (which is further elaborated in the individual subsections below), Servier's claim can be rejected. It is for Servier to prove that the conduct was objectively justified. Nonetheless, the Commission will examine whether the conditions could be fulfilled in the case of the Azad Technology Acquisition

8.2.2.2.4.1 Efficiencies from the Azad Technology Acquisition

(2891) Servier never used the Azad technology, nor was it able to present any contemporaneous or posterior feasibility studies or investment plans capable of demonstrating that the Azad technology was indeed bought, as now claimed by Servier, in order to improve Servier's production processes,[3709] and not to "*strengthen the defense mechanism for its own alpha, betha* [sic] *and gamma forms*", as Servier itself recognised in the Azad Agreement[3710] *in tempore non suspecto*.

(2892) In the absence of such cost studies, Servier took "*a gamble*"[3711] and purchased the Azad technology for over EUR 13 million. This "gamble" – which could be seen as surprising even to Servier employees[3712] – "*did not pay off*",[3713] further testing apparently having revealed that "*producing the delta form on an industrial scale would require substantial investment*", which would have been too costly since at that point Servier allegedly decided to focus on arginine. Servier does not explain why the necessity of such further investments was not checked and revealed during the due diligence, which started, after early discussions began in late June 2004, in late August/early September 2004, two months prior to the acquisition.[3714] The study Servier provided, which already showed the necessity of optimisation, apparently lasted less than 20 days and was over by the end of September 2004, thus leaving sufficient time to do further studies to assess its commercial value for Servier.[3715]

3707 Judgment in *Post Danmark*, C‑209/10, EU:C:2012:172, paragraph 42.

3708 Servier submitted a few documents to that effect in its reply to the Statement of Objections (Annexes 00-04, ID9054, and 13-04, ID9066), without explaining why they had not been submitted earlier in reply to a number of RFIs. In particular, question 33 of the 6 August 2009 RFI (ID0904 p. 13-14) required the provision of information and supporting contemporaneous documents regarding technology acquisitions, notably their potential technological/commercial value (as assessed for the acquisitions) and whether they were then used or not for the production of perindopril. To this question Servier only responded in very general terms on how the production process in general could be improved, and indicated that the Azad technology could be used to improve the crystallisation phase (ID1151, p. 24). However, it provided no supporting contemporaneous documents. When the Commission asked Servier why it had not provided supporting documents in response to the abovementioned RFI, Servier merely answered that question 33 was unclear and that it only requested the submission of documents which were necessary to support Servier's statements, which, even if the documents had been identified at the time of the RFI, would purportedly not have been the case here (ID9666, p. 6).

3709 See paragraphs (374) and (375).

3710 See paragraph (369)

3711 See paragraph 100 of Annex 00-04 to the Servier reply to the Statement of Objections, ID9054, p. 36.

3712 See paragraph (288).

3713 See paragraph 101 of Annex 00-04 to the Servier reply to the Statement of Objections, ID9054, p. 36-37, and paragraph 2288 of Servier's reply to the Statement of Objections, ID10114, p. 605.

3714 See section 4.2.2.4.

3715 See Annex 13-04 to Servier's reply to the Statement of Objections, ID9066, and footnote 523.

(2893) According to Servier, "**The AZAD Technology was intended to isolate another crystalline form of tert-butylamine salt which, had it been easier to isolate, would have allowed significant time savings. However, SERVIER subsequently decided to focus on the production of arginine salt […] and to eventually abandon the production of tert-butylamine salt"*.[3716]

(2894) However, according to the facts pertaining to Servier's switch between salts, the decision to pursue the arginine product launch was made long before Servier acquired Azad's technology.[3717] Notably, Servier filed the (abridged) applications for marketing authorisation for perindopril arginine already in October 2003, more than a year before the conclusion of the Azad Agreement.[3718]

(2895) In addition, it is recalled that perindopril arginine was – and still is, or was until very recently – obtained by Servier […]*.[3719] Hence, switching investment efforts to arginine does not necessarily entail improvements […]* being discarded. On the contrary, it seems likely that a reduction of production costs […]* would also result in lower production costs for arginine, as Servier explicitly acknowledged.[3720]

(2896) Moreover, Servier at the same time claimed it already had another, more efficient alternative for the production of perindopril erbumine […]*.[3721] At the time of the acquisition, Servier had not only acquired [company name]*'s technology, but was also buying significant commercial quantities of perindopril API from [company name]* and was minded to assist [company name]* to obtain a European Pharmacopoeia Certificate.[3722]

(2897) It is also questionable, from a commercial point of view, whether the Azad technology had the potential to optimise the production process technologies already held by Servier. The principal goal and perceived advantage of Azad's API was the avoidance of the crystalline forms protected by Servier. Therefore, even though it

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3716 See paragraph (376).

3717 Servier denies that this is the case (paragraphs 2292 to 2295 of its reply to the Statement of Objections, ID10114, p. 606). It argues that, although it had begun regulatory steps, the "strategic and irrevocable" decision to switch to arginine had not been made by Servier management at the time, and would be made later on a case by case basis depending on local regulatory frameworks for generic substitution (see also paragraph (233)). In fact, it seems that the switch was decided in principle, even if specific dates for launches in different countries were yet to be decided taking into account the full regulatory and commercial context (see paragraphs (234) to (238)). In any case, the applications for marketing authorisations demonstrate a serious consideration of the switch, which should have all the more prompted an in-depth assessment of the potential benefit of the Azad technology acquisition in that situation. The fact that Servier launched arginine in Poland in April 2006 further indicates that, taking into account the time required to prepare such a launch, the decision must have been made in the time frame indicated by the above-mentioned elements, around 2002-2003, long before the Azad acquisition.

3718 See paragraph (231).

3719 See, for example, paragraphs (280) and (298).

3720 See paragraph 2295 of its reply to the Statement of Objections, ID10114, p. 606.

3721 Servier states that the two technologies related to different aspects of the production process and were not mutually exclusive (paragraphs 2296 and 2297 of Servier's reply to the Statement of Objections, ID10114, p. 606). In that regard, it must be noted that, even if ultimately Servier claims to have been interested in the Azad technology only to improve the crystallisation phase specific to erbumine, it originally considered the technology also for earlier production phases, where it would potentially have been redundant with the [company name]* technology (ID3842 p. 30). Furthermore, Servier does not explain why, at the time of the acquisition and even if the switch to arginine would have entailed that the crystallisation aspect of the Azad technology would no longer be of interest to Servier, it apparently did not fully assess the commercial interest for itself of the Azad technology before buying it.

3722 See section 4.2.1.5.

still was an essential source of API for new entry in view of the absence (scarcity) of other potentially enabling sources, Azad's API was by no means cheap: Azad was selling its pilot batches of API at around EUR 31,400 per kg,[3723] whereas, for example, [company name]*'s pilot batches cost around EUR [0–25,000]* per kg.[3724] Concerning commercial batches, Azad was planning to sell them at USD [20,000-35,000] per kg (around EUR [16,000-28,000]),[3725] while Servier's cost of in-house API production revolved around EUR [0–5,000]*, and [company name]*'s average prices for commercial API batches went down from the initial EUR [8,000-12,000] per kg in 2002 to EUR [5,000-7,999] per kg.[3726]

(2898) The above is corroborated by the perceptions of generic companies. Notably, Krka claimed that Azad's process was "**long and complex […], for which very pure intermediates were necessary […]*".[3727] The Commission considers that Azad was an important source of API for possibly viable (including non-infringing) market entry. Given the non-availability of alternatives, this can explain why generics were willing to pay a premium price: the source was, in relative terms, not cost effective, but it could allow them to be amongst the first ones to launch (as already explained in paragraph (2836)). On the other hand, Servier had, owing to its patent portfolio, already a guaranteed freedom to operate and a process which appears to be incomparably more cost-effective than Azad's.[3728]

(2899) It follows from the above that Servier's abovementioned efficiency claims were not plausible and cannot be upheld for the purpose of analysing them as a possible justification for the Azad Technology Acquisition. Nonetheless, for the sake of completeness, it will be examined whether Servier's conduct was necessary to achieve the claimed efficiencies and whether the efficiencies could outweigh the exclusionary effects.

8.2.2.2.4.2 The Azad Technology Acquisition was not necessary to achieve any efficiencies

(2900) To assess whether the Azad Technology Acquisition was objectively necessary to achieve the claimed efficiencies, it needs to be ascertained whether these efficiencies could be achieved by resorting to alternatives with less restrictive or less exclusionary effect.

(2901) In the *Tetra Pak I* case, the Commission found that "*the little protection that may be necessary to encourage Tetra to bear any technical and commercial risks associated with the development and dissemination of new technology is not sufficient to overcome the extremely serious disadvantages created by the loss of competition entailed by this exclusivity. In addition, in the circumstances of this case, where the*

3723 See paragraph (354).

3724 See paragraph (250).

3725 See paragraph (310).

3726 See paragraphs (300) – (301).

3727 See paragraph (347).

3728 In reply to this point, Servier argues (paragraphs 2299 to 2301 of its reply to the Statement of Objections, ID10114, p. 607) that the high-level of these prices is explained by the fact that they are sale prices to third parties and not internal production costs, especially taking into account the efficiencies Servier could bring to the production process with its know-how. It is noted that these considerations highlight how important a profitability study would have been for Servier to assess whether or not the Azad acquisition was in its interest (see paragraph (373)). Servier does not explain why it acquired the technology without first verifying the commercial interest for itself, considering that Servier – with its important expertise – was already on the market with a viable and profitable technology (see paragraph (2891)).

licensee is dominant, there is less need for exclusive protection since there is no obligation for the licensee to grant back any improvements in the technology to the licensor".[3729]

(2902) Thus, the Commission considered that an acquisition by a dominant company of exclusive rights to an alternative technology was not objectively justified, as the exclusivity was not needed in view of the dominant incumbent's existing technology and commercial know-how, and Tetra Pak was not obliged to grant back any improvements it made to the licensed technology.

(2903) In the same manner, it will be analysed whether, by allegedly undertaking a project to improve its process for the manufacture of perindopril API (erbumine and arginine), Servier would incur any significant risk (be it technological or commercial) associated with the further development and industrial application of the technology which justified it obtaining exclusive access to the technology.

(2904) Concerning technological risks, Servier had been, at the time of the Azad Technology Acquisition, manufacturing perindopril API for commercial use for at least 15 years since the first launch of perindopril tablets in 1989. Not only that, it was the only company to do so in view of its compound patent for perindopril. Moreover, Servier's patenting exercise whereby over 30 patent applications – mostly for alternative production processes – were filed in the period 2000 - 2003 demonstrates its comprehensive expertise concerning perindopril manufacture.[3730] In addition, the acquired technology does not relate to the development of a whole new product, or of an improved product, but of a substitute manufacturing method as an alternative to the ones already developed/controlled by Servier. Notably, Servier's cost savings from a successful application of the transferred technology would not be contingent on whether another company could have access to the same technology. In fact, in view of its specific market position (owing to its patent portfolio) and its uncontested expertise in the production of perindopril, Servier would in all likelihood hold a competitive advantage over any other licensee/user of the Azad technology, even without the exclusivity over the acquired technology.

(2905) That the use of this technology was not indispensable for Servier was best confirmed by Servier itself, which did not consider the development of Azad technology as a development priority and in fact never made any significant attempts to develop it for industrial application.[3731]

(2906) While patent exclusivity on Azad's technology was capable of affecting the competitive process in favour of Servier's market position, this exclusivity was therefore not indispensable for the attainment of the claimed objectives of reducing production costs. The same goal could be achieved by obtaining a non-exclusive licence from Azad.

(2907) On the basis of the above, even if Servier's unsubstantiated efficiency claims would be accepted as legitimate efficiencies for the purpose of assessment of objective justification (*quod non*), such efficiencies could have been attained by alternative

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3729 88/501/EEC: Commission Decision of 26 July 1988 – IV/31.043 – *Tetra Pak I (BTG licence)*, OJ L 272, 04/10/1988, p. 27-46, paragraph 49.

3730 See, for example, Servier's reply to the Statement of Objections, paragraph 2026, ID10114, p. 565.

3731 See paragraph (376).

means,[3732] in particular by a non-exclusive licence. The Azad Technology Acquisition was thus not indispensable for the attainment of these efficiencies.

8.2.2.2.4.3 Any efficiencies would be outweighed by the exclusionary effect

(2908) Servier's unsubstantiated claims invoke only potential efficiencies by reducing the crystallisation time of perindopril erbumine. There were no actual efficiencies. There were no projected or expected efficiencies demonstrated by Servier's internal documents related to the Azad Technology Acquisition. Therefore, no specific assessment of possible consumer benefit from the acquisition is possible. The discussion of the magnitude of efficiency and capability of being passed on to consumers can only be a hypothetical one.

(2909) Even assuming that Servier would, in good faith, expect efficiency gains from the acquisition of Azad's technology (which is in itself not plausible), it is questionable whether the gains would be capable of outweighing the consumer harm the acquisition was capable of producing, and if they would be passed on to the consumer.

(2910) As demonstrated above, Servier faced no significant price constraints prior to generic entry. Only the latter was able invariably to lower consumer prices by a considerable degree.[3733] However, the same data also shows that, absent generic entry, there was little or no downward price movement. In particular, no price reductions in either the United Kingdom, the Netherlands, France or Poland have been observed after Servier introduced a more efficient process based on [company name]* […]* even though Servier claimed considerable cost savings.[3734]

(2911) Even if it were claimed that the Azad Technology Acquisition was expected to prevent a price increase due to the introduction of perindopril arginine, which was more expensive to produce than perindopril erbumine, such a contention would have no foundation in the observed market conditions. Production costs represent only a very limited proportion of the finished product price, and are generally not considered to be important factors for price formation in the absence of strong generic competition. Based on Servier's sales and cost data, it has been shown that the operating margin of Servier, i.e. the proportion of a company's revenue that is left over after variable costs of production, has on average not fallen below 90%. Thus, the combined costs of production and distribution (Servier provided no breakdown of the two cost items) never exceeded 10%.[3735] An increase in operating costs due to higher costs of perindopril arginine production (potentially up to 30% according to Servier)[3736] would thus, in the most conservative scenario where the operating cost was limited to production cost and this cost would only consist in the API cost (*quod non*), amount to around 3%[3737] of Servier's price for finished perindopril products.

3732 In paragraph 1960 of its reply to the Statement of Objections, ID10114, p. 555, Servier even argues that Azad had not "**acquired a considerable know-how which cannot easily be replicated**" (internal quotations omitted). If indeed this technology could be quickly replicated, the necessity of the technology acquisition is further put into question.

3733 See section 6.5.1.2.6.

3734 See, for example, section 8.4.2.

3735 Servier did not provide for a break up between production and distribution costs which are both comprised in this figure. See section 6.4.5.3.

3736 See paragraph (282).

3737 That is to say, 30% savings on the cost which amounted to 10% of the price amounts to 3% of the price.

(2912) On the other hand, where generic perindopril was eventually launched, average price reductions for all perindopril products (i.e. also including Servier's perindopril) ranged from around 18% in Poland (where Servier successfully switched to perindopril arginine and limited generic penetration) to 90% in the United Kingdom (where, following the annulment of the '947 patent, there was considerable generic entry) compared to Servier's prevailing prices prior to generic entry.[3738]

(2913) The hypothesis that, if Servier had managed to extract efficiencies from the Azad Technology Acquisition (*quod non*), it would have passed on sufficient efficiency gains to consumers is not supported by any evidence and seems improbable. For example, when Servier switched its production to a new, more efficient, production process (reportedly based […]* [company name]* […]*) and allegedly achieved considerable savings, no reduction in Servier's prices for perindopril were observed.[3739]

(2914) However, even assuming that such a pass-on did take place, a simple comparison of the possible savings from an improved production process for perindopril erbumine API (a price reduction of less than 3%) with possible consumer savings from generic entry (spanning, as mentioned above, from 18% to 90% across the investigated markets), which the acquisition was capable of delaying, shows a huge disparity in the order of the potential savings. Potential consumer harm from generic delay is 6 to 30 times higher than potential savings to Servier if the acquisition led to a more efficient production process (which was not seriously explored by Servier with respect to the Azad technology).

(2915) Thus, even if Servier's efficiency claims were to be qualified as admissible for the present assessment and the Azad Technology Acquisition considered indispensable for the attainment of these efficiencies (*quod non*), it should be concluded that these efficiencies would not be passed on to consumers, nor would they outweigh the consumer harm that Servier's conduct was capable of producing.

8.2.2.2.4.4 Conclusion concerning objective justification

(2916) Overall, the Commission has no reason to consider that there was an objective justification for the Azad Technology Acquisition.

8.2.2.2.5 Overall conclusion on the Azad Technology Acquisition

(2917) Servier's acquisition effectively distorted the emerging competitive structure of the market for perindopril API technology and of the potential supply of non-infringing perindopril API and thus it was capable of contributing to the foreclosure effects as of the moment Servier acquired the Azad technology on 9 November 2004. This acquisition directly affected the development of generic perindopril formulations. Since the Azad technology (and the resulting API) was rendered inaccessible as an input to other generic companies, a number of generic projects were excluded at an advanced stage and needed to be started anew, disabling generic launch by 2007 of generic perindopril not covered by Servier's patents. Unlike many other technology acquisitions, the Azad Technology Acquisition deviated from competition on the merits in that it consisted, as part of a broader strategy to eliminate competitive threats, in the acquisition by a dominant undertaking of scarce potentially viable technology liable to enable early entry by interested generic companies, which it

[3738] See section 6.5.1.2.6.

[3739] See section 8.4.2.

acknowledged did not infringe its patents and with the stated purpose of strengthening the defence mechanism for these patents, and its branded product. These prominent generic companies had even ordered significant quantities of perindopril API, whereas Servier never even seriously considered using the acquired technology. In this case – where Servier's acquisition of the Azad technology explicitly aimed to defend Servier's existing perindopril business, while the Azad technology was non-infringing, had a significant time lead over other technologies and was being relied on by at least one generic producer – the Commission finds that the Azad Technology Acquisition deviated from competition on the merits, was capable of significantly delaying generic entry and was abusive behaviour, contributing to Servier's overall single and continuous exclusionary strategy which the Commission considers an infringement of Article 102 of the Treaty (see section 8.4 below).[3740] In that regard, the assessment in this section must be seen as forming a constitutive part of the assessment of Servier's other anticompetitive activities and overall strategy of delaying generic entry (five patent settlements were concluded in the period directly following the acquisition of the Azad technology). Accordingly, the finding in this case with regard to the technology acquisition is limited to the circumstances of this case and should not be construed as a general prohibition of technology acquisitions by dominant undertakings.

(2918) The period during which the acquisition of Azad technology was capable of contributing to the foreclosure effects was, in the market for perindopril formulations, at least until July 2007 in the United Kingdom (annulment of the '947 followed by effective generic entry), December 2007 in the Netherlands (first effective generic entry, followed by the annulment of the '947 in June 2008), and at least May 2009 in France and Poland (the EPO annulment of the '947). In the market for perindopril API technology, the period lasted until July 2007. The conclusion on the combined effects of Servier's single and continuous strategy to delay generic entry is set out in section 8.4.

8.3 Servier's strategy to remove the close sources of competition as implemented through a series of patent settlement agreements with generic companies

8.3.1 Introduction

(2919) The grant of the '947 patent in February 2004 enhanced Servier's potential to exclude generic competition. The corollary of this was that the generic companies sought to overcome this patent barrier either by developing non-infringing forms of perindopril, or by contesting the validity of the '947 patent. While Servier did, on the one hand, acquire the non-infringing Azad technology "*to strengthen the defense mechanism for its own […] alpha form[…] of perindopril*", it was, on the other hand, facing legal challenges to its patents, notably the '947 patent protecting the alpha form of perindopril. In the context of the strategy to delay generic entry by removing close competitive threats, Servier thus resorted to a number of patent settlement agreements with its generic competitors. The complementarity of technology acquisitions and patent settlements is further emphasised by the fact that patent settlement agreements with Lupin and Krka were also accompanied by an acquisition by Servier of their respective perindopril technologies.

[3740] Concerning the abuse of a dominant position, the subject-matter of this decision is the overall infringement of Article 102, which consists in the combination of the chain of patent settlements agreements and the acquisition of the Azad technology.

(2920) Section 5 established that each of the five reverse payment patent settlements that Servier concluded with its generic competitors, respectively Niche/Unichem, Matrix, Teva, Krka and Lupin, amounts to a restriction of competition contrary to Article 101 of the Treaty. In this section, the Commission will examine if these settlements constitued behaviour falling outside the scope of competition on the merits and was capable of contributing to the foreclosure effects of Servier's single and continuous exclusionary strategy, that is to say rendering generic entry more difficult and/or delayed. The Commission will demonstrate in the present section that Servier engaged in conduct capable of having foreclosure effects by successively concluding these five agreements in the context of Servier's overall strategy to exclude generic competition, which also comprised the earlier Azad Technology Acquisition. The five agreements formed part of a continuous course of conduct by Servier whereby it used its market power in order to hinder effective competition on the market for perindopril. This behaviour by a dominant company falls outside the scope of competition on the merits.

8.3.2 Applicable legal framework

(2921) In *Continental Can*[3741] the Court of Justice held that Article 102 of the Treaty was aimed not only at practices or behaviour which may cause damage to consumers directly, but also those which are detrimental to them through their impact on the structure of effective competition.[3742] Abuse may occur if any undertaking in a dominant position strengthens such a position in such a way that the degree of dominance reached substantially fetters competition. Moreover, it is important to underline that the strengthening of the position of an undertaking may be an abuse and prohibited under Article 102 of the Treaty regardless of the means and procedure by which it is achieved.[3743]

(2922) In *Hoffman-La Roche*, the Court of Justice stated that the fact that the dominant company's (Roche's) contracting partner was itself a powerful undertaking, and that the contract containing fidelity rebates was "*clearly not the outcome of pressure brought to bear by Roche on its partner*", does not preclude the existence of an abuse of a dominant position.[3744] In that case, the abuse consisted of "*the additional interference, due to the obligation to obtain supplies exclusively from Roche, with the structure of competition in a market in which in consequence of the presence there of an undertaking occupying a dominant position the degree of competition has already been weakened*".[3745]

(2923) Separately the Court of Justice has stated that where an agreement has been concluded between two undertakings, both Articles 101 and 102 of the Treaty may

3741 Judgment in *Europemballage Corporation and Continental Can Company v Commission*, C- 6/72, EU:C:1973:22.

3742 More recently, the Court of Justice confirmed in TeliaSonera that "*Article 102 of the Treaty must be interpreted as referring not only to practices which may cause damage to consumers directly […], but also to those which are detrimental to them through their impact on competition*". See judgment in *TeliaSonera Sverige*, C-52/09, EU:C:2011:83, paragraph 24.

3743 Judgment in *TeliaSonera Sverige*, C-52/09, EU:C:2011:83, paragraphs 26-27. Judgment in *France Telecom v Commission*, C-202/07 P, EU:C:2009:214, paragraphs 105-106.

3744 Judgment in *Hoffman-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraph 120.

3745 Judgment in *Hoffman-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraph 120. See also Judgment in *Gemeente Almelo and Others v Energiebedrijf IJsselmij*, C-393/92, EU:C:1994:171,, paragraph 44.

be applicable and may be applied concurrently.[3746] The Horizontal Guidelines also state that the assessment under Article 101 of the Treaty is without prejudice to the possible parallel application of Article 102 of the Treaty to horizontal cooperation agreements.[3747]

(2924) In *Compagnie Maritime Belge*, the Court held that "*it is clear from the very wording of Articles 85(1)(a), (b), (d) and (e) and 86 (a) to (d) of the Treaty that the same practice may give rise to an infringement of both provisions. Simultaneous applications of Articles 85 and 86 of the Treaty cannot be therefore ruled out a priori*".[3748] [3749]

(2925) In *Tetra Pak*, the General Court rejected the argument of the applicant that there needed to be some element, external to the agreement, to justify the concurrent application of Article 102 of the Treaty to an agreement.[3750] Citing *Ahmed Saeed*, the General Court put emphasis on the need for there to be an "*additional element*". In *Ahmed Saeed*, the additional element was the pressure imposed by the dominant company on the co-party to the agreement. In *Tetra Pak*, the additional element was the fact that the acquisition of the exclusive license had "*the practical effect of precluding all competition in the relevant market"*. In the *Van den Bergh Foods Ltd* case, the Commission identified an infringement of Article 101 of the Treaty and, concurrently, an infringement of Article 102 of the Treaty. The General Court agreed that, by inducing retailers to obtain supplies exclusively from the dominant company, that company had abused its dominance[3751] and rejected the argument that the Commission had simply recycled its findings under Article 101 of the Treaty in order to find an infringement of Article 102 of the Treaty.[3752]

3746 Judgment in *Hoffman-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraph 116; Judgment in *Ahmed Saeed Flugreisen v Zentrale zur Bekampfung unlauteren Wettbewerb, C-* 66/86, *EU:C:1989:140*, paragraph 37; Judgment of 6 October 1994, *Tetra Pak v Commission*, T-83/91, ECR, EU:T:1994:246, paragraphs 21, 25 and 30; Joined Judgments in *Compagnie maritime belge transports and Others v Commission*,C-395/96 P and C-396/96 P EU:C:2000:132, paragraph 33.

3747 *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements*, OJ C 11 of 17 January 2011, p. 1, point 16 ("Horizontal Guidelines").

3748 Joined Judgments in *Compagnie maritime belge transports and Others v Commission*,C-395/96 P and C-396/96 P EU:C:2000:132, paragraph 33.

3749 See also Commission Decision 98/531/EEC of 11 March 1998 *Van den Bergh Foods Ltd*, OJ 1998 L 246 p. 1. This is not the first Commission decision based on both Articles, see Commission Decision 89/113/EEC, *Decca Navigator System*, OJ 1989 L 43, p. 23. See also Commission Decision 1999/243 /EC *Trans-Atlantic Conference Agreement*, OJ 1999 L 95, p. 1.

3750 Judgment of 10 July 1990, *Tetra Pak v Commission*, T-51/89, ECR, EU:T:1990:41, paragraph 24.

3751 In *Van den Bergh Foods*, the additional element was the inducement of retailers in the form of an offer to supply freezer cabinets and to maintain them for free in circumstances in which, for the purposes of stocking impulse ice cream, the said retailers did not have their own freezer cabinets or a freezer cabinet made available by another competing ice-cream supplier.

3752 Notably the Commission concurrently applied Article 101 and 102 of the Treaty to the same practice in the *Van den Bergh* case (Commission Decision 98/531/EEC of 11 March 1998 *Van den Bergh Foods Ltd*, OJ 1998 L 246 p. 1, paragraph 264). The Decision was upheld by the Court of First Instance (Judgment of 23 October 2003, *Van den Bergh Foods Ltd v Commission*, T-65/98, ECR, EU:T:2003:281) and the Court of Justice (Judgment in *Unilever Bestfoods v Commission*, C-552/03 P, EU:C:2007:605).

8.3.3 Assessment under Article 102 of the Treaty of Servier's conclusion of successive reverse payment patent settlement agreements

(2926) First, this section will examine the unilateral aspects of Servier's conclusion of five settlement agreements with its generic competitors, Niche/Unichem, Matrix, Teva, Krka and Lupin, for the purposes of applying Article 102 of the Treaty. These aspects are also relevant for the question whether Articles 101 and 102 of the Treaty can simultaneously apply to these settlement agreements. Then, this section will examine if Servier, a company dominant both in the upstream market for perindopril API technology and in the four national markets for perindopril formulations (France, Poland, the UK and the Netherlands), breached its special responsibility[3753] when inducing generic companies to enter into a series of patent settlements which were capable of delaying generic entry. The following elements will be assessed:

- Servier's unilateral conduct consisting in the inducement of generic companies to accept restrictions on competition in a series of consecutive reverse payment patent settlements deviates from competition on merits (section 8.3.3.1);
- the combined effect of the reverse patent settlement agreements was capable of delaying competition on the API market and the perindopril formulation market, and thus strengthening or maintaining Servier's market power (section 8.3.3.2).

8.3.3.1 Unilateral aspects of the reverse payment patent settlements reached by Servier, and application of Article 102 of the Treaty

(2927) In the present case, the abusive conduct under Article 102 of the Treaty arises from the unilateral behaviour of Servier. As a dominant undertaking implementing its exclusionary strategy, Servier offered to generic companies, which were a threat to Servier's market position, inducements in the form of an offer to pay them a significant sum of money, or provide other significant commercial advantages. As will be explained in the present section, these inducements changed the generic companies' incentives to enter the market, which instead committed not to enter the market and not to challenge Servier's key patents.

(2928) Servier's dominance on the perindopril market(s) was singularly strong until 2007/2008. With the isolated exception of Krka, only Servier was present on the market. Servier was effectively a monopolist in most investigated national markets.[3754] It should be recalled that perindopril was protected by a "*maze*" of patents, some of which were internally considered as "**paper patents*" and involving no inventive activity. Besides these, there were key patents which greatly contributed to Servier's privileged position of market power. These were the process patents ('339, '340, and '341) and the '947 patent, which had the potential to bar most generic companies from entering.[3755] The '947 was strategically very important for Servier, as the vast majority of alternative routes for synthesising perindopril likely to be used by generic companies led to the alpha crystalline form of perindopril protected by this patent (as Servier had already acquired Azad technology as the most advanced "non-alpha" technology). However, generic companies had doubts as to the validity

3753 Judgment in *Post Danmark*, C‑209/10, EU:C:2012:172, paragraph 23.

3754 See section 6.5.2.2 above.

3755 See, for example, paragraph (126).

of this patent,[3756] as shown by the fact that a number of them had launched annulment actions before the national courts and/or were opposing the patent before the EPO. It is thus no coincidence that all the patent settlement agreements concluded between Servier and the generic companies included a clause not to challenge the validity of the '947 patent, even in those cases in which the '947 patent was not the subject of actual litigation or even of a threat of litigation by Servier (see Niche/Unichem and Matrix Settlement Agreements). Thus, avoiding validity challenges to the '947 patent was very important, as the revocation or annulment of this patent would have opened the market not only for the counterparty to the agreement but for other generic competitors as well.

(2929) Servier had considerable financial resources at its disposal because of the profits it had made as a result of the sales of perindopril. Servier used a portion of these rents to induce its competitors to enter into the successive reverse payment patent settlement agreements.

(2930) Between February 2005 and January 2007, Servier entered into five patent settlements with Niche/Unichem (February 2005),[3757] Matrix (February 2005),[3758] Teva (June 2006),[3759] Krka (October 2006)[3760] and Lupin (January 2007).[3761]

(2931) It follows from the case law cited at paragraphs (2923)-(2925) that Article 102 of the Treaty may apply to an agreement between undertakings (or a set of agreements) concurrently with Article 101 of the Treaty provided that there is "*an additional element*". Contrary to what Servier argues in its reply to the Statement of Objections,[3762] the assessment, as further developed in this section, clearly shows that the Commission does not merely recycle under Article 102 of the Treaty the facts previously objected to under Article 101 of the Treaty. This section will analyse elements which are inherent to a competitive assessment under Article 102 of the Treaty and show that the series of patent settlements had also a distinct unilateral aspect, based on the fact that Servier used its market power in order to induce a number of close generic threats to withdraw from competition with Servier with their respective generic products.

3756 See sections 5.2.1.2, 5.3.1.2, 5.4.1.2, 5.5.2 and 5.6.1.2.

3757 See section 4.3.1.

3758 See section 4.3.1.4.2.

3759 See section 4.3.2.

3760 See section 4.3.3.

3761 See section 4.3.4.

3762 Servier's reply to the Statement of Objections, paragraphs 2326-2328, ID10114, p. 612. Servier argues that the inducements in the form of value transfers constituted the heart of the infringements under Article 101 of the Treaty and therefore cannot also constitute an infringement under Article 102 of the Treaty. The absence of any additional inducement would allegedly be confirmed by the fact that the generics took the initiative of settlement negotiations. Both arguments are incorrect. First, the "additional element" here is not the individual inducements in each settlement, but the overall exclusion of potential competition from the market resulting from a single unilateral exclusionary strategy implemented through these settlements in combination with the technology acquisition and enabled by Servier's unique position on the market (see also paragraph (2964)). Second, liability for unilateral conduct implemented through agreements does not depend on which of the contracting parties initiated the negotiations of the agreement as a whole, or of any specific terms thereof. What matters is that the dominant firm, which has a responsibility not to do so, engaged in abusive conduct by entering into the agreement.

(2932) Servier's actions clearly sought to either block or delay entry into the market of those generic companies which could potentially threaten its market position at the time of the conclusion of the different agreements.

(2933) The patent settlement agreements can be considered as the result of a unilateral course of conduct by Servier for a number of separate reasons. Servier had a strategy of using all possible means to protect Coversyl from the threat of generic entry, which included using part of the substantial profits that it was reaping from its sales of perindopril to fend off generic challengers. As the holder of the key patents protecting perindopril, only Servier could devise a strategy of different settlement agreements with the different generic challengers. Thus Servier was the counterparty in each of the agreements and could, through this situation, use its market power to induce generic companies to enter into reverse payment patent settlement agreements by paying in total more than EUR [80–95]* million to the generic companies to keep them off the market. The chain of agreements was likely to have a cumulative and self-reinforcing effect, which was stronger than that of each agreement taken individually and sought to maximise the potential of perpetuating Servier's monopoly on the perindopril market.

Only Servier was party to all patent settlements

(2934) Servier was a contractual party to all the settlement agreements concerning perindopril. It was thus at the centre of contractual relationships which governed the ability and incentives to compete with most of the operators which represented an immediate generic threat to Servier. Servier was also uniquely able to take advantage of its own detailed knowledge of the scope and nature of existing agreements and accordingly adapt its commercial strategy, but also its approach to any new litigation with generic companies and possible related settlement attempts.

(2935) This contrasts with the position of the generics, which were aware of Servier's strategy (see section 8.1.3), but were not necessarily privy to the particulars of other settlements.

Expression of a single strategy to exclude competition

(2936) Servier's strategy to delay generic entry by removing close competitive threats has been described in detail in section 8.1.2.2. As shown in that section, the consistent conclusion of patent settlements inducing generic competitors to refrain from competing played an important role in containing the threat that the contested Servier patents would be annulled or found non-infringed, thus opening floodgates to generic entry. Patent settlements were consistently sought as of the first litigation with Niche (parallel to the Azad Technology Acquisition), and followed a clear pattern to the extent that the possibility of further settlements to buy-out competitors were expected by generic operators.[3763]

Servier's unilateral conduct was possible in view of its market power

(2937) Servier used its financial resources to "pay off" the generic companies in question so they would not challenge Servier’s patents and would not enter the market and therefore compete. Servier paid out a total of more than EUR 90 million in the five agreements.[3764] This expenditure is a further illustration of the unilateral conduct by a

[3763] See section 8.1.3.

[3764] For each reverse patent settlement agreement, this decision has shown that the value transferred to the generic company party to the agreement could be regarded as a small fraction of the total profits that

company with considerable market power. In the patent settlement agreement between Servier and Niche/Unichem, a distinctive element of the abusive conduct was the fact that the dominant company was inducing the generic company by an offer to pay an amount which was equivalent to several years of profit expected by the generic company, Niche.[3765] In exchange, Niche/Unichem needed to commit not to challenge Servier's patents concerning perindopril (including the '947) and to restrict their ability to compete.[3766] Regarding Teva, the one-off payment of GBP 5 million and 11 monthly payments of GBP 0.5 million can be compared to Teva's earning expectations in the first year of its market presence.[3767] In the Krka case the economic inducement consisted in the licence from Servier effectively shielding Krka from competition of other generic companies in seven CEE Member States where the presence of Krka was strong,[3768] in return for Krka's withdrawal from competition in the remaining 20 EU markets, including in particular two of Servier's biggest markets world-wide. Lupin was induced into the patent settlement agreement by a payment of EUR 40 million and a royalty-free licence for the Lupin technology sold to Servier.[3769] This has to be compared to the gross margin of USD [3.7 - 10.5] million expected from Lupin's perindopril sales in the financial year 2007/2008.[3770] The generic companies cashed the expected profit without running the risk of competition. This clearly changed their incentives to enter the market.

(2938) The amounts paid were self-financing since they enabled Servier to keep its rents for a longer time period. For example, with respect to the GBP 10.5 million payment pursuant to the Teva Settlement Agreement,[3771] Servier's accountants stated that: "*current management forecasts indicate that [Servier] should make sufficient future sales over the contract period to generate profits in excess of the amortisation charge [of the payment to Teva]*".[3772] If the market for perindopril was contested by generic entry or another significant competitive constraint, Servier's ability to provide such significant inducements would have been undermined. In addition, in a competitive market, Servier would, as a reasonable economic operator, not have the incentive to hand out such inducements, as the restrictions imposed on a single generic company would be offset by remaining competition.

Servier hoped to protect by entering into the settlement in question (See for Niche, section 5.2.1.3.3.3; for Matrix, section 5.3.1.3.3.3; for Teva, section 5.4.1.3.3.3; for Krka, sections 5.5.3.3.2.3 and 5.5.3.3.3; for Lupin section 5.6.1.3.3.5).

3765 The Commission refers to the amount of GBP 11.8 million paid to Niche, which according to an internal Niche email "*was equivalent to over [0–20]* year planned sales and [10–50]* years planned gross profit*". See above section 5.2.1.3.3.3.

3766 Compare the inducement by a dominant supplier of a customer to grant it exclusivity, so as to prevent competing suppliers from dealing with the customer, see para 264 of the Decision of the Commission in the *Van den Bergh Foods Ltd* Case, cited above para 11, and Judgment of 23 October 2003, *Van den Bergh Foods Ltd v Commission*, T-65/98, ECR, EU:T:2003:281), paragraph 160. See also Judgment in *Hoffman-La Roche v Commission*, C-85/76, EU:C:1979:36; Judgment in *AKZO v Commission*, C-62/86, EU:C:1991:286 ; and Judgment of 1 April 1993, *BPB and British Gypsum*, T-65/89, ECR, EU:T:1993:31.

3767 See above section 5.4.1.3.3.3.

3768 See above sections 5.5.3.3.2.3 and 5.5.3.3.3.

3769 See section 4.3.4.7.

3770 See above section 5.6.1.3.3.5.

3771 See sections 4.3.2.5 and 4.3.2.6.

3772 ID0030, p. 169.

The chain of patent settlements had a cumulative self-reinforcing effect

(2939) By concluding a series of reverse payment patent settlement agreements, Servier maximised the potential restrictive effect on competition. Each agreement taken individually restricted competition because the individual generic counterparty of Servier agreed to withdraw from the competition to enter the market in return for financial consideration. After having impaired generics' access to the non-infringing API technology with the Azad Technology Acquisition, the combined effect of all five agreements was to greatly increase the chances that Servier's significant market power would be protected from competition by creating the greatest possible foreclosure effect. In this respect, the abusive conduct was an attempt by Servier to use its significant market power to hinder effective competition on the market for as long as possible.

(2940) The simultaneous conclusion of the settlement agreements with Niche/Unichem and Matrix is an obvious example of this. As Niche was developing formulations based on Matrix' API, it appears that, in order for the restrictions agreed with Niche/Unichem to be effective for Servier, it was necessary for Servier to also agree on almost identical restrictions with Matrix. Thus, by entering into the Matrix agreement, which prevented Matrix from continuing to develop perindopril with another generic company after the Niche/Unichem Settlement Agreement, Servier also reinforced the impact of the Niche/Unichem agreement itself.

(2941) In addition, by entering into a new patent settlement, Servier extended the effects of the previous agreements. Each time potential competitors developed generic products to the extent that they presented an immediate threat to Servier, and put at stake the restrictions achieved with the preceding settlement(s), a further settlement agreement with, respectively, Teva, Krka and Lupin additionally postponed the moment where Servier's position could be effectively challenged in one or more investigated markets.

(2942) Based on the above, leveraging monopoly rents to systematically induce competitors to withdraw from competition, by a chain of agreements which were mutually reinforcing, in an attempt to prolong or perpetuate the monopoly, does not constitute competition on the merits. The combined effects of concluding multiple settlement agreements will be further examined in sections 8.3.3.2 and 8.4.

8.3.3.2 The combined effect of patent settlement agreements was capable of limiting competition on the API technology market and the final product market

(2943) First, it is recalled that Servier held a dominant position on both the market for perindopril API technology (to which all settlements related directly or indirectly[3773]) and the market for perindopril formulations (see sections 6.5.2 and 7.3). In a nutshell, during the period of conclusion of reverse payment patent settlements, Servier held a position with perindopril which was unrivalled throughout the EU and marked by an almost absolute absence of actual competitors.[3774]

(2944) Second, only few generic competitors had access to potentially viable API technology and could enter the market with perindopril formulations in the period

[3773] Niche and Teva did not develop the API on their own, but had exclusive access to a source of API technology.

[3774] Krka entered in Poland (and other CEEs) due to a different patent situation (notably, the national equivalent of the '947 had not yet been granted).

2005 - 2008.[3775] Amongst the generic companies developing perindopril in alpha form, the vast majority was involved in court challenges to Servier's patent position in the English courts: Niche/Unichem (with the assistance of Matrix),[3776] Krka,[3777] Apotex,[3778] Teva/Hetero,[3779] Lupin[3780] (in approximate order of development time leads). Glenmark[3781] was the only company not to take any active steps to challenge Servier's position before national courts. It can immediately be observed that Servier reached settlement agreements with all challengers other than Apotex, where Servier reported that there was "**an indication that Apotex might perhaps consider a settlement*", although no settlement was reached, and at least as of March 2007, Servier envisaged discontinuance rather than settlement.[3782] The latter was also facing claims of perindopril compound patent infringement in Canada, where Apotex's production was located.

(2945) The pattern of settlements suggests that Servier's conduct systematically targeted close potential competitors at a given point in time.

(2946) The first two settlements, the Niche/Unichem and Matrix Settlement Agreements, were concluded in February 2005 with companies which clearly had a time lead over other generic companies, and could possibly launch in the United Kingdom, the world's biggest market for perindopril, as early as 2005. The two settlements can be seen to seek complementary foreclosure effects: the Niche/Unichem Settlement Agreement would have a much more limited impact if its API supplier, Matrix, remained free to team up with another generic company for the development of generic perindopril formulations.[3783] The Matrix and Niche/Unichem settlements thus simultaneously removed advanced sources of perindopril API, and formulations, respectively.

(2947) The third settlement, the Teva Settlement Agreement in June 2006, targeted Teva as the first company to initiate a national court action (before the High Court[3784]) for annulment of the '947 patent. Teva not only had an advanced development of its own perindopril, but was also in intensive negotiations for supplies from Krka, which in May 2006 received a marketing authorisation as the first generic company in the United Kingdom. Teva's position was also unique due to Servier's undertaking (provided in the context of a stay of annulment proceedings) not to legally pursue Teva if it launched a product covered by the '947 patent. Thus, it can possibly be regarded as the only company in the United Kingdom which could launch perindopril in alpha form without being exposed to litigation risks. Therefore, it was all the more important for Servier to prevent Teva from proceeding to a launch.[3785]

3775 It is recalled that two such sources, [company name]* and Azad, were removed by Servier's technology acquisitions. section 7.3.3.1.

3776 See sections 4.3.1.1 and 4.3.1.2.

3777 See sections 4.3.3.1. and 4.3.3.5.

3778 See paragraph (2717) and subsequent.

3779 See section 4.3.2.2.

3780 See sections 4.3.4.1 and 4.3.4.5.

3781 See section (2722) and subsequent.

3782 See paragraph (191).

3783 See sections 5.3.1.3.2.2 and 5.3.2.4.

3784 It was considered that litigation in the United Kingdom allows a quick, albeit expensive, solution. See, for example, paragraph (844).

3785 Subsequently, Teva and Servier also discussed a similar arrangement for the entire EU, but no agreement was ultimately concluded.

(2948) The fourth reverse payment patent settlement, namely the Krka Settlement Agreement, was concluded in October 2006 and involved a company which was, together with Apotex, the only generic company to have received a marketing authorisation for its perindopril. In addition, Krka was also a source of technology of perindopril API and formulations, for which patent applications were filed, and a potential supplier to several generic companies, including Ratiopharm and Teva. Krka also internally considered to have a particularly strong case for the annulment of the '947 patent.[3786] Therefore, Krka was a major risk to Servier through its legal actions, completed development, partnerships with other generic companies, and as a source of API technology. These threats were effectively discontinued for the 20 EU markets, including France, the Netherlands and the United Kingdom.

(2949) After Krka settled, Lupin remained, in Servier's words, one of only two remaining "hostile players" with Apotex,[3787] both of which were challenging the validity of the '947 patent before the High Court. Moreover, Lupin was not only developing perindopril formulations, but was also supplying perindopril API to other generic companies. Lupin was at the time of the settlement expecting to enter the United Kingdom market within months and was also seeking market launch elsewhere (in France, and elsewhere through distribution partners).

(2950) On the other hand, while Glenmark had a timeline comparable to Lupin, it was a less immediate threat as its development was somewhat less advanced at the time. It did not launch annulment actions before national courts in any of the investigated Member States.[3788] Moreover, Glenmark did not only produce perindopril in alpha form covered by the '947 patent, but also appeared to violate Servier's process patents.[3789]

(2951) The only remaining threat of potential competition between 2005 and 2008 through the annulment of the '947 patent was thus Apotex. Like with all other immediate competitive threats, Servier considered various options to avoid generic entry by Apotex. First, there was "**an indication that Apotex might perhaps consider a settlement*", although no agreement was reached, and at least as of March 2007, Servier envisaged discontinuance rather than settlement of the litigation.[3790] Second, in parallel to the infringement proceedings in the United Kingdom, Servier also attempted to block Apotex in Canada, where Apotex's perindopril was produced, and where Apotex was deemed to infringe Servier's perindopril compound patent, which was still in force. While Servier finally prevailed in the Canadian infringement action, Apotex in the meantime found a way to source perindopril elsewhere.[3791]

(2952) In addition, Sandoz[3792] and Cipla,[3793] which were timewise somewhat lagging behind most of the abovementioned companies, were developing perindopril forms which were expected not to be covered by Servier's patents, and did not lead to patent litigation or disputes with Servier. With the exception of Azad, the remaining sources

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3786 See, for example, paragraphs (844) and (853).

3787 See paragraph (1024)

3788 Although it participated in the EPO opposition/appeal, this way was considered lengthier as compared to litigation in, for example, the United Kingdom and the Netherlands.

3789 See paragraph (2724).

3790 See paragraph (191).

3791 See paragraph (2717) and subsequent.

3792 See section 4.2.2.8.4

3793 See paragraph (2693) and subsequent.

not covered by Servier's patents (notably Sandoz) were lagging two to three years behind the most advanced sources of perindopril (potentially covered by Servier's patents), such as Niche/Matrix, Krka, Apotex and Teva, and time-wise presented a less immediate competitive threat, even if one factors in the duration of potential litigation.[3794]

(2953) Third, Servier's conduct was capable of delaying generic entry.[3795] The settlements removed all the respective generic companies as a direct patent challenger to Servier's patent position, and excluded the possibility that these challenges would bring about an earlier patent annulment, either in the United Kingdom or elsewhere.[3796] The settlements also prevented Niche/Unichem, Matrix and Lupin and to a lesser extent Krka[3797] and Teva[3798] from manufacturing and supplying perindopril for the purpose of launches at risk or to serve as a commercial basis for a patent challenge brought by a third party.

(2954) The removal of competition from these generic companies (or at least the delay in their entry) is mirrored by the maintenance, or strengthening, of Servier's market position. On the upstream market for perindopril API technology, Servier was able to discontinue the earlier claims of invalidity of the '947 patent or the non-infringing nature of generic companies' production processes. Patent settlements blocked the generic companies' attempts to establish the API technology on which their generic perindopril formulation was based as a viable technology (i.e. not covered by any valid patents), and thus affected also the structure of the market for perindopril API technology.[3799] This allowed Servier to maintain its dominance in all viable perindopril API technologies for a longer period of time, and also rendered generic entry more difficult.[3800]

(2955) On the four national downstream markets for perindopril formulations in France, Poland, the UK and the Netherlands, not only were Niche/Unichem, Matrix, Teva,[3801] Krka,[3802] and Lupin eliminated for the material time periods as potentially viable suppliers of perindopril formulations in the relevant markets where they themselves were planning to launch, they were also removed on the market for perindopril API technology as a potential source of perindopril for distribution by other companies, in the same or other territories, for the duration of the agreements. Niche, Krka and Lupin had concluded a number of agreements with other generics (Ratiopharm, Stada, and many others), ensuring a potentially much wider distribution of perindopril. Those distribution channels were cut off for the duration of the respective patent settlement agreements.

3794 See Table 49.

3795 In *AstraZeneca*, the General Court held that conduct which aims to delay generic entry may under certain conditions constitute an abuse under Article 102 of the Treaty. Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraphs 829 and 831.

3796 This does not relate to the Teva Settlement Agreement, which only concerned the United Kingdom market.

3797 Krka Settlement Agreement granted Krka a licence to market in Poland.

3798 As mentioned above, the settlement was for the United Kingdom only.

3799 Matrix and Lupin were not only removed as a source of potentially viable API technology but also as a potential source of API supplies.

3800 See judgment in *TeliaSonera Sverige*, C-52/09, EU:C:2011:83, paragraph 63.

3801 For the United Kingdom only.

3802 Not for Poland.

(2956) As a consequence, Servier's conduct was capable of depriving consumers of the possibility that the most advanced generic companies successfully legally and/or commercially challenge Servier's market exclusivity, not only in the United Kingdom but across the entire EU, in particular in France, Poland and the Netherlands, in a timely manner.

(2957) The conclusion of five reverse payment patent settlements in the framework of Servier's single and continuous strategy was capable of producing anticompetitive effects by foreclosing competitors on the upstream EU-wide market for perindopril API technology and in the four national markets for perindopril formulations in France, the Netherlands, Poland and the United Kingdom as of February 2005 (the conclusion of the Niche/Unichem Settlement Agreement). The series of settlements hindered a number of projects to develop generic perindopril and considerably affected the competitive structure of the market with immediate effect, and was capable of delaying generic entry and harming consumers. In the United Kingdom, the conduct was capable of producing foreclosure effects at least until July 2007 (annulment of the '947 and effective generic entry). In the Netherlands, the conduct was capable of producing such effects at least until December 2007. In France and Poland, the conduct was capable of producing such effects at least until May 2009 (when effective generic entry ensued once the '947 patent was annulled by the EPO Board of Appeals).

8.3.3.3 Objective justifications for Servier's inducement to conclude reverse payment patent settlements

(2958) An undertaking may demonstrate[3803] that its conduct was objectively necessary or that the exclusionary effect produced may be counterbalanced by efficiencies that also benefit consumers.

(2959) Servier's conclusion of the reverse payment patent settlements was not objectively justified for the reasons already developed in section 5.7.

8.3.4 Overall conclusion on the reverse payment patent settlements

(2960) By pursuing a chain of five reverse payment patent settlements, Servier induced almost all of its immediate generic challengers to withdraw from competition. The agreements, which formed part of an overall strategy, were mutually reinforcing in delaying generic entry. Pursuing these successive patent settlements was capable of protecting Servier's market position in France, the Netherlands, Poland and the United Kingdom on the market for perindopril formulations and on the market for API technology, for the duration specified in section 8.3.3.2.2. The Commission finds that Servier's conclusion of the five settlements was abusive behaviour, contributing to Servier's overall single and continuous exclusionary strategy which the Commission considers an infringement of Article 102 of the Treaty (see section 8.4 below).[3804] In that regard, the assessment in this section must be seen as forming a constitutive part of the assessment of Servier's other anticompetitive activities and overall strategy of delaying generic entry (five patent settlements were concluded in the period directly following the acquisition of the Azad technology).

3803 Judgment in *Post Danmark*, C‑209/10, EU:C:2012:172.

3804 Concerning the abuse of a dominant position, the subject-matter of this decision is the overall infringement of Article 102, which consists in the combination of the chain of patent settlements agreements and the acquisition of the Azad technology.

8.4 The Azad Technology Acquisition and the reverse payment patent settlements constitute a single and continuous infringement of Article 102 of the Treaty

(2961) Sections 8.2 and 8.3 above concluded that the acquisition of technology from Azad and the reverse payment patent settlements with Niche/Unichem, Matrix, Teva, Krka and Lupin, were capable of producing foreclosure effects on the market for perindopril formulations in France, Poland, the United Kingdom and the Netherlands and on the market for perindopril API technology, and constituted, respectively, abusive behaviour under Article 102 of the Treaty. This section shows that these practices, which were related to Servier's broader strategy to delay or block generic entry upon loss of patent protection for the perindopril compound (first patent expiries in 2001), constituted a single and continuous exclusionary strategy infringing Article 102 of the Treaty. This section will (i) recall the factors demonstrating the existence and implementation of an overall exclusionary strategy by Servier, (ii) examine the combined effects that the overall strategy was capable of producing, (iii) address the "effect on trade" condition, (iv) determine the duration of the behaviour at issue, and (v) reach the conclusion that, in view of Servier's overall strategy and their combined anti-competitive effects, the technology acquisition and the reverse payment patent settlements amount to a single and continuous infringement of Article 102 of the Treaty.

8.4.1 Single and continuous strategy

(2962) The following factors corroborate the fact, explained in section 8.1, that Servier's API technology acquisition and reverse payment patent settlements formed part of a single exclusionary strategy to buy out potential sources of generic competition as a part of its broader anti-generic strategy:

- The existence of an exclusionary strategy by Servier within its overall strategy to confront generic entry, characterised by a consistent course of conduct targeting most of the generic threats. When regulatory and patent barriers were on the point of failing to prevent generic entry, Servier used its revenues from perindopril sales to buy off close competitors one by one, either through the acquisition of IPRs or by means of patent settlements including a significant value transfer.[3805] That consistent and sustained course of conduct sought to address most of the close threats to Servier's market position at the time: this started at the latest in November 2004[3806] and ended by mid-2008 (failure to acquire technology from Sandoz). During this period, Servier not only acquired the technology from Azad, but also attempted to conclude settlements with all sources of patent challenges to Servier (Niche/Unichem, Matrix, Teva, Apotex, Krka, Lupin) and only failed with respect to Apotex (it also dropped the attempt to extend the United Kingdom arrangement with Teva to the entire Union). Moreover, Servier demonstrated its interest in acquiring technology from most of these generics.

- The high degree of centralisation which characterised the abusive behaviour: the Azad Agreement and all reverse payment patent settlements were negotiated and signed by the same Servier representative, [employee name and function with Servier]*. At the same time, [employee name of Servier]* was

3805 See section 8.1.2.2.

3806 Servier acquired API technology from [company name]* in […]* 2001, however this transaction is not legally assessed in this Decision.

also the author of the aforementioned strategy document "*Coversyl: defense against generics*", which also refers to concluded patent settlements.

- The technology acquisition and patent settlements followed a common method of excluding competition and were complementary: Servier engaged in a consistent line of behaviour which had the common goal of blocking, or at least delaying, generic entry, and followed essentially the same method. In spite of Servier's patent portfolio, none of these companies were excluded on the merits of Servier's patents, or on the merits of competition in perindopril technology. Instead, Servier achieved the exclusion by way of sharing its sustained supracompetitive rents from perindopril in the form of significant payments to the generic/API companies that committed to withdraw their projects and/or actions which challenged Servier's market position. In total, Servier paid more than EUR [110–130]* million[3807] (and was willing to pay a further EUR [30–40]* million to Sandoz[3808]) to induce its challengers to cancel on-going projects for generic competition. Moreover, the technology acquisition and the patent settlement agreements were complementary in seeking to attain foreclosure effects, and they only differed as to the stage of advancement of the generic threat that Servier was trying to eliminate. A generic threat can be eliminated early through a technology acquisition, or later on through a reverse payment settlement agreement. The complementarity can also be shown by the fact that the patent settlement agreements encompassed one or more technology acquisitions. Thus, before entering into the Niche/Unichem Settlement Agreement, Servier appeared interested in acquiring any patent-protected technology of Niche. Moreover, in addition to agreeing on settlement terms, Servier also acquired perindopril technology from Krka and Lupin (the only parties to patent settlements which had filed patent applications for their technology). Blocking entry by generic companies is likely to be even more efficient if non-challenge and non-compete provisions are combined with technology acquisitions.

(2963) In light of the above, it can be concluded that the acquisition by Servier of API technology and the conclusion of a series of reverse payment patent settlements with generic companies with an own source of API supply together constituted Servier's comprehensive and long-term exclusionary plan to prevent or delay generic entry through patent-related means. Servier's conduct follows the same objective, the same methods, occurred in a consistent sequence of time, and covered a broad range of potential sources of competition.[3809] The patent acquisition and reverse payment patent settlements thus emanated from a single and continuous exclusionary strategy by Servier.

8.4.2 Combined effects of the single and continuous exclusionary strategy

(2964) Separate conclusions as to the anticompetitive effects Servier's strategy was capable of producing by, on the one hand, the acquisition of API technology and, on the other hand, the series of reverse payment patent settlement, have already been drawn

3807 See sections 8.2 and 8.3.

3808 See paragraph (407).

3809 See e.g. conditions for single and continuous infringement of Article 102 in Commission Decision COMP/C-3 /37.990 – Intel, Official Journal C 227, 22.9.2009, p. 13–17, p. 495-499; and of Article 101 in Joined Judgments of 12 December 2007, *BASF AG and UCB SA v Commission*, T-101/05 and T-111/05 , ECR, EU:T:2007:380, paragraph 209.

above in sections 8.2.2.2.4 and 8.3.4. Those sections should be read together with the present section, which will demonstrate that the effects of the two types of practices were largely complementary, and jointly contribute to the overall foreclosure effects of Servier's single and continuous exclusionary strategy.

(2965) In view of the largely overlapping timeline, it is impossible to disentangle the effects and apportion them to individual practices. However, it follows clearly from the above that Servier's technology acquisition and the reverse payment patent settlements worked together in a consistent way to remove those sources of competition which found a way though the "*maze of patents*" and those that were contesting the validity of an allegedly blocking patent.

(2966) In addition to acquisition of API technology and reverse payment patent settlements, Servier further extended its cooperation with the possible sources of generic competition by entering into distribution arrangements for perindopril with a number of generic companies, including [company name]* and [company name]*/Mylan,[3810] for several key markets (including the United Kingdom, Netherlands, France and Ireland). It is evident that Servier, in one way or another, concluded distribution or settlement agreements affecting most of the biggest generic companies in the Union.

(2967) Servier's strategy was capable of producing anticompetitive effects and delaying generic entry by removing close competitive threats starting with the Azad Technology Acquisition in November 2004. This acquisition immediately disrupted the market structure across the EU and caused a number of generic companies to delay their development, and the related product launch plans. This also eliminated the possibility of a generic entry with a non-infringing form of perindopril (not covered by the '947 patent) by mid-2007,[3811] as the remaining scarce non-infringing sources implied a delay in the time to entry.

(2968) The effects from the Azad Technology Acquisition were soon complemented by the effects of the reverse payment patent settlements between Servier and Niche/Unichem and Matrix, respectively, as well as the three later settlements.

(2969) The Niche/Unichem and Matrix Settlement Agreements were concluded in February 2005. Niche had to then terminate 14 agreements for license and supply of its perindopril with generic companies, which meant these companies had to restart the search for a source of perindopril supplies, and restart product development, incurring delays in the overall launch timelines.[3812]

(2970) While the exclusion of Matrix and Niche was capable of causing the longest delay of generic entry, as well as foreclosure effects on the perindopril API technology market, these effects were compounded by the subsequent reverse payment patent settlements, which removed most of Servier's close competitors one by one. Thus the competitive pressure on Servier's market exclusivity for perindopril was weakened. With the exception of Teva, the effects of the abusive conduct were not limited to the United Kingdom but excluded these competitors from competing, including by challenging Servier's patent position, across the entire Union, including the investigated Member States, as shown below.

[3810] See section 4.1.2.5.

[3811] See paragraph (2874).

[3812] See section 4.3.1.5.2.

(2971) The abusive conduct ended with effective generic entry, which in most cases (Teva, Krka and Lupin settlements) coincided with the termination of the main restrictions in the patent settlement agreements. The dates of effective generic entry differ from one Member State to another, but overall generic competition was able to effectively emerge only after the revocation of the '947 patent by the EPO Board of Appeals in May 2009. The annulment of the '947 patent also removed the importance of the Azad technology, and the effects of Servier's acquisition, for the competitive process as it was no longer necessary to have a non-infringing form of perindopril to enter the market. Whether generic entry was eventually successful also depended on whether Servier had been able to switch prescriptions from perindopril erbumine to perindopril arginine.[3813] In certain Member States, where substitution between perindopril erbumine and arginine was not automatically possible due to the difference in dosages (e.g. France, Belgium, Italy, Ireland), generic versions of perindopril erbumine could not be dispensed when Servier's perindopril arginine was prescribed. Thus, in France, the anticompetitive foreclosure was capable of having effects even after the patent and regulatory barriers had been overcome successfully by generic companies.

(2972) On the perindopril API technology market, the abusive conduct lasted until the moment when the annulment of the '947 perindopril by the EPO on 6 May 2009 allowed the sources of API technology, such as Krka, Matrix and Lupin, to re-establish themselves as potentially viable sources of API technology, along with other sources of API technology which were previously blocked by the '947 patent.

(2973) The following figures show the temporal scope for effects resulting from Servier's conduct separately for the United Kingdom, the Netherlands, France and Poland. In all of these figures, the effects on the development of generic perindopril could be perceived as of November 2004 (acquisition of Azad's technology) and were reinforced by the subsequent removal of Niche and Matrix by way of reverse payment settlement agreements. The effects of all of the subsequent patent settlements were, from an *ex ante* perspective, capable of having long lasting effects. The patent situation and the product switch to perindopril arginine suggest the scope for actual effects from an *ex post* point of view.

Figure 13: **Temporal scope for effects Servier's strategy was capable of producing: United Kingdom**

[…]*

Source: company data and Commission file

(2974) Figure 13 above for the United Kingdom shows that the effects on the market structure could be perceived until the successful annulment of the '947 patent by Apotex. Owing to the latter, generic entry could effectively occur in July 2007, bringing average consumer prices down almost ten-fold. Servier's branded perindopril sales (Coversyl) virtually disappeared, and Servier's strategy could not produce actual anticompetitive effects from this point onwards. Consequently, Servier was not able to switch the market successfully to perindopril arginine to protect its perindopril turnover.

Figure 14: Temporal scope for effects Servier's strategy was capable of producing: the Netherlands

[…]*

Source: company data and Commission file

[3813] See section 6.4.1.4.

(2975) Figure 14 above for the Netherlands shows that the effects on the market structure could be perceived until the entry at risk by Apotex in December 2007. Apotex's entry, followed by others, brought average consumer prices down more than five-fold. Servier's branded perindopril sales (Coversyl) virtually disappeared, and Servier's strategy could not produce actual anticompetitive effects from this point onwards. Consequently, as in the United Kingdom, Servier was not able to switch the market successfully to perindopril arginine to protect its perindopril turnover.

Figure 15: Temporal scope for effects Servier's strategy was capable of producing: France

[…]*

Source: IMS, company data and Commission file

(2976) Figure 15 above for France shows that the effects on the market structure could be perceived until at least the entry of Sandoz's perindopril not covered by Servier's patents in September 2008. Unlike in the United Kingdom and the Netherlands, generic competition in France only resulted in a limited reduction of the average price, and Servier succeeded in safeguarding the majority of its sales. This can be explained by Servier's campaign aimed at slowing down generic substitution, in particular by Sandoz, and its subsequent switch to perindopril arginine in April 2009, a month before the annulment of the '947 patent in May 2009 that triggered the entry of additional generic companies.

Figure 16: Temporal scope for effects Servier's strategy was capable of producing: Poland

[…]*

Source: company data and Commission file

(2977) Figure 16 above for Poland shows that the effects on the market structure could have allowed Servier to successfully switch to perindopril arginine in April 2006 in the absence of any generic competition. These effects were only partly reduced by Krka's entry in June 2006. Krka received the exclusive licence for the '947 patent from Servier in October 2006 as a part of the reverse payment settlement with Servier, whereby Krka remained the only generic company in Poland. Unlike in the United Kingdom and the Netherlands, generic competition in Poland only resulted in a limited reduction of the average price, and Servier succeeded in safeguarding the quasi totality of its sales. This can be explained by Servier's timely and uncontested product switch to perindopril arginine as well as by the absence of other generic competitors until February 2009, which led to limited competition only.

(2978) The preceding analysis showed that anticompetitive foreclosure from combining the Azad Technology Acquisition and the five settlements was capable of delaying generic entry and harming consumers for relatively long periods of time, in some instances for a period of more than three years.

(2979) According to settled case law,[3814] the Commission needs to demonstrate that the impugned conduct was capable of producing anti-competitive effects, and not that it produced actual effects. The Azad Technology Acquisition and the five reverse payment patent settlement agreements delayed or blocked a number of projects to develop generic perindopril and considerably affected the competitive structure of the market with immediate effect. Certain facts, which suggest that this impact on the

[3814] See Judgment of 14 February 2001, *British Airways v Commission*, T-219/99, EU:C:2001:90, Paragraph 293; judgment in *TeliaSonera Sverige*, C-52/09, EU:C:2011:83, paragraph 63, referring to Judgment in *Deutsche Telekom v Commission*, C-280/08 P, EU:C:2010:603, paragraph 253.

competitive structure may have contributed to actual effects on consumers and to the overall success of Servier's anti-generic strategy, will be presented for the purposes of illustration.

(2980) Servier's anti-generic strategy was a comprehensive one, and only certain of its aspects were found to belong to the abusive strategy as assessed in this Decision.[3815] However, the strategy to buy out generic threats through the purchase of API technology and by reverse payment patent settlements took a central role in Servier's broader endeavours to delay generic entry, and had the most direct effects on competition.

(2981) The conclusion that the Azad Technology Acquisition and the reverse payment patent settlements were seen as a successful strategy to confront the threat of generic entry can be inferred from the aforementioned presentation "*Coversyl: defense against generics*" from June 2006.[3816] The Azad technology is listed amongst process patents which were considered as "*protective measures against generics*", and Servier's analysis of sources of API and final product refers to no other technology with a non-infringing form of perindopril. The "*Did it work?*" subsection expressly referred to Niche and Matrix Settlement Agreements among other examples of successful defense against generic entry (the document mentions that the first announcement of generic entry was in early 2001, that APIs were not complying with European Pharmacopoeia specifications or infringing Servier's patents, and that marketing authorisations have been granted but have not led to marketing). In addition, the document also mentions Teva, not as one of the biggest generic companies worldwide and, correspondingly, a major threat to Servier, but as a partner of Servier "*to launch Servier perindopril if/when mandatory*" (emphasis added).

(2982) The presentation of Servier's anti-generic strategy ends with the aforementioned graph of Servier's turnover from perindopril, depicted below.

Figure 17: "Coversyl: defense against generics" – projected vs actual budget for perindopril, June 2006

[…]*

Source: ID0105, p. 184.

(2983) The graph shows two scenarios; the expected, budgeted one, where a break in the trend was expected to take place by the end of 2005. The other – actual - scenario shows a continuing growth trend irrespective of the breaking point. The break is not explained but, as the graph forms part of, and serves as a conclusion to, a document exclusively devoted to Servier's anti-generic strategy, it can legitimately be assumed

3815 In that regard, Servier argues in paragraphs 2345 to 2349 of its reply to the Statement of Objections (ID10114, p. 617 - 619) that the Commission cannot conclude that reverse payment patent settlements do not fall within competition on the merits on the sole basis that that they are included within an anti-generic strategy, because such a strategy is, in itself, legitimate. For Servier, the legality in terms of competition law of each element of such a strategy must therefore be assessed separately, independently of the legality of the other elements. Hence, in the present case, the legality of the other elements of the strategy, against which no objections were formed, should be irrelevant to assess the legality of the reverse payment patent settlements. The Commission emphasises that it is uncontested that an anti-generic strategy is not intrinsically anti-competitive. However, some or all of its elements may be, and the full context – of which the other elements of the strategy form part – will be taken into account when assessing this legality. This applies to the Azad Technology Acquisition and the reverse payment patent settlements, which were found to contribute to the overall anti-competitive effects of Servier's strategy.

3816 See, for example, paragraphs (111) and (605).

that the breaking point corresponds to expected generic entry at least in the United Kingdom, where generic pressure was strongest. The gap between the actual and the expected sales shows that Servier across the entire perindopril family sold EUR [25–50]* million more than initially expected during the first half year period from the breaking point until the date of the presentation alone.

(2984) Servier's reactions to the outcome of the Apotex litigation in the United Kingdom demonstrate that the ultimate objective behind the enforcement of the '947 patent was to delay generic entry. A casual observer would expect that the annulment of this important patent would be a cause for concern for the originator company. On the contrary, the annulment was received with the comment "**[…] 4 years gained = great success*", which shows that Servier considered the underlying strategy to delay generic entry by the enforcement and defence of the '947 patent as successful. This was in mid-2007, two years ahead of effective generic entry in markets like France or Poland.

(2985) This allows for two conclusions. First, Servier was not expecting a full protection term from the '947 patent (running until 2021); even after "losing" a patent litigation, it considered this a big success, as the generics only effectively entered four years after the expiry of the perindopril compound patent/SPC. As explained, the reverse payment patent settlements were not accountable for the entire delay, but were capable of prolonging it until July 2007 for the United Kingdom, as they all targeted United Kingdom patent disputes and litigation, and even longer in France, the Netherlands, and Poland.

(2986) Second, the statement "**objections raised only in the UK"* as an aspect of the "**great success*"[3817] shows the importance of the EU-wide geographic scope of patent settlements (with Teva as an exception): the companies were not only removed as patent challengers in the United Kingdom but for the rest of the EU as well. It needs to be added that the United Kingdom was, ultimately, the market where the generic delay that Servier's strategy was capable of producing was probably the shortest.

(2987) On the basis of the above, it can be concluded that Servier pursued a single and continuous exclusionary strategy, consisting of the Azad Technology Acquisition and reverse payment patent settlements, which was capable of producing foreclosure effects. This was through considerably affecting the competitive structure of the market for perindopril from November 2004 onwards, which was capable of delaying generic entry and causing harm to consumers. Servier's strategy should therefore be considered to constitute a single and continuous infringement of Article 102 from November 2004 to May 2009, aimed at foreclosing competitive threats both on the upstream market for perindopril API technology as well as directly on the markets for the final product in the United Kingdom, France, the Netherlands and Poland.

8.4.3 Effect on trade

(2988) Article 102 of the Treaty prohibits an abuse of a dominant position "*in so far as it may affect trade between Member States*". That criterion has three basic elements.

(2989) First, "*trade between Member States*" must be affected. According to settled case law, abuses that have an impact on the competitive structure in more than one

[3817] See paragraph (2984) above.

Member State are by their very nature capable of affecting trade between Member States.

(2990) Second, it is sufficient that the abuse "*may affect trade*", that is to say, that it is sufficiently probable that the practice is capable of having an effect on the patterns of trade based on an objective assessment (as well as subjective elements if any). Trade need not necessarily be reduced. The pattern of trade must simply be capable of being affected by the abusive practices.

(2991) Third, the effect on trade of the abuse must be appreciable. That element requires that the effect on trade between Member States must not be insignificant and it is assessed primarily with reference to the position of the undertakings on the market for the product concerned.

(2992) The single and continuous infringement committed by Servier covered the entire EU by means of a set of agreements, one covering the United Kingdom (Teva), the others covering all the countries worldwide where Servier's patents mentioned in these agreements were in force. As has been analysed above, the agreements were capable during their operation of precluding competition on the at least EU-wide perindopril API technology market and the four national markets of perindopril formulations in France, Poland, the UK and the Netherlands. With regard to the technology acquisition, it was at least EU-wide.

(2993) As such, the infringement is by its very nature capable of affecting trade between the Member States.

(2994) The actual and potential effects of the abuse on the EU markets were appreciable in view of the magnitude of perindopril sales in the Member States concerned (see, for example, paragraph (2129)), and because generic competition tends to quickly replace originator sales.

(2995) The Commission concludes that Servier's single and continuous infringement may affect trade between Member States within the meaning of Article 102 of the Treaty.

8.4.4 Conclusion – Servier's single and continuous strategy combining a patent acquisition and reverse payment patent settlements constitutes a single and continuous infringement of Article 102 of the Treaty

(2996) It is in the fact-specific circumstances of this case that Servier's practices, consisting in Servier's acquisition of API technology combined with the conclusion of reverse payment patent settlements with competitors constitutes conduct which is not objectively justifiable,[3818] and which forms a single and continuous strategy. Servier's strategy deviated from its special responsibility as a dominant company "*not to allow its conduct to impair genuine undistorted competition on the common market*"[3819] and constituted "*recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators*".[3820] Servier did not exclude the operators representing a close competitive threat on the technology market or the final product market by outperforming them with the strength of its patent portfolio, quality of its products, or superior manufacturing efficiency, but by a series of direct transactions with these operators to effectively buy them out of the market by purchasing their technology or

[3818] See sections 8.2.2.2.4.4 and 8.3.3.3.

[3819] See paragraph (2761).

[3820] See paragraph (2760).

by providing inducements for them to accept restrictions of competition. Servier's conduct was capable of leading to "*the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition*".[3821]

(2997) Consequently, Servier's acquisition of API technology combined with its conclusion of reverse payment patent settlements amount to an abuse of Servier's dominant position in the market for perindopril formulations in France, Poland, the United Kingdom and the Netherlands and on the market for perindopril API technology, and constitute a single and continuous infringement of Article 102 of the Treaty. The various practices constituting this abuse, which enabled Servier to each time remove a close potential competitor, were complementary and, in consequence, mutually-reinforcing in their effects. Indeed, each transaction made all the more sense for Servier that it could effectively delay generic entry for as long as possible, which it could only do if later competitive threats were also eliminated. Moreover, in addition to cumulating its own foreclosure effects with those of previous transactions in further delaying generic entry, each practice also served to make the following one interesting for Servier. The cumulative nature of the foreclosure effects resulting from the implementation of the anti-generic strategy as a single and continuous infringement of Article 102 of the Treaty thus strongly increases the likelihood of it having effects on competition, in particular by delaying generic entry in the market for perindopril, and the ensuing consumer harm in terms of sustained higher perindopril prices for patients and health systems in the United Kingdom, the Netherlands, France and Poland.

8.4.5 Duration of the infringement

(2998) The single and continuous infringement of Article 102 of the Treaty by Servier is established for the period from 9 November 2004[3822] until 6 May 2009. The 9 November 2004 start date is based on the date Servier acquired the exclusive rights to Azad's potentially viable perindopril API technology.[3823] Various actions by Servier formed part of this infringement during the subsequent years, namely the Niche/Unichem Settlement Agreement (8 February 2005), the Matrix Settlement Agreement (8 February 2005), the Teva Settlement Agreement (13 June 2006), the Krka Settlement Agreement (27 October 2006) and the Lupin Settlement Agreement (30 January 2007). The effects of this infringement continued until 6 May 2009, when the '947 patent was revoked by the EPO and effective generic entry was generally enabled.[3824] In the United Kingdom and the Netherlands, the infringement

3821 See paragraph (2760).

3822 For France, the SPC for the compound patent only expired there on 22 March 2005. However, this fact alone does not justify the conclusion that generic companies in France were unable to prepare their entry on the market in France well before that date. Taking into account that generic development times in the case of perindopril were on average two to three years and the fact that no generic product had been launched in any other Member States before the SPC expiry in France, the Commission conservatively assumes that the infringement started in France at least on 9 November 2004.

3823 See, for example, case 88/501/EEC: Commission Decision of 26 July 1988 relating to a proceeding under Articles 85 and 86 of the EEC Treaty (IV/31.043 - Tetra Pak I (BTG licence), OJ L 272, 04/10/1988 p. 27-46, paragraph 47(3).

3824 While the Krka and Lupin Settlement Agreements remained in force in certain markets even after the effective generic entry, the Commission chose an earlier end date which was more favourable to Servier.

is considered to have lasted at least until the time of generic entry.[3825]

[3825] Earlier lasting generic entry was observed in the United Kingdom as of 9 July 2007, the date of the annulment of the '947 patent in the United Kingdom, and in the Netherlands, as of 13 December 2007, the date of Katwijk (Apotex's) launch at risk. For details concerning generic entry in these Member States see sections 6.4.1.4, 6.4.2.4, 6.4.3.4 and 6.4.4.4. Concerning the assessment of lasting generic entry, see also section 6.5. While the Niche/Unichem and Matrix Settlement Agreements remained in force in these markets even after the effective generic entry, the Commission chose an earlier end date which was more favourable to Servier.

9 ADDRESSEES OF THIS DECISION

9.1 Principles

(2999) Article 101 of the Treaty is addressed to undertakings. The concept of 'undertaking' encompasses any entity engaged in an economic activity. The 'undertaking' that committed the infringement can therefore be broader than the legal entity whose representatives actually took part in the infringing activities. As the Court of Justice ruled in *Akzo Nobel v Commission, "When such an economic entity infringes the competition rules, it falls, according to the principle of personal responsibility, to that entity [i.e. the undertaking] to answer for that infringement"*.[3826]

(3000) At the same time, the infringements of Union competition law in this case must necessarily be imputed to a legal person on whom fines may be imposed. This Decision must therefore be addressed to legal persons.[3827] It is accordingly necessary for the Commission to identify, for each undertaking that is held accountable for its infringement(s) of Article 101 and/or 102 of the Treaty in this case, one or more legal entities that represent the undertaking concerned.

(3001) It is well-established case-law that the conduct of a subsidiary may be imputed to the parent company in particular where, while having a separate legal personality, that subsidiary does not decide independently upon its own conduct on the market, but carries out, in all material respects, the instructions given to it by the parent company. This is the case because, in such a situation, the parent company and its subsidiary form a single economic unit and therefore a single undertaking.[3828]

(3002) The Court of Justice has ruled that the Commission cannot merely find that a legal entity is able to exert decisive influence over another legal entity. The Commission has to demonstrate that such decisive influence was actually exerted on the basis of factual evidence, including, in particular, any management power one of the legal entities may have over the other.[3829] In this respect, account must be taken of all the relevant factors relating to economic, organisational and legal links which tie the subsidiary to the parent company.[3830]

(3003) However, for the specific case where a parent company has a 100% shareholding in a subsidiary which has infringed Union competition rules, the Court has clarified that there is a rebuttable presumption that the parent company does in fact exercise decisive influence over the conduct of its subsidiary.[3831] In those circumstances, it is sufficient for the Commission to prove that the subsidiary is wholly-owned (or almost wholly-owned) by the parent company in order to presume that the parent exercises decisive influence over the commercial policy of the subsidiary. The Commission will be able to regard the parent company as jointly and severally liable for the payment of the fine imposed on its subsidiary, unless the parent company,

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3826 Judgment in *Akzo Nobel and Others v Commission,* C-97/08 P, EU:C:2009:536, paragraph 56.

3827 Judgment in *Akzo Nobel and Others v Commission,* C-97/08 P, EU:C:2009:536, paragraph 57.

3828 Judgment in *Akzo Nobel and Others v Commission,* C-97/08 P, EU:C:2009:536, paragraphs 58-59 and the case-law cited there.

3829 See for instance Judgment of 14 March 2013, *Fresh del Monte produce, Inc. v Commission* , T-587/08, ECR, EU:T:2013:129, paragraph 56 and the jurisprudence cited there.

3830 Judgment in *Akzo Nobel and Others v Commission,* C-97/08 P, EU:C:2009:536, paragraph 74.

3831 Judgment in *Akzo Nobel and Others v Commission,* C-97/08 P, EU:C:2009:536, paragraph 60.

which has the burden of rebutting that presumption, adduces sufficient evidence to show that its subsidiary acts independently on the market.[3832] This also applies to situations where the parent company indirectly holds a 100% ownership in a subsidiary, i.e. via one or more intermediary companies.[3833]

(3004) In this case, the Commission considers that the parent company which at the time of the events directly or indirectly wholly owned a subsidiary that directly participated in the infringements of Union competition rules should be held liable for the infringement. In addition, the Commission also holds jointly and severally liable a subsidiary that actually signed the agreement or that played a prominent role in its negotiation or implementation.

(3005) Infringements of Union competition law can, under certain conditions, be also imputed to entities which exercise decisive influence over subsidiaries that are not wholly-owned by them. According to settled case-law, "[t]*he fact that a subsidiary is not wholly owned by a parent company does not exclude the possible existence of an economic unit, in the competition law sense (Case C407/08 P Knauf Gips v Commission [2010] ECR I6375, paragraph 82). However,* […] *it is, as a rule, for the Commission to demonstrate, on the basis of factual evidence, including, in particular, any management power one of the undertakings may have with regard to the other, that the parent company exercises a decisive influence over its subsidiary*".[3834] In this respect, all the relevant economic, organisational and legal links which tie the subsidiary to the parent company have to be considered.[3835] Advocate General Kokott explained that decisive influence of the parent company does not necessarily have to result from specific instructions, guidelines or rights of co-determination regarding market conduct. "*Such instructions are merely a particularly clear indication of the existence of the parent company's decisive influence over its subsidiary's commercial policy. However, autonomy of the subsidiary cannot necessarily be inferred from their absence"*.[3836] Nor is actual knowledge of the anticompetitive conduct by the parent company necessary.[3837] "*In the end, the decisive factor is whether the parent company, by reason of the intensity of its influence, can direct the conduct of its subsidiary to such an extent that the two must be regarded as one economic unit*".[3838] For example, the economic unit may have an informal basis in the form of personal links between the two companies.[3839]

3832 Judgment in *Akzo Nobel and Others v Commission,* C-97/08 P, EU:C:2009:536, paragraphs 60-61 and the case-law cited there.

3833 See for instance Judgment of 14 July 2011, *Total SA and Elf Aquitaine SA v Commission,* T-190/06, ECR, EU:T:2011:378, paragraph 42.

3834 See for example, order of the Court of Justice in Judgment in *Otis Luxembourg Sàrl and others v Commission,* C-494/11 P, ECR, EU:C:2012:356 , paragraph 43; and Judgment of 14 March 2013, *Fresh del Monte Produce, Inc. v Commission,* T-587/08, ECR, EU:T:2013:129 , paragraph 56.

3835 Judgment in *Akzo Nobel and Others v Commission*, C-97/08 P, EU:C:2009:536, paragraph 74.

3836 Opinion of Advocate General Kokott delivered on 23 April 2009 in Judgment in A*kzo Nobel and Others v Commission,* C-97/08 P, EU:C:2009:536, paragraphs 89 and 91. See also Judgment in *Akzo Nobel and Others v Commission*, C-97/08 P, EU:C:2009:536, paragraph 73.

3837 Judgment in *Akzo Nobel and Others v Commission*, C-97/08 P, EU:C:2009:536, paragraph 59.

3838 Opinion of Advocate General Kokott in delivered on 23 April 2009 in Judgment in *Akzo Nobel and Others v Commission*, C-97/08 P, EU:C:2009:536, paragraph 93.

3839 Opinion of Advocate General Kokott delivered on 29 November 2012 in Judgment in *Commission v Stichting Administratiekantoor Portielje,* C-440/11 P, EU:C:2013:514, paragraph 74.

9.2 Servier

(3006) The Servier group participated in the infringements of Article 101 and of Article 102 of the Treaty. In the period 2004 - 2009, various legal entities belonging to the Servier group participated in the different infringements (the term Servier group is understood to comprise all direct and indirect subsidiaries of Servier S.A.S.). The following entities directly participated in the infringements:

(a) Niche/Unichem Settlement Agreement

- Les Laboratoires Servier, for the entire period of this infringement.[3840] This was through the conclusion of the agreement by Les Laboratoires Servier (signed by [employee name of Servier]* as "proxy").[3841]
- Servier Laboratories Limited, for the entire period of this infringement. This was through the conclusion of the agreement by Servier Laboratories Limited (signed by [employee name of Servier]* as "proxy").[3842]
- Biogaran, for the entire period of this infringement. This was through the conclusion of the "Licence and Supply Agreement" with Niche related to the Niche/Unichem Settlement Agreement (signed by [employee name and function with Servier]*).[3843]

(b) Matrix Settlement Agreement

- Les Laboratoires Servier, for the entire period of this infringement.[3844] This was through the conclusion of the agreement by Les Laboratoires Servier (signed by [employee name of Servier]* as "proxy").[3845]

(c) Teva Settlement Agreement

- Servier Laboratories Limited, for the entire period of this infringement.[3846] This was through the conclusion of the agreement by Servier Laboratories Limited (signed by [employee name and function with Servier]*).[3847]
- Les Laboratoires Servier, for the entire period of this infringement. This was through the participation of Les Laboratoires Servier in the negotiation of the agreement. The negotiations were conducted from the headquarters of Les Laboratoires Servier in France by [employee name of Servier]* (also acting, for example, as proxy for Les Laboratoires Servier) and [employee name and function with Servier]*.[3848]

3840 See section 5.8.1 for the duration of the infringement in the case of the Niche/Unichem Settlement Agreement.

3841 See section 4.3.1.4.1.

3842 See section 4.3.1.4.1.

3843 See section 4.3.1.4.1.3.

3844 See section 5.8.2 for the duration of the infringement in the case of the Matrix Settlement Agreement.

3845 See section 4.3.1.4.2.2.

3846 See section 5.8.3 for the duration of the infringement in the case of the Teva Settlement Agreement.

3847 See section 4.3.2.5.

3848 See section 4.3.2.3.2

(d) Krka Agreements

- Les Laboratoires Servier, for the entire period of this infringement.[3849] This was through the conclusion of the Settlement Agreement, Licence Agreement, and Assignment and Licence Agreement by Les Laboratoires Servier (signed by [employee name of Servier]* as "proxy").[3850]

(e) Lupin Settlement Agreement

- Les Laboratoires Servier, for the entire period of this infringement.[3851] This was through the conclusion of the agreement by Les Laboratoires Servier (signed by [employee name of Servier]* as "proxy").[3852]

(f) single and continuous infringement of Article 102 (comprising the Azad technology acquisition and patent settlements by Servier)

- Les Laboratoires Servier, for the period from 9 November 2004 to at least 6 May 2009. This was through the participation by Les Laboratoires Servier in the agreements under (a) to (e) above and through the conclusion of the Azad Technology Acquisition[3853] (agreement signed by [employee name of Servier]*, [employee name of Servier]* and [employee name of Servier]* as "proxies").

(3007) In addition, Servier S.A.S. should be held liable as a parent company of the Servier group. Servier S.A.S. is the holding company of the Servier group.[3854] Servier S.A.S. is a "pure financial holding without any commercial or operational activity".[3855] As a holding company, its function was to regroup shareholdings in various companies and to ensure that they are run as one.[3856] Either directly or indirectly, Servier S.A.S. wholly owned, amongst others, the following subsidiaries during the period in which they participated directly in the relevant infringements: Les Laboratoires Servier, Servier Laboratories Limited and Biogaran.[3857] Therefore, it is presumed that Servier S.A.S. exercised decisive influence over those subsidiaries.[3858] The Commission considers that this presumption is enough to establish the liability of Servier S.A.S. and there is no need to add any further elements in this regard.

(3008) However, for the sake of completeness, the Commission notes that there is further evidence showing that Servier S.A.S. actually exercised decisive influence over its subsidiaries. The extensive top management overlaps between Servier S.A.S. and its subsidiaries reinforce the above presumption. [employee name and function]* of Servier S.A.S., was also the [employee function with Servier]* of, amongst others, Les Laboratoires Servier during the infringement period.[3859] [Employee name of Servier]* was involved in key strategic decisions concerning generic entry in

3849 See section 5.8.4 for the duration of the infringement in the case of the Krka Agreements.
3850 See sections 4.3.3.6 and 4.3.3.7.
3851 See section 5.8.5 for the duration of the infringement in the case of the Lupin Settlement Agreement.
3852 See section 4.3.4.7.1
3853 See section 4.2.2.5.
3854 See section 1.1.
3855 ID5064, p. 9.
3856 See Judgment of 8 October 2008, *Schunk v Commission*, T-69/04,ECR, EU:T:2008:415, paragraph 63.
3857 ID1632, ID1630, ID7049.
3858 See, for example, Judgment of 8 October 2008, *Schunk v Commission*, T-69/04,ECR, EU:T:2008:415, paragraph 70.
3859 ID1632, p. 1.

perindopril and the ensuing action plans.[3860] The very significant presence of [employee name and function with Servier]*, and other personnel overlaps[3861] show the extent to which Servier S.A.S. actually influenced its wholly-owned subsidiaries and the corresponding lack of independence of the subsidiaries of Servier S.A.S., including in particular Les Laboratoires Servier.[3862] The Commission in addition notes that, in the context of this investigation, all replies of entities of the Servier group have been made by, and on behalf of, Servier S.A.S.[3863]

(3009) Within the Servier group, Servier S.A.S.'s wholly owned subsidiary Les Laboratoires Servier holds the status of a "**pharmaceutical laboratory*" and is in charge of all originator medicines of the Servier group.[3864] Following this arrangement, Les Laboratories Servier determined and coordinated, for the entire Servier group (i.e. including subsidiaries of Servier S.A.S. which were not subsidiaries of Les Laboratoires Servier), the commercial policy concerning perindopril world-wide.[3865] In this respect, the Commission considers that Les Laboratories Servier was acting on behalf of its parent company, Servier S.A.S., for the reasons set out in paragraphs (3007) - (3008).

(3010) Biogaran claims that the Statement of Objections has not demonstrated the direct involvement of Biogaran in an infringement of competition rules. According to Biogaran, it cannot be held liable for alleged practices by other Servier entities which have concluded the settlement agreement with Niche/Unichem, the only act that is alleged to be anticompetitive by the Commission. According to Biogaran, the Biogaran agreement was described by the Commission as an additional inducement and can be presumed as such to be in conformity with competition law rules. Even if a link was established between the Biogaran agreement and the settlement agreement concluded between Servier and Niche/Unichem, Biogaran argues that it has not been established that Biogaran was aware of the anticompetitive nature of the settlement agreement and cannot be sanctioned for having concluded an agreement which induced a party to conclude another agreement.[3866]

(3011) In the assessment of the Niche/Unichem settlement agreement, the Commission has demonstrated the parallelism that existed between the conclusion of that agreement and the Biogaran agreement based on the following elements (see section 5.2.1.3.3.5): (i) identical dates of conclusion of the Biogaran agreement and the Niche/Unichem Settlement Agreement and dates for execution of the payment, (ii) a draft of the settlement agreement contains a hand-written reference to "ramipril" (the main dossier of the three dossiers for which the Biogaran agreement was concluded), (iii) Niche's statements that the Biogaran agreement formed part of "*the total overall consideration"* agreed for entering into the Niche/Unichem Settlement Agreement.

3860 See, for example, ID0111, p. 9, ID0112, p. 14.

3861 For example, [employee name of Servier]* acted both as [employee function]* (ID2082) and as [employee function]* for Les Laboratoires Servier (for example, ID0110, p. 59, ID0104, p. 73). [Employee name of Servier]* also participated in activities concerning perindopril described in this Decision. See, for example, ID0116, p. 143.

3862 See, for example, Judgment of 16 June 2011, *FMC v Commission,* T-197/06, ECR, EU:T:2011:282, paragraph 117; Judgment of 16 November 2011, *Almando Alvarez v Commission,* T-78/06, ECR , EU:T:2011:673, paragraph 37.

3863 ID2365, p. 2.

3864 ID1631, p.1.

3865 ID7049.

3866 Biogaran's reply to the Statement of Objections, paragraphs 145-148 and f., ID9243, p.19.

These mutually corroborated elements demonstrate the existence of a link between these two agreements. Moreover, the email sent by Biogaran to Niche on 4 February 2005 negotiating *"further rights on additional products"*[3867] was sent whilst the litigation between Niche and Servier was still on-going and shows plainly that Niche had requested a fixed sum from Biogaran before actually agreeing on the exact scope of the products to be covered by the agreement. Therefore, whilst it is not necessary to prove Biogaran's awareness of the anticompetitive nature of the settlement agreement, the above elements show that Biogaran was in a position to understand that the Biogaran agreement was related to the Niche/Unichem Settlement Agreement. As the Biogaran Agreement provided an additional inducement to Niche for concluding the settlement with Servier, Biogaran thus directly participated in the infringement of Article 101 of the Treaty by signing the agreement with Niche.

(3012) Consequently, the parent company Servier S.A.S. should be held jointly and severally liable with Les Laboratoires Servier, Servier Laboratories Limited and Biogaran for the entire duration of the respective relevant infringements established in this Decision and in which these three entities participated (see points (a) to (f) in paragraph (3006)).

(3013) Accordingly, this Decision should be addressed to Servier S.A.S., Les Laboratoires Servier, Servier Laboratories Limited and Biogaran.

9.3 Niche and Unichem

(3014) The following entities directly participated in the infringement of Article 101 of the Treaty consisting of the Niche/Unichem Settlement Agreement:

- Niche (full name: Niche Generics Limited), for the entire period of this infringement.[3868] This was through the negotiation and conclusion of the Niche/Unichem Settlement Agreement and the "Licence and Supply Agreement" with Biogaran, related to the Niche/Unichem Settlement Agreement.[3869]

- Unichem (full name: Unichem Laboratories Limited), for the entire period of this infringement. This was through the negotiation and conclusion, as a co-signatory with Niche, of the Niche/Unichem Settlement Agreement.[3870]

(3015) Moreover, as well as being liable for its direct participation, Unichem should also be held liable as a parent company of Niche. Unichem owned 60% of Niche as of 2002, when the latter company was incorporated,[3871] while the other 40% was owned by Niche's management, i.e. four former Bioglan directors. As of December 2006, Niche became a wholly-owned subsidiary of Unichem.[3872] The following evidence will demonstrate that, contrary to Unichem's claims that will be presented in the next paragraph, Unichem exercised decisive influence over Niche in the period from the

3867 See paragraph (566).
3868 See section 5.8.1.
3869 See sections 4.3.1.4.1.2 and 4.3.1.4.1.3.
3870 See section 4.3.1.4.1.2.
3871 ID0383, p. 1.
3872 See section 1.2.4.

date of conclusion of the settlement agreement until the acquisition of 100% of Niche's shares, as of when the presumption of exercise of decisive influence applies.

(3016) Unichem claims that it did not actually exert decisive influence over Niche and that it cannot therefore be regarded as forming one economic unit with it.[3873] Unichem also argues to have had no control in the day-to-day affairs or business of the company which had its own sales team and since Unichem was inexperienced in doing business in Europe, it delegated the management of European operations to Niche and never issued instructions to the latter.[3874] Moreover, Unichem claims that it did not exercise decisive influence over Niche as it was only a passive investor in Niche much like a venture capitalist.[3875] In this respect, the General Court clarified that "… *a 'pure financial investor'*" […] *refer*[s] *to the case of an investor who holds shares in a company in order to make a profit, but who refrains from* ***any*** *involvement in its management and in its control (emphasis added)*".[3876] This was clearly not the case of Unichem based on the evidence set out in this section, which shows that Unichem exercised decisive influence over Niche.

(3017) First, Unichem can be considered to have exercised decisive influence over Niche through its prevailing presence on Niche's Board of Directors (hereafter: "Niche's Board"). Niche's Board met regularly (approximately each quarter).[3877] It consisted of nine to eleven directors depending on the relevant timeframe,[3878] the majority of whom were Unichem appointed directors.[3879] In addition, Dr P.A. Mody, Unichem chairman and managing director since 1999, was also the chairman of Niche's Board. Mr BK Sharma, Unichem Executive Director and member of Unichem's Board since 1994,[3880] was a member of Niche's Board.[3881] Given that Dr Mody and Mr Sharma held the most senior positions in the parent company, it is reasonable to conclude that

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3873 Unichem's reply to the Statement of Objections, ID8520, p.13.

3874 Unichem's reply to the Statement of Objections, ID8520, p.4, 8 and 14.

3875 Unichem's reply to the Statement of Objections, ID8520, p.6. Unichem also claims that Niche did not use Unichem's trade name (reply to Statement of Objections, ID8520, p.6) – this argument is not convincing since this is still the case today (whereas Unichem now wholly-owns Niche). Unichem also puts forward the argument that it was not kept updated of the on-going litigation with Servier in the UK (reply to Statement of Objections, ID8520, p.8). While the Commission cannot comment on whether this was the case or not, it is noted that Unichem was kept informed on perindopril updates in Niche Board meetings attended by Unichem employees (see paragraph (3017)).

3876 Judgment of 12 December 2012, *1. garantovaná a.s. v Commission,* T-392/09, ECR, EU:T:2012:674, paragraph 52.

3877 See ID0028, p. 209, p. 212, p. 214 - 220, p. 224 – 226 and p. 234.

3878 ID7450 p.10 and ID0028, p.215.

3879 See, for example, ID7560 and Unichem's reply to Statement of Objections, ID8520, p.36. Unichem tries to minimise the role of the Board in arguing that Niche's non-executive Directors on the Board did not receive any direct remuneration (Unichem's reply to the Statement of Objections, ID8520, p. 14). As a general point, the Commission cannot agree with the purely formal view that Unichem puts forward of the company governing bodies established in accordance with the law. The directors have a general duty to direct the affairs of the company, or at least to supervise the running of its affairs where that is delegated to others. It is clear therefore that, by appointing a majority of directors on Niche's Board, Unichem set out to exercise regular supervision of its subsidiary.

3880 ID10197, p. 7.

3881 ID1124, p. 12-14. See also ID0027, p. 54 and ID5494, p. 1. No specific corporate information has been given to the Commission by Unichem with the exception of the information on Dr Mody. There is however evidence that certain other Niche directors, such as Mr Rakesh Parikh and Mr Rajeev Lamba were also employees of Unichem (respectively, vice presidents for finance and international business division). See, for example, Unichem Annual Report 2006-2007, ID10197, p. 15, ID0028, p. 226 and ID7451, p. 9.

Unichem, through Dr Mody and the rest of the Unichem-appointed directors, exercised decisive influence over the Niche Board.[3882] Minutes of Board meetings confirm that, in general, Dr Mody, as the chairman of both Unichem's and Niche's Boards, often issued operational instructions or guidance on a range of matters discussed by the Board.[3883] Furthermore, in these board meetings, commercial and development issues concerning perindopril were also discussed.[3884] Moreover, Dr Mody and other Unichem-appointed members on Niche's Board also participated in decisions concerning the financial restructuring of Niche's balance sheets following the settlement agreement with Servier (which included repayment of loans to Unichem). It also appears that signatures by Dr Mody and Mr Sharma were needed to comply with Niche's bank mandate.[3885] Finally, Niche's CEO, Ms Foster, was appointed by virtue of the Shareholders' Agreement and was *"subject always to the control of the Board"* in her general control and management of the business.[3886] As the General Court has stated, *"the position of member of the board of directors of a company entails by its very nature legal responsibility for the activities of the company as a whole, including its conduct on the market"*.[3887] Therefore, Niche's Board, consisting of a majority of Unichem appointed directors, controlled the activities of Niche's CEO, and consequently the management of the business of the company.

(3018) Second, according to section 7 of the Shareholders' agreement between Unichem and Niche's "B" shareholders (four non-Unichem managers) relating to Niche dated 15 April 2002, Unichem's prior consent was required in a number of matters ([…]*). These matters included issues related to personnel ([…]*), assets ([…]*), finance ([…]*) and commercial matters ([…]*).[3888] Evidence shows that agreement by Unichem was effectively sought, for example, concerning the decision to invest into a new Niche laboratory.[3889]

(3019) Third, with respect to financial information, the following facts demonstrate that the parent company monitored its subsidiary's financial performance. In this respect, Unichem denies that its involvement was required for major financial decisions.[3890] It also notes that Niche did not require Unichem's consent to obtain third party funding.[3891] These arguments are misguided for the following reasons. First, with respect to third party funding, Unichem's argument remains imprecise – pursuant to clause 13.1 of the Shareholders' Agreement, Niche could require funding only on terms acceptable to its Board (which was chaired by [employee name and function with Unichem]*, and had a majority of Unichem-appointed Directors).[3892] Clause 7.1, cited by Unichem in its reply to the letter of facts (liability), does not state anything to the contrary – for other funding arrangements, clause 7.1.11 makes it clear that such arrangements cannot be entered into without the prior consent of

3882 For relevant case law regarding significant personnel overlaps, see footnote 3862.
3883 See, for example, ID0028, p. 199, 219.
3884 See, for example, ID0028, p. 209, p.214 and 226.
3885 ID0028, p. 204 - 208.
3886 ID7452, p.4.
3887 Judgment of 6 March 2012, *FLSmidth & Co AS v Commission*, T-65/06, ECR, EU:T:2012:103, paragraph 32.
3888 ID7450, p. 15 - 18.
3889 ID0028, p. 212.
3890 Unichem's reply to Statement of Objections, ID8520, p. 37.
3891 Unichem's reply to Statement of Objections, ID8520, p. 37.
3892 ID7450, p. 28.

[…]* [Unichem]*.[3893] More generally, the Shareholders' Agreement provides that Niche shall supply to Unichem […]* a copy of the management accounts of the former and a Report on the marketing, regulatory and development of current products and products in development […]*.[3894] In addition, the […]* business plan drafted by Niche's managers was to be submitted to Unichem who could discuss […]* *"any amendments that it may consider desirable"*.[3895] In case of disagreement [in Unichem]*, it was the Board who had the final word on the plan to be adopted.[3896] Moreover, the financial statements of Niche were consolidated with those of Unichem in the period concerned.[3897] As confirmed by the General Court, the consolidation of financial accounts "*certainly corroborates*" the conclusion that a company exerted decisive influence "*even if that consolidation is […] mandatory under the national law applicable*".[3898] In practice, the parent company through its Directors on Niche's Board monitored its subsidiary's financial performance.[3899] One Unichem-appointed Director had also asked, in January 2003, that *"profit by sales type should be prepared on a monthly basis"* by Niche which is a strong indication of Unichem exercising a decisive influence over Niche's business.[3900]

(3020) Fourth, according to the Court of Justice, information flows from the subsidiary to the parent company may constitute an additional indication of decisive influence.[3901] The Commission notes, for example, that during the due diligence discussions between Niche and Servier, Unichem was kept informed and was also aware of a possible patent settlement that Servier could propose.[3902] Unichem also sought to be informed of certain agreements by Niche and was given project development updates.[3903] Dr Mody at one occasion stressed that Niche's communication with Unichem *"needed to be improved"*.[3904]

(3021) Fifth, Unichem and Niche were co-signatories of the settlement agreement with Servier, which implies that Unichem agreed to the restrictions imposed on Niche in the context of the agreement. In addition, the Niche Board composed of a majority of Unichem appointed directors discussed the legal implications of the settlement agreement in view of Article 101 of the Treaty in connection to company audits.[3905]

3893 ID7450, p.17, cited by Unichem in its reply to the letter of facts (liability), ID10590, p. 3.

3894 See clause 5.2., ID7450, p. 12.

3895 ID7450, p. 13.

3896 See also Unichem's reply to the letter of facts (liability), ID10590, p. 3. This would mean that the final word would be taken by a Board composed of a majority of Unichem-appointed directors.

3897 ID10196, p.90 (Unichem Annual Report 2005-2006, Schedule 18). In its reply to the letter of facts (liability), Unichem claims that it was not obliged to include the consolidated statements in the Annual Report since it had an exemption under Indian company law (ID10590, p. 4). This is however incorrect since the exemption pertained only to the financial statements of the subsidiaries. The annual report cited by Unichem states explicitly that *"the consolidated financial statements present a full and fair view of the state of affairs of [Unichem] as a whole"* (ID10590, p. 4).

3898 Judgment of 12 December 2012, *1. garantovaná a.s. v Commission*, T-392/09, ECR, EU:T:2012:674, paragraph 57.

3899 A Unichem-appointed Director *"raised several questions relating to Niche's financial performance"*, see ID0028, p. 219.

3900 ID5697, p. 233.

3901 Judgment in *General Quimica v Commission*, C-90/09 P, EU:C:2011:21, paragraph 107.

3902 ID2450, p. 4 - 5.

3903 ID0028, p. 198, 199

3904 ID0028, p. 227.

3905 ID0028, p. 201 - 203.

(3022) Finally, the stated aim of Niche's purchase by Unichem at the time should be underlined: […]*.[3906] A document prepared by Servier's auditors in 2004 confirms this idea – it shows that part of Unichem's growth strategy focused on consolidating its EU presence through Niche,[3907] hence the aim of the acquisition of 60% of Niche's shares […]*.[3908] […]*.[3909] This was already enshrined as a possibility in the Shareholders' Agreement whereby Unichem and the four non-Unichem Directors […]*.[3910] Moreover, the fact that the non-Unichem directors who held 40% of Niche's shares had the right to sell these to Unichem after four years leads to the assumption that the parent company would not keep an arm's length approach in a subsidiary that it is likely to acquire in its entirety within four years from the date of the acquisition, a relatively short timeframe.[3911] With respect to this, a document from November 2005 points to [employee name of Niche]*'s proposal for an agenda point for the next Niche Board meeting concerning *"the process to be followed for acquiring management team's stake in Niche"*, i.e. the remaining shares not owned by Unichem.[3912]

(3023) In light of the above elements, the Commission concludes that Unichem exercised decisive influence over Niche.[3913]

(3024) Niche became a wholly-owned subsidiary of Unichem in December 2006, as of which point the presumption of exercise of decisive influence fully applies.[3914]

(3025) Unichem and Niche should therefore be held jointly and severally liable for the infringement described in this Decision.[3915]

(3026) Accordingly, this Decision should be addressed to Unichem Laboratories Limited and Niche Generics Limited.

9.4 Matrix (now called Mylan Laboratories Limited)

(3027) The evidence described in this Decision shows that Matrix (full name: Matrix Laboratories Limited, now called Mylan Laboratories Limited) signed the patent

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3906 ID7560. Unichem claims that this document has no probative value, that it is made by a third party with no links to Unichem and should not be relied upon by the Commission (Unichem's reply to the letter of facts (liability), ID10590, p. 6). The Commission considers that although this article was drafted by a third party not connected to Unichem, it appears to have been well-informed given all the other information featuring this same article. The article is also consistent with the Shareholder's agreement and the actual purchase by Unichem of the remaining shares in Niche in 2006.

3907 ID1124, p.11.

3908 ID1124, p.8. The same document mentions that 69% of Unichem's total sales outside India in 2004 were made through Niche.

3909 ID0028, p. 220.

3910 Clause 15.1 Shareholders' Agreement (ID7450, p. 29).

3911 See ID7450, p. 14-15, corroborated by the actual developments (see Unichem's reply to the Statement of Objections, ID8520, p. 6).

3912 ID0028, p. 262.

3913 Unichem is not only held liable on the basis of its exercise of decisive influence over Niche, but also, as indicated in paragraph (3014), for its direct participation in the infringement through the conclusion of the settlement agreement with Servier, a fact confirmed by Unichem (see Unichem's reply to the Statement of Objections, ID8520, p. 12-13).

3914 ID0383, p. 1.

3915 See section 5.2.

settlement agreement with Les Laboratoires Servier and therefore directly participated in the infringement of Article 101 of the Treaty for its entire duration.[3916]

(3028) In addition, according to case-law, if the legal entity that committed the infringement is acquired by another company, the buyer can only be held responsible for the conduct of that legal entity from the date of the acquisition[3917] (and insofar it can be deemed to exercise decisive influence over the acquired entity). In the present case, Mylan Inc. ("Mylan") should be held liable as a parent company of Matrix in the period from 8 January 2007, when it raised its stake in Matrix to 71.5% (through its wholly-owned subsidiary, MP Laboratories),[3918] until the end of the infringement.[3919] The 2008 Mylan Annual Report explicitly described this as a *"controlling interest"*.[3920] The following evidence shows that Mylan exercised decisive influence over Matrix's commercial policy as of 8 January 2007.[3921]

(3029) First, Matrix had systemic and timely access to strategic information and had leverage in the decision making processes.

(3030) Following Mylan's acquisition of the 71.5% share in Matrix, authorisation schedules were put in place in March 2007. The authorisation schedules required Matrix to consult Mylan in relation to business development agreements [confidential] in the EU.[3922] Moreover, certain strategic transactions [confidential] could only be taken after Mylan's consent.[3923] [confidential].[3924] Matrix confirmed that these schedules were implemented and that Mylan was indeed consulted on significant matters.[3925]

3916 See section 5.8.2. Mylan claims that the letter of facts (liability) setting out further evidence goes beyond merely identifying additional evidence in support of the Statement of Objections' objections, but is instead an attempt to alter the fundamental nature of the objections raised against Mylan and can only be undertaken on the basis of a supplementary Statement of Objections (reply to the letter of facts (liability), paragraphs 1.3 and 2.6, ID10599, p. 2 and 4). The Commission considers that the evidence used in this Decision and adduced in this letter of facts is not used for the purpose of issuing new objections or altering the *"intrinsic nature of the infringement"* (see Best Practices for the conduct of antitrust proceedings, paragraph 110). The objections set out in the Statement of Objections are only corroborated by the new evidence brought to the attention of the parties and on which the Commission intends to rely upon in this Decision and on which Mylan had the opportunity to comment.

3917 See, for example, Judgment of 17 May 2013, *Parker ITR Srl and Parker-Hannifin Corp. v Commission*, T-146/09, ECR, EU:T:2013:258, paragraphs 125-129.

3918 ID5392, p. 2. For ease of reference, this transaction will also be referred to as "*acquisition of a 71.5% stake in Matrix*".

3919 ID3308, p. 2 and ID4088, p. 8. See paragraph (28).

3920 ID4958, p. 3. Mylan noted in particular that its *"purchase of a <u>controlling stake</u> in Matrix was a pivotal transaction in this regard because it gave the company direct access to the world's third largest portfolio of API and intermediates"* (emphasis added) and that *"As a result of […] and the acquisition of a controlling interest in Matrix in January 2007, we are a leader in branded specialty pharmaceuticals and the third largest API manufacturer with respect to the number of DMFs filed with regulatory agencies"* (ID4958, p. 17 and 72). During the investigation, Matrix explained that the term "*controlling interest was used to reflect the fact that Mylan owned more than 50% of the shares in Matrix and as such was the largest single shareholder in Matrix*" (ID5392, p. 4). Standard definitions of this term include *"the holding by one person or group of a majority of the stock of a business, giving the holder a means of exercising control"* (oxforddictionaries.com) or *"enough shares to control a company"* (http://lexicon.ft.com/Term?term=controlling-interest), i.e. the exercise of control over a subsidiary.

3921 Concerning this conclusion, also see confidential annex to Matrix/Mylan.

3922 ID5392, p.7, ID5389, p. 2.

3923 ID5389, p. 3.

3924 [confidential].

3925 ID5392, p. 7.

(3031) As to the consultation in relation to business development agreements, Mylan argues that its right to be consulted by Matrix was only an exception rather than the norm and that the Commission provided no examples of instances where it was actually consulted. Moreover, this right is not sufficient to demonstrate that Matrix carried out in all material respect the instructions given to it by Mylan and does not call into question Matrix's ability to act independently.[3926]

(3032) However, decisive influence of the parent company does not necessarily have to result from specific instructions, guidelines or rights of co-determination regarding market conduct. According to Advocate General Kokott in the *Akzo Nobel* case, "*Such instructions are merely a particularly clear indication of the existence of the parent company's decisive influence over its subsidiary's commercial policy. However, autonomy of the subsidiary cannot necessarily be inferred from their absence"*.[3927] In addition, the decisive influence capable of justifying the imputation to the parent company of liability for the infringement committed by its subsidiary concerns not only the commercial policy *stricto sensu* of that subsidiary (e.g. distribution and pricing policy) – *"the parent company's influence over the subsidiary's strategy may suffice"*.[3928] First, it is important to note that the consultation of Mylan was not only a right, but an obligation *"to discuss"* prior to entering into specific agreements. [confidential].

(3033) As to the requirement to obtain consent prior to entering into certain strategic transactions, Mylan argues that such transactions are relatively exceptional and not day-to-day business and do not confer on Mylan the ability to exercise decisive influence.[3929] First, the Court has recognised that *"the exercise of decisive influence over the commercial strategy of a subsidiary does not necessarily involve the day-to-day management of the subsidiary's activities"*.[3930] Second, Mylan's consent was required and reflected the involvement of Mylan in Matrix's strategic decisions. [confidential],[3931] the Commission recalls Matrix's express confirmation that "*Mylan was consulted on occasion in relation to significant matters, for example, [confidential]*"[3932].

(3034) […]*.[3933] According to Matrix, these […]* reporting lines are insufficient to alter the general position that Matrix ran itself independently. The […]* reporting lines did not involve interactions between the decision-making organs of the two companies and concerned only departments with a purely operational function relating to aspects which could be in the mutual interest of both companies.[3934] The […]* reporting lines however show that Mylan was kept informed of the business developments relating to commercial affairs, regulatory affairs, etc. and could

3926 Mylan's reply to the Statement of Objections, paragraphs 2.4-2.5, ID8828, p. 5.

3927 Opinion of Advocate General Kokott delivered on 23 April 2009 in the Judgment *Akzo Nobel and Others v Commission*, C-97/08 P, EU:C:2009:536, paragraphs 89 and 91. See also Judgment in *Akzo Nobel and Others v Commission*, C-97/08 P, EU:C:2009:536, paragraph 73.

3928 Judgment of 13 December 2013, *Holding Slovenske elektrarne v Commission*, T-399/09, ECR, EU:T:2013:647, paragraphs 53 and 80. See also Judgment in *Otis v Commission*, C-494/11 P , EU:C:2012:356, paragraph 42.

3929 Mylan's reply to the Statement of Objections, paragraph 2.7, ID8828, p. 6.

3930 See Judgment of 16 September 2013, *Keramag Keramische Werke and Others v Commission*, T-379/10, ECR, EU:T:2013:457, paragraph 320.

3931 Mylan's reply to the Statement of Objections, paragraph 2.7, ID8828, p. 6.

3932 ID5392, p. 7.

3933 ID5392, p. 7. [confidential]

3934 Mylan's reply to the Statement of Objections, paragraphs 4.2 to 4.4, ID8828, p. 9.

possibly intervene in case Matrix acted contrary to Mylan's position. In addition, minutes of the Matrix Board meetings illustrate that with respect to a conversion of a finished dosage unit into an export oriented unit, […]*.[3935]

(3035) Second, [employee name and function with Mylan]*, was appointed as a [employee function]* of Matrix in January 2007, following Mylan's acquisition of a 71.5% stake in Matrix. [Details of an employee with a casting vote]*.[3936] Mylan argues in this respect that [employee name of Mylan]* could not have exercised decisive influence since […]*.[3937] The Commission disagrees with Mylan's claim that [employee name of Mylan]* could not have exercised decisive influence for the following reasons. First, Matrix's Board minutes of 30 January 2007 show that [employee name of Mylan]* informed Matrix's Board of *"Mylan's expectations of Matrix in the coming quarters"* and advised the Management *"to frame strategies to meet such expectations"*.[3938] […]*. Moreover, the directors seating on the Board of a company have a general duty to direct the affairs of the company or to at least supervise the running of the affairs.

(3036) Moreover, Mylan's CEO was not the only person to hold simultaneous directorship positions within Matrix and Mylan. As of January 2007, [employee name of Matrix/Mylan]*, who was previously Matrix's [employee function]*, assumed the role of [employee function]* of Matrix's Board while at the same time becoming Mylan's [employee function]* and a member of Mylan's [employee function]*.[3939] [Employee name of Matrix/Mylan]* was [employee functions]* of Matrix from January 2007 until 30 June 2008 on deputation from Mylan - he was appointed Mylan's [employee functions]* in October 2007.[3940] Both [employee name of Matrix/Mylan]* and [employee name of Matrix/Mylan]* were employees of Mylan.[3941] They held, due to the functions exercised in Matrix already prior to the acquisition, unique expertise and insight into Matrix's operations and decision making, particularly important in view of their parallel positions in Mylan and Matrix after Mylan's acquisition of the 71.5% stake in Matrix. As the General Court has stated, *"the fact that the parent company maintains in their posts the persons who managed the company prior to its acquisition […] is incapable of proving the*

3935 Matrix's Board meeting minutes of 25 July 2007, ID10488, p. 15. [confidential].

3936 ID5392, p.6. According to Matrix, [employee name of Mylan]* was one of at least six [employee functions]* on the Matrix board. [Employee name]*, then Matrix's [employee function]*, became [employee function]* of Matrix and joined the Mylan board (of ten [employee functions]*). Both held these functions until October 2009 and since that period, no directors of Matrix have been appointed to Mylan's board and vice versa. For relevant case-law regarding significant personnel overlaps, see footnote 3862 above.

3937 Mylan's reply to the Statement of Objections, paragraphs 3.3 to 3.5, ID8828, p. 7-8.

3938 Matrix's Board minutes of 30 January 2007, ID10486, p. 7. Mylan claims that there is no indication in the minutes as to what Mylan's expectations were of Matrix. It also claims that [employee name of Mylan]* is not issuing instructions or dictating the strategy (Mylan's reply to the letter of facts (liability), paragraph 3.17, ID10599, p .9). While it is true that Mylan's expectations are not specified, this statement came from [employee name and function with Mylan]*, and appears to be made in his capacity of Mylan CEO. The Matrix Board Chairman made it clear that strategies should be framed by the management to ensure that expectations are met and was in this sense guiding the latter towards a certain outcome desired by Mylan.

3939 See ID5392, p.6.

3940 See Matrix Annual Report 2007-2008 (ID10207, p.5 and 11) and ID5392, p. 6.

3941 See in relation to [employee name of Matrix/Mylan]*, ID10487, p. 6. For [employee name of Matrix/Mylan]*, ID10207, p. 11.

absence of a decisive influence by the parent company …".[3942] The Matrix Board met several times a year, generally in [non-EEA jurisdiction]*, but also in [non-EEA jurisdiction]* during the first months following the acquisition by Mylan (January to May 2007).[3943] In addition to the Mylan CEO and the two directors employed by Mylan, […]*.[3944]

(3037) Third, Mylan's influence over Matrix can also be inferred from Mylan's intervention in the management of Matrix's subsidiaries. During the first Matrix Board meeting following Mylan's acquisition of a 71.5% share in Matrix, [employee name of Matrix]* advised the Senior Management to enhance its focus on the management of Matrix's subsidiaries to achieve better results.[3945] […]*.[3946] Finally, Mylan also appointed the [employee function]* of Mylan Europe to the Board of [company name]*, a Matrix subsidiary, "*to give a strategic shift to [company name]*'s operations*" around the end of 2008.[3947]

(3038) Fourth, Matrix confirmed that pursuant to US law on financial reporting obligations, Mylan was required to produce and file consolidated financial statements incorporating the financial statements of Matrix.[3948] In this respect, the General Court has noted that the consolidation of financial accounts "*certainly corroborates*" that a company exerted decisive influence "*even if that consolidation is* […] *mandatory under the national law applicable*".[3949]

(3039) Fifth, Mylan contends that the transactions entered into by the two entities [confidential].[3950] The Commission observes that, apart from tax purposes, [confidential] between a parent company and a subsidiary (related party transactions) may also serve to protect financial interests of minority shareholders of the subsidiary, as the balance sheet of the subsidiary could be negatively affected if it concluded deals biased in favour of the parent company. Therefore, concluding

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3942 Judgment of 13 December 2013, *Holding Slovenske elektrarne v Commission*, T-399/09, ECR, EU:T:2013:647, paragraph 85.

3943 See ID10485 to ID10487 (Matrix's Board minutes of January-May 2007). In this respect, the Commission also notes that the Directors' Report (which is a part of the Matrix's Annual report for 2007/2008) was signed for and on behalf of Matrix's Board of Directors by [employee name and function with Mylan]* in Pittsburgh, USA and not at Matrix's Indian headquarters (ID10207, p. 13).

3944 See e.g. Matrix's Board minutes of 30 October 2007, ID10490, p.1.

3945 Matrix's Board minutes of 30 January 2007, ID10486, p. 8. Matrix Board's meeting of 30 October 2007 discussed a proposal of the […]*(ID10490, p. 19).

3946 Matrix's Audit Committee meeting minutes of 25 July 2007, ID10523, p. 4. […]* (Mylan's reply to the letter of facts (liability), paragraph 3.28, ID10599, p. 12). […]*.

3947 […]* (Mylan's reply to the letter of facts (liability), paragraph 3.29, ID10599, p. 12), […]*.

3948 ID9701. Mylan also explained that amongst others Matrix reported its own separate financials in accordance with Indian GAAP and had its own individual listing on the BSE and NSE stock exchanges in India during the infringement period.

3949 Judgment of 12 December 2012, *1. garantovaná a.s. v Commission*, T-392/09, ECR, EU:T:2012:674, paragraph 57. Mylan states that the legal test for decisive influence under EU competition law is separate from the question of the legal requirement Mylan was subject to under US law (Mylan's reply to the letter of facts (liability), paragraph 3.22, ID10599, p. 10). However, the question of whether or not the financials were consolidated is an important element which corroborates the conclusion of decisive influence exercised by Mylan. In fact, through this consolidation, Matrix contributed to the economic performance data of Mylan.

3950 Mylan's reply to the Statement of Objections, paragraph 3.5 c), ID8828, p. 8.

transactions [confidential] basis is in itself not an indication that the parent company exercises no decisive influence over its majority-owned subsidiary.[3951]

(3040) An examination of certain transactions between Mylan and Matrix reveals that they were not necessarily concluded on arm's length terms. For example, a review of inter-company loans from Mylan Group to Matrix Group shows that during the period from July 2007 to March 2008, Mylan granted three loans to Matrix for a total amount of EUR [100-200] million, at an interest rate of 6.75%. According to Mylan's Senior Vice President for Finance, these loans demonstrate "*Mylan Group's commitment towards Matrix*", as "*due to the global melt down, when it has become difficult to raise funds from the banks, Mylan Group has stepped in to provide the required funds".* It was added that "*the average interest cost on borrowings was [0–20]* %, as against the budgeted cost of [0–20]* %*".[3952] From this example there are three elements which should be noted. First, Mylan, for which financing is not amongst its primary activities, granted loans to Matrix at a time when it was generally difficult to raise such funds in the financial markets. In other words, instead of relying on the open market, Mylan and Matrix sought in-house financial solutions inherent to integrated businesses. Second, the loans (EUR [100-200] million) were relatively large compared to Matrix's sales (in the region of EUR 300 million)[3953] and therefore generated considerable financial exposure. Finally, the applicable interest rates of [0–20]* % were significantly below the cost of borrowing of Matrix which averaged [0–20]* %.[3954] These three elements suggest that Mylan's loans to Matrix were not at arms' length. Moreover, Mylan's acceptance of such significant financial exposure to Matrix can best be explained by Mylan's exercise of decisive influence over Matrix as a safeguard for the protection of its investments in Matrix.

(3041) Lastly, at the time of the acquisition of the controlling interest (8 January 2007), Mylan was aware of the Matrix Settlement Agreement. In advance of this acquisition, an audit company carried out a due diligence of Matrix for Mylan.[3955] The due diligence report[3956] notes, under the title "*Income from patent infringement*" that, in 2005, Matrix "*received a favourable settlement of $21.9 million*". As a result of this settlement, the report recognised that Matrix "*is not allowed to manufacture and sell the specific product over the remaining term of the contract*". The due diligence report also notes that […]*.

(3042) It follows from the above that Mylan was aware that Matrix had agreed to stay out of the market with perindopril in return for a large sum of money. The Commission considers that Mylan knew, or should have known,[3957] that the Matrix Settlement

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3951 For example, Matrix concluded arm's length transactions with its wholly-owned subsidiaries (Matrix's Audit Committee meeting minutes of 31 October 2006, ID10520, p. 4) while saying that Matrix "*[…]**" (Matrix's Audit Committee meeting minutes of 27 July 2006, ID10519, p. 3).

3952 Matrix's Audit Committee meeting minutes of 26 January 2009, ID10530, p. 5-6.

3953 Matrix Annual Report 2007/2008, ID10207, p. 10, at average exchange rates in 2007 and 2008.

3954 Mylan argues that this evidence does not establish that at the relevant time when Mylan loaned funds to Matrix, Matrix somehow benefited from a superior rate to that which it could have obtained from an independent third party (Mylan's reply to the letter of facts (liability), paragraph 3.34 b), ID10599, p. 14). However, this document is clear – the average cost of borrowing of Matrix amounted to [0–20]* %, whereas 6,75% were obtained from Mylan. Hence, the intercompany interest rate was lower than Matrix's average costs of borrowings demonstrating Mylan's commitment towards Matrix.

3955 ID5392, p.4 and ID5383.

3956 ID5383.

3957 For example, Mylan informed Matrix that it also instructed external advisors to prepare a due diligence report. ID5392, p. 4.

Agreement was a restriction of competition contrary to Article 101 of the Treaty. Mylan must be taken to be aware of the content of the agreement, including that Matrix could not enter the market until the expiry of the patents in 2008. Also, the key restrictions in clauses 1, 5 and 6 of the Matrix Settlement Agreement also extend to entities controlling Matrix.[3958] In addition, Mylan also knew that, in accountancy terms, Matrix was still deriving benefit from the Matrix Settlement Agreement.[3959]

(3043) However, Mylan never raised any objections to the Matrix Settlement Agreement or took any measures aimed at terminating the agreement or otherwise discontinuing Matrix's involvement in the infringement, notwithstanding the risk of legal proceedings or claims for damages from third parties to which it was exposing itself. The Commission considers that this shows that Mylan tacitly approved the infringement and this, in itself, amounts to additional evidence that Mylan exercised decisive influence over the conduct of Matrix.[3960] In its reply to the Statement of Objections, Mylan disagrees with the Commission's proposition that it knew or should have known that the settlement was a restriction of competition by putting forward several supporting reasons (e.g. no legal precedent that a reverse payment settlement is contrary to Article 101 of the Treaty) and alleges that knowledge of the agreement cannot be equated with tacit approval of an infringement. In addition, Mylan claims it did not have the capacity to amend or terminate the settlement and it is not clear what it could have done to remedy the alleged infringement.[3961] Finally, Mylan argues that the application of parental liability in circumstances where the parent had no stake in the capital of the subsidiary at the date of signature of the agreement is unprecedented. Mylan adds that when the shareholding was acquired two years later, the alleged infringement had been consummated and the agreement could no longer be unwound.[3962]

(3044) In this regard, it suffices to reiterate that the agreement was still in force after Mylan acquired a controlling interest in Matrix, and Matrix was at that time still bound by its obligations under the settlement agreement. Hence, Mylan was aware that Matrix was bound by an agreement with Servier (see paragraph (3041)) regarding a product which was expected to yield significant revenues, and under which Matrix received significant monies in return for its commitment not to enter with perindopril for the remaining term of the agreement.[3963] As a US-based large generic company, Mylan was undoubtedly aware of antitrust scrutiny of similar patent settlements by the competent US authorities, and could be aware that such scrutiny could also ensue in the EU.

(3045) In view of the above, Matrix should therefore be held liable for the period from 8 February 2005 to 7 January 2007. For the period from 8 January 2007 until the end

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3958 See ID0119, p. 147-149. The term "Affiliate", as defined in Section 1 Definitions, also covers "*any entity that directly or indirectly controls another entity*".

3959 ID5383.

3960 See, by analogy, Judgment of 12 October 2011, *Alliance One International, Inc. v European Commission*, T-41/05, ECR, EU:T:2011:586, paragraph 136. See also Judgment of 14 May 1998, *Stora Kopparbergs Bergslags v Commission*, T-354/94, ECR, EU:T:1998:104, paragraph 84; Judgment in *Stora Kopparbergs Bergslags AB v Commission*, C-286/98 P, EU:C:2000:630, paragraphs 31-32; Judgment of 11 December 2003, *Minoan v Commission*, T-66/99, ECR, EU:T:2003:337, paragraphs 145-147.

3961 Mylan's reply to the Statement of Objections, paragraphs 5.2 to 5.4, ID8828, p.10-12.

3962 Mylan's reply to the letter of facts (liability), paragraphs 3.2 and 3.3, ID10599, p.5.

3963 Confirmed by Mylan in its reply to the Statement of Objections, paragraph 5.2, ID8828, p.10.

date of the infringement,[3964] Mylan and Matrix should therefore be held jointly and severally liable for the infringement described in this Decision.[3965]

(3046) Accordingly, for the infringement committed by Matrix, this Decision should be addressed to Matrix Laboratories Limited, now Mylan Laboratories Limited and Mylan Inc..

9.5 Teva

(3047) The evidence shows that the following entities of the Teva undertaking directly participated in the infringement of Article 101 of the Treaty consisting of the Teva Settlement Agreement:

- Teva UK Limited, for the entire period of this infringement.[3966] This was through the conclusion of the agreement by Teva UK Limited.[3967]
- Teva Pharmaceuticals Europe B.V., for the entire period of this infringement. This was through the involvement of top management of Teva Pharmaceuticals Europe B.V. in the preparations for the conclusion of the Teva Settlement Agreement.[3968]
- Teva Pharmaceutical Industries Limited, for the entire period of this infringement. This was through the involvement of Teva Pharmaceutical Industries Limited in the preparations for the conclusion of the Teva Settlement Agreement.[3969]

(3048) Moreover, the entity Teva Pharmaceuticals Europe B.V. wholly owns Teva UK Limited, and should also be held liable as a parent company. It is presumed that Teva Pharmaceuticals Europe B.V. exercised decisive influence over its subsidiary. The Commission considers that this presumption is enough to establish the liability of Teva Pharmaceuticals Europe B.V. and there is no need to add any further elements in this regard.

(3049) Finally, the entity Teva Pharmaceutical Industries Limited directly or indirectly wholly owns Teva UK Limited and Teva Pharmaceuticals Europe B.V., and should be held liable as the ultimate parent company. Therefore, it is presumed that Teva Pharmaceutical Industries Limited exercised decisive influence over these subsidiaries. The Commission considers that this presumption is enough to establish the liability of Teva Pharmaceutical Industries Limited and there is no need to add any further elements in this regard.

(3050) In view of this, Teva UK Limited, Teva Pharmaceuticals Europe B.V. and Teva Pharmaceutical Industries Limited should be held jointly and severally liable for the infringement described in this Decision.[3970]

3964 See section 5.8.2.
3965 See section 5.3.
3966 See section 5.8.3
3967 See section 4.3.2.5.
3968 See, for example, sections 4.3.2.3.2. and 4.3.2.4, ID0358, p. 637 - 639.
3969 See, for example, ID0358, p. 712 – 715 and p. 800, ID0085, p. 19 - 20. ID0088, p. 32 - 33, ID0358, p. 637 - 641.
3970 See section 5.4.

(3051) Accordingly, this Decision is addressed with regard to the above mentioned infringement to Teva UK Limited, Teva Pharmaceuticals Europe B.V., and Teva Pharmaceutical Industries Limited.

9.6 Krka

(3052) The evidence described in section 4.3.3 shows that Krka, tovarna zdravil, d.d., Novo mesto, the top parent company of the Krka Group,[3971] directly participated in the infringement of Article 101 of the Treaty consisting of the Krka Agreements for the entire period of this infringement.[3972] This was through the negotiation and conclusion, by Krka, tovarna zdravil, d.d., Novo mesto, of the Settlement Agreement, Licence Agreement, and Assignment and Licence Agreement.

(3053) In view of this, Krka, tovarna zdravil, d.d., Novo mesto should be held liable for the infringement described in this Decision.[3973]

(3054) Accordingly, this Decision should be addressed with regard to the above mentioned infringement to Krka, tovarna zdravil, d.d., Novo mesto.

9.7 Lupin

(3055) The evidence described in section 4.3.4 shows that Lupin Limited directly participated in the infringement of Article 101 of the Treaty consisting of the Lupin Settlement Agreement, for the entire period of this infringement.[3974] This was through the conclusion of the agreement by Lupin Limited[3975] and the preparation and negotiation of the agreement through Lupin Limited's UK representative branch Lupin (UK) Limited[3976] (later Lupin (Europe) Limited[3977]).

(3056) Lupin Limited should therefore be held liable for the infringement described in this Decision.[3978]

(3057) Accordingly, this Decision should be addressed with regard to the above mentioned infringement to Lupin Limited.

3971 ID7110, ID7111.

3972 See section 5.8.4.

3973 See section 5.5.

3974 See section 5.8.5.

3975 See section 4.3.4.7.

3976 See, for example, sections 4.3.4.6 and 4.3.4.9.2.

3977 Source: UK Companies House. See also ID0434, p. 5 - 6.

3978 See section 5.6.

10 REMEDIES AND FINES

10.1 Remedies

(3058) Where the Commission finds that there is an infringement of Articles 101 or 102 of the Treaty, it may by decision require the undertakings concerned to bring such infringement to an end, in accordance with Article 7(1) of Regulation No 1/2003.[3979]

(3059) Concerning the infringements of Article 101 and Article 102 of the Treaty, the undertakings concerned should be required to refrain henceforth from any practice which would have the same or similar object or effect as the infringing behaviour described in this Decision.

10.2 Fines

(3060) Under Article 23(2) of Regulation No 1/2003, the Commission may by decision impose fines upon undertakings where, either intentionally or negligently, they infringe Articles 101 or 102 of the Treaty. According to the same provision, for each undertaking participating in an infringement, the fine shall not exceed 10% of its total turnover in the preceding business year.

(3061) As described in section 4 and assessed in sections 5 and 8, the infringements consisted of (i) patent settlement agreements between the parties concerned which objectively aimed at preventing or stopping the generic undertaking from selling generic perindopril in one or more markets in the EU in exchange for a transfer of value from the originator undertaking, (ii) the dominant undertaking's single and continuous strategy to delay generic entry by excluding close sources of competition through a combination of the Azad Technology Acquisition and the patent settlement agreements. The Commission therefore intends to impose fines on the undertakings to which this Decision is addressed.[3980]

(3062) Pursuant to Article 23(3) of Regulation No 1/2003, the Commission shall, in fixing the amount of the fines, have regard to all relevant circumstances and particularly to the gravity and duration of the infringement, which are the two criteria explicitly referred to in that Regulation. In doing so, the Commission will set the fines at a level sufficient to ensure deterrence. Moreover, the role played by each undertaking in the infringement(s) will be assessed on an individual basis.

(3063) In setting the fines to be imposed in this case, the Commission also follows the principles laid down in its Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003 (hereafter referred to as *"the Guidelines on fines"*).[3981]

10.2.1 Intentional or negligent infringement

(3064) In the present case, the Commission considers that, based on the facts described in this Decision, the infringements have been committed intentionally.

3979 Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 101 and 102 of the Treaty, OJ L1 of 4.1.2003, page 1.

3980 See section 9.

3981 *Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003*, OJ C 210, 1.9.2006, page 2.

(3065) The assessment of the patent settlement agreements concluded between the originator undertaking Servier and, respectively, the generic undertakings Niche/Unichem, Matrix, Teva, Krka and Lupin also analysed the intentions underlying each agreement. The conclusion for each agreement is that the contractual parties knew or should have known that the respective agreements had the object and necessary consequence of restricting competition.

(3066) In any event, even if the parties had not deliberately infringed Article 101 of the Treaty, they acted at least negligently in entering into such clearly anti-competitive agreements. In addition, the Commission found that these agreements were also capable of causing or likely to cause anti-competitive effects.

(3067) The legal assessment of the patent settlement agreements along with the acquisition of API technology was also undertaken from the perspective of Servier as a dominant undertaking on the relevant markets established for the purpose of this case (the markets for perindopril formulations in the UK, France, the Netherlands and Poland and for perindopril API technology in the entire Union). It was concluded that Servier's exclusionary strategy to remove close sources of competition by combining the Azad Technology Acquisition with the five patent settlements mentioned in paragraph (3065) to delay generic entry amounted to an abuse of Servier's dominant position in the market for perindopril as well as that for perindopril API technology and the infringement was intentionally aimed at preventing or delaying generic competition.

(3068) In any event, even if Servier had not deliberately infringed Article 102 of the Treaty, it acted at least negligently.

(3069) In their replies to the Statement of Objections, the parties claimed the lack of intent or negligence.

(3070) Niche argued in its reply to the Statement of Objections that it has not intentionally violated Article 101 of the Treaty. The alleged intention of Niche was to bring an end to patent specific litigation. Niche contended that it did not act negligently either as it, in the position of a normally informed and sufficiently attentive person, foresaw that by the terms of the Settlement Agreement it could develop and commercialise perindopril that circumvented Servier's patent.[3982]

(3071) Matrix contended that it had no intention of infringing Article 101 of the Treaty as it did not share the anti-competitive intention of Servier and its sole reason for entering into the Settlement Agreement was to recoup its investment in the perindopril project.[3983] Matrix further asserted that a reverse payment in the context of a settlement agreement has never before been characterised as an infringement of Article 101 of the Treaty and therefore it is not possible that Matrix could have negligently (or intentionally) engaged in anticompetitive conduct.[3984]

(3072) Lupin also asserted that it did not knowingly or intentionally commit any infringement of Article 101 of the Treaty and that it did not act negligently either. [3985]

(3073) Regarding the alleged lack of intent or negligence, the Commission rejects the arguments raised by the parties for the following reasons. According to well-

[3982] ID8722, p. 60 and 61.
[3983] ID8835, p. 66.
[3984] ID8835, p. 67.
[3985] ID9012, p. 100.

established case-law of the Courts of the European Union, "[f]*or an infringement of the competition rules to be regarded as having been committed intentionally, it is not necessary for an undertaking to have been aware that it was infringing those rules; it is sufficient that it could not have been unaware that its conduct was aimed at restricting competition*".[3986] The judgment requires only that a company "*could not have been unaware*" that the "***conduct** was aimed at restricting competition*" (emphasis added). A published precedent is therefore not required.

(3074) Some of the generic companies with whom Servier concluded settlement agreements actually reflected on or questioned the competition law compliance of these agreements. For example, Niche examined the antitrust liabilities associated with the conclusion of the settlement agreement. In a letter to Niche's financial auditor it is stated that the Board of Directors *"has considered the implications of Article 81 EC Treaty on the company in connection with the Servier Agreement and have studied carefully the legal opinion received. […] in their opinion there is no need for any note in the accounts regarding any potential contingent liability".*[3987] Teva also considered the legal implications of the agreement with Servier. First, in the beginning of May 2006 (before any letter of intent was sent), Teva discussed internally the possible terms of such an agreement and stated that "*if Servier are seeking to extend [the agreement] to preclude Teva - questionably not a party to the [company name]* agreement - from marketing Krka or any other product this could be anti-competitive".*[3988] Second, in an internal memorandum post settlement agreement, Teva stated that: *"[…] part of the £5m compensation payment received may relate to a non-compete aspect of the contract, since the contractual terms of the supply agreement prevent Teva launching its own generic product or seeking alternative suppliers in the UK".*[3989]

(3075) For the same reasons as these generic companies, Servier realised, or in any case should have realised, at the time that its policy of concluding those types of agreements carried considerable risks under Union competition law. The generic undertakings concerned should have also realised that the value transfers which they accepted from Servier served the purpose of inducing them to accept the limitations on their commercial autonomy in the agreements and thus distorting their incentive to continue their independent efforts to enter with generic perindopril in concerned markets in the EU for the duration of the agreement. Advocate General Trstenjak stated the following: *"The Community judicature has found an anti-competitive aim or tendency of an agreement to exist in particular where the necessary consequence of the agreement was the restriction of competition. In such a case in principle the parties may not argue that they did not intend any restriction of competition or that their agreement also pursued a different aim".*[3990] It was well established at the time of events that excluding actual or potential competitors from the market was likely to constitute an infringement of Union competition law.

3986 Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 227; Judgment of 14 May 1998, *Enso Española SA v Commission,* T-348/94, ECR, EU:T:1998:102, paragraph 277.

3987 See paragraph (597).

3988 See paragraph (717).

3989 See paragraph (789).

3990 Opinion of Advocate General Trstenjak delivered on 4 September 2008 in Judgment in *Beef Industry Development and Barry Brothers,* C-209/07, EU:C:2008:643,, paragraph 44.

(3076) What matters from a competition policy perspective is whether, at the time when those agreements were concluded, there was uncertainty about whether entry in one way or another would be successful. It is the elimination of this uncertainty through value transfers, that is to say the fact that Servier made sure by the value transfers that the generic companies in question would not enter the market with their product for the duration of the agreement, which characterises the agreements in question as anti-competitive. As analysed in section 5, the parties knew or should have known that such agreements could amount to an infringement of Article 101 and in the case of Servier also Article 102 of the Treaty.

10.2.2 General arguments of the parties against the imposition of fines

(3077) In their replies to the Statement of Objections, the parties raised a number of general arguments as to why no fines or why only symbolic fines should be imposed in the present case. These arguments are addressed below.

10.2.2.1 Non-existence of the infringements

(3078) Some of the parties, in particular Servier,[3991] Niche[3992] and Matrix,[3993] asserted that they did not or could not have infringed Article 101 or 102 of the Treaty and therefore no fine should be imposed. The parties' infringements were clearly established throughout this decision and the parties' arguments were addressed in the relevant sections above. There is therefore no need to repeat in the section on fines the arguments made already above. The Commission refers for further details to those sections.[3994]

10.2.2.2 No effects on competition

(3079) Lupin in its Reply to the Statement of Objections contends that its settlement agreement with Servier did not give rise to any actual or potential effects on competition[3995] and had no economic importance. Therefore no fine should be imposed on Lupin.[3996]

(3080) It was already established in section 5.6 above that the Lupin Settlement Agreement appreciably restricted potential competition among Servier and the generic companies by its very object and barred real concrete possibilities for Servier and Lupin to compete between each other or for a new competitor to penetrate the relevant market and compete with the undertakings already established. In addition, the Lupin Settlement Agreement was also found likely to entail restrictive effects for

3991 ID10114, p. 647-650.

3992 ID8722, p. 60-61.

3993 ID8835, p. 67.

3994 For Servier: concerning the issue of dominance and the relevant market see section 6, in particular 6.5, and section 7; concerning the competition assessment of the agreements at stake in the present case see section 5; concerning the competition assessment of Servier's acquisition of technology and patent settlements under Article 102 of the Treaty see section 8.
For Niche: concerning the alleged possibility to develop and commercialise non-infringing perindopril see, in particular, paragraphs (1311) and (1312). Concerning the issue of actual or potential competitors see section 5.2.1.2 and 5.2.2.2.
For Matrix: concerning the issue of the potential competitors, see section 5.3.1.2.

3995 ID9012, p. 100.

3996 ID9012, p. 107.

competition. For detailed explanations reference is therefore made to the relevant section above.[3997]

10.2.2.3 No sanctions for agreements encouraged by the public policy

(3081) Servier argued that there should be no sanctions for patent settlements, which were generally encouraged by the public authorities and public policy. According to Servier, forcing parties to litigate until the final decision would be violating fundamental rights, costly for society and would disturb the equilibrium of the patent system. The patent settlements including the value transfer should, according to Servier, not be defined as restrictions by object and should not be sanctioned *per se*.[3998]

(3082) As already recognised above, companies are entitled to settle patent litigation. Patent settlements may benefit both the parties to the dispute and, more generally, society.[3999] However, patent settlements are not immune from the application of competition law. Compliance with competition law is assessed on the basis of specific facts of each individual agreement or practice.[4000] The Commission's assessment is not only based on the existence of any value transfer, but examines, on a case by case basis, the entire agreement and the relationship between the parties, in their legal and economic context.[4001] There is therefore no automatic, or *per se*,[4002] finding that a settlement agreement with a value transfer is restrictive under Article 101(1) of the Treaty, as Servier erroneously asserts.

(3083) In this context, reference is made to section 5.1.2 above where the issue whether patent settlements can be considered as restrictions of competition by object was discussed in detail.

10.2.2.4 Novelty

(3084) Servier invoked the novel nature of the case and the absence of a precedent on the illegality of patent settlements with a value transfer. To support its argument, Servier referred, by way of example, to statements of Commission representatives, to an external legal opinion, and an academic article from 2009, in order to demonstrate that the Commission's theory concerning the reverse patent settlements is new and that there were no precedents under the EU competition law specifically dealing with patent settlements at the time of the agreements. Servier also referred to the decisions of the US courts which, at the time of the agreements, did not consider patent settlements with reverse payments as illegal.[4003] Furthermore, according to Servier the market definition at the level of the molecule in the present case is without a precedent.[4004] It is also without a precedent, according to Servier, to qualify the same facts simultaneously as infringements of Article 101 and Article 102 of the Treaty.[4005]

3997 See section 5.6.2.5.

3998 ID10114, p. 647-648.

3999 See paragraph (1118).

4000 See, for example, paragraph (1102).

4001 See paragraph (1195).

4002 Moreover, the notion of *per se* infringement derives from US case law and is not an equivalent to restriction by object, as characterised in section 5.1.1 above. See paragraph (1199) and footnote 1687.

4003 ID10114, p. 630-633.

4004 ID10114, p. 652.

4005 ID10114, p. 652.

(3085) Similar arguments were raised also by other parties. Niche[4006] and Unichem[4007] argued that only a symbolic fine should be imposed as the present case is set in completely novel circumstances with which the Commission has no experience and that similar agreements were not found to infringe the principles of competition law in the US.

(3086) Matrix submitted that the anti-competitive nature of settlement agreements including a reverse payment was, and remains, novel and unprecedented in EU competition law and therefore no fine or only a symbolic fine should be imposed.[4008]

(3087) Teva contended that the Commission should refrain from imposing a fine or should apply only a symbolic fine in view of the Commission's standard practice not to impose fines (or to impose only symbolic fines) for novel and/or unclear infringements.[4009] Teva further submitted that reverse payment settlements are a novel and unresolved issue, in view of the lack of EU precedent, legal uncertainty increased by US precedents and Commission's nuanced views on patent settlements even after the Teva agreement.[4010]

(3088) Lupin asserted that this case is novel and there is uncertainty as to the law, therefore no fine should be imposed, which would be consistent with the Commission's and European Courts' approach to date. [4011]

(3089) In AstraZeneca, the Court of Justice stated the following: "… *concerning the novelty of the two abuses of a dominant position, it must be stated that those abuses, as the General Court pointed out at paragraph 900 of the judgment under appeal, had the deliberate aim of keeping competitors away from the market. It is therefore common ground that even though the Commission and the Courts of the European Union had not yet had the opportunity to rule specifically on conduct such as that which characterised those abuses, AZ was aware of the highly anti-competitive nature of its conduct and should have expected it to be incompatible with competition rules under European Union law".*[4012]

(3090) The Commission considers that as established throughout this Decision, Servier was aware that the examined agreements were aimed at excluding competitors. It was the very purpose of Servier's strategy in concluding those agreements. Similarly, given the nature of the commitments, which they agreed to, the generic companies were fully aware that the aim of the agreements in question was their exclusion, at least temporarily, from the market.

(3091) The notion that such practices which are aimed at market exclusion in exchange for a inducement are/capable or likely to constitute a restriction of Article 101 and/or Article 102 of the Treaty is, and was at the time of the agreements, well established and cannot be seen as novel. It is well established case law of the Court that agreements between competitors are not immune from the application of competition law because they concern IP rights or because their purpose is to put an end to

4006 ID8722, p. 65 and 66.
4007 ID8720, p. 18.
4008 ID8835, p. 70.
4009 ID9300, p. 158.
4010 ID9300, p. 160-164.
4011 ID9012, p. 101-103.
4012 Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 164.

litigation.[4013] In the *Irish Beef* case, an agreement financially encouraging competitors to exit the market was found to restrict competition by its very object.[4014] The practices at stake in the present case clearly fall within the prohibition of Article 101[4015] and/or Article 102 of the Treaty[4016] and their qualification, based on the assessment of the specific facts and the economic and legal context of the present case, as anti-competitive cannot be seen as novel.

(3092) As to the various statements of the Commission officials invoked by Servier and the Commission documents from the period after the agreements, those statements merely suggest that there were no specific Commission or Court decisions addressing specifically reverse payment agreements in the pharmaceutical sector at that time. Similarly, the Commission does not contest the conclusions of the legal opinion and of the article invoked by Servier (see paragraph (3084)) that there were no precedents under EU competition law explicitly dealing with patent settlements.[4017] However, this does not put in question the fact that it was a common ground at the time of the agreements that practices aiming at excluding competitors from the market were likely to be considered anti-competitive and that the parties should have expected their practices to be incompatible with competition rules under Union law.[4018] As the Court stated recently in *Intel*, "[…] *the fact that conduct with the same features has not been examined in past decisions does not exonerate an undertaking"*.[4019] In any event, these statements gave a clear indication that reverse payment settlements deserve close scrutiny as they could potentially infringe competition.

(3093) Concerning the case-law of the US courts invoked by the parties, it should be recalled that Union law is distinct from US law, and that therefore decisions by US bodies are without legal bearing for the application of Article 101 and/or 102 of the Treaty (see paragraph (1199)). In any event, given that the US case-law was not unanimous at the time of the agreements[4020] and given the position of the Federal Trade Commission on the issue of the reverse payment settlements at that time, the parties should have been aware of (at least) the possibility that the practices under scrutiny in the present case could have been considered illegal even under US law.

(3094) Concerning the arguments that the Commission should, as in certain past cases, refrain from imposing a fine in this case due to its novelty, the fact that the Commission may not have imposed fines in certain other cases is immaterial. In the circumstances of this case the Commission considers it appropriate to impose fines having regard to the need for appropriate sanctioning and deterrence. The former is

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4013 See paragraph (1119), (1122) and the case-law cited therein.

4014 Judgment in *Beef Industry Development and Barry Brothers*, C-209/07, EU:C:2008:643, paragraphs 31-34 and 36.

4015 See section 5.1.2

4016 See section 8.2

4017 See ID10114, p. 652.

4018 Moreover, the quotes from the academic article provided by Servier are selective. For example, concerning the issue of value transfers, the article also stated: "*Even so, a significant value transfer to the generic firm in a scenario where the originator's patent is prima facie weak, may constitute an indication that the originator was paying the generic firm to not enter the market, in particular when the parties to the agreement do not have any plausible explanation for the disproportionate nature of the payment"*. Marc Van der Woude, "Patent settlements and reverse payments under EU law", Competition Policy International, Vol. 5, Number 2, Autumn 2009, p. 194.

4019 Judgment of 12 June 2014, *Intel Corp. v Commission*, T-286/09, ECR, EU:T:2014:547, paragraph 1602.

4020 See, for example, In Re Cardizem 332 F.3d 896 (2003).

aimed at ensuring parties do not profit from illegal practices. The latter has a dual objective, ensuring that both the parties to this Decision specifically and other undertakings generally refrain from entering into such types of anti-competitive agreements. The Commission's discretion in this case is not fettered by its approach in other cases. Whilst a consistent approach must be adopted by the Commission within the same case to ensure the respect of the principle of equal treatment, an undertaking cannot rely on the Commission's approach in distinct cases to escape sanctions.[4021] As confirmed recently by the Court, previous decisions by the Commission imposing fines can be relevant from the point of view of observance of the principle of equal treatment "*only where it is demonstrated that the facts of the cases in those other decisions, such as markets, products, the countries, the undertakings and periods concerned, are comparable to those of the present case*".[4022] Clearly, none of the past decisions invoked by the parties concerns facts, such as markets, products, the countries, the undertakings and periods concerned, that would be comparable to those of the present case.

(3095) Regarding the allegedly unprecedented market definition at the level of a molecule, this issue was already addressed in section 6.[4023] It is settled case law that the condition that the infringement was committed intentionally or negligently is satisfied where the undertaking concerned cannot be unaware of the anticompetitive nature of its conduct, whether or not it was aware that it was infringing the competition rules of the Treaty.[4024] Thus, the fact that there may not have been established precedents relating to reverse payment agreements cannot mean that the Commission was barred from imposing a fine on the parties.[4025]

(3096) Concerning the claimed novelty of qualifying the same facts simultaneously as infringements of Article 101 and Article 102 of the Treaty without their being any additional element, reference is made to the case-law cited in paragraphs (2923) and (2924) and to section 8.3.3.1 where this issue was discussed in detail. Contrary to Servier's assertions in its reply, the Commission does not merely recycle under Article 102 the facts previously objected to under Article 101. The "additional element" here is not the individual inducements in each settlement, but the overall exclusion of potential competition from the market resulting from a single unilateral strategy implemented through these settlements in combination with the technology acquisition and enabled by Servier's unique position on the market.[4026] This issue therefore cannot be seen as novel either.

10.2.2.5 Nullum crimen, nulla poena sine lege

(3097) According to Servier, the Commission did not clearly define the infringements for the purpose of imposition of the fines of criminal nature, whereby it allegedly

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4021 See Judgment of 27 February 2014, *InnoLux v Commission*, T-91/11, ECR, EU:T:2014:92, paragraph 144, and the case-law cited therein.

4022 Judgment of 12 June 2014, *Intel Corp. v Commission*, T 286/09, ECR, EU:T:2014:547, paragraph 1615.

4023 See, in particular, footnotes 3215 and 3297.

4024 Judgment of 6 October 1994, *Tetra Pak v Commission*, T-83/91, ECR, EU:T:1994:246, paragraph 238; Judgment of 10 April 2008, *Deutsche Telekom v Commission*, T-271/03, ECR, EU:T:2008:101, paragraph 295; and Judgment of 12 June 2014, *Intel Corp. v Commission*, T-286/09, ECR, EU:T:2014:547, paragraph 1601.

4025 *Judgment in Michelin v Commission*, 322/81, EU:C:1983:313, paragraph 107; Judgment of 10 April 2008, *Deutsche Telekom v Commission*, T-271/03, ECR, EU:T:2008:101, paragraphs 124 and 127; and Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 164.

4026 See paragraph (2931).

violated its obligations under the European Convention for the Protection of Human Rights and Fundamental Freedoms.[4027] Servier further argued that the Commission may not impose fines retroactively, for the practices that were not considered illegal and could not have been reasonably considered as illegal by the undertaking at the time of the events. [4028]

(3098) Similarly, Matrix submitted that due to the legally unprecedented nature of this case, the alleged infringement of Article 101 of the Treaty committed by Matrix was not considered unlawful at the time. Therefore the imposition of the fine would breach the principle of legality in relation to crime and punishment ("*nullum crimen, nulla poena sine lege*").[4029] And as it allegedly could not have been reasonably foreseeable at the time that entering into a settlement agreement with a reverse payment was automatically anti-competitive, imposing a fine would also undermine the principle of legal certainty.[4030]

(3099) The "*nullum crimen, nulla poena sine lege*" principle implies that a provision may not be applied extensively to the detriment of the defendant and that provisions of criminal law may not have retroactive effect (Article 7 of the European Convention on Human Rights and Article 49 of the Charter of Fundamental Rights of the European Union). This principle applies to fines imposed by the Commission pursuant to Article 23 of Regulation (EC) No 1/2003.

(3100) It is settled case–law that the principle of *nullum crimen, nulla poena sine lege* cannot be interpreted as prohibiting the gradual clarification of the rules of criminal liability through interpretation by the courts.[4031] However, this principle may preclude the retroactive application of a new interpretation of a rule establishing an offence. "*That is particularly true if the result of that interpretation was not foreseeable at the time when the offence was committed, especially in the light of the interpretation attributed to the provision in the case-law at the material time. Furthermore, the notion of foreseeability depends to a considerable degree on the content of the text at issue, the field it is designed to cover and the number and status of those to whom it applies, and does not preclude the person concerned from taking appropriate legal advice to assess, to a degree that is reasonable in the circumstances, the consequences which a given action may entail. This is particularly true in the case of persons engaged in a professional activity, who are used to having to proceed with a high degree of caution when pursuing their occupation. They can thus be expected to take special care in assessing the risks that such activity entails […]*"[4032]

(3101) For the reasons set out in section 10.2.2.4, the type of infringement at stake in this case, in particular the exclusion from the market in return for a value transfer, was not new and its illegality was foreseeable for the parties. The literal wording of the prohibitions laid down in Articles 101 and 102 of the Treaty [4033] itself did suggest that these practices were infringing Union competition law.

4027 ID10114, p. 647.

4028 ID10114, p. 647 and 653-654.

4029 ID8835, p. 68.

4030 ID8835, p. 68.

4031 See Judgment of 8 July 2008, *AC-Treuhand AG v Commission*, T-99/04, ECR, EU:T:2008:256, paragraph 141.

4032 Judgment in *AC-Treuhand AG v Commission*, footnote 4070 above, EU:T:2008:256, paragraph 142.

4033 Articles 81 and 82 EC in the relevant period.

(3102) Moreover, the present decision established that Servier and its generic competitors took the decision to enter into the examined agreements being aware of the consequences of this type of agreement. The investigated practices concerned the core business of Servier and the other addressees of this Decision, which were all undertakings engaged in sophisticated professional activity, having recourse to both internal and external legal advice. They could thus be "*expected to take special care in assessing the risks*" that the investigated practices entailed.[4034] Moreover, certain parties sought legal advice on compliance with Union competition law[4035], and one party even explicitly considered that the agreement may be problematic under competition law.[4036] Nothing suggests that they could not have known that their conduct was infringing Article 101 and, in case of Servier, Article 102 of the Treaty.[4037]

(3103) Therefore, the allegation of breach of the principle of *nullum crimen nulla poena sine lege* does not hold.

(3104) Servier also invoked the Commission's decisional practice, which, according to Servier, is not to impose fines if the nature of the infringement is entirely new,[4038] or if the infringement was not clearly established by a Community precedent,[4039] or if it is one of the first cases where the competition rules are applied in the sector concerned,[4040] or if there is a reasonable doubt as to the practices concerned,[4041] or if the subject matter is legally complex.[4042]

(3105) First, as mentioned in paragraph (3094), the fact that the Commission may not have imposed fines in certain other cases is immaterial. Whilst a consistent approach must be adopted by the Commission within the same case to ensure the respect of the principle of equal treatment, an undertaking cannot rely on the Commission's approach in distinct cases to escape sanction.[4043]

(3106) Second, as established in section 10.2.2.4, the infringement at stake in the present case, namely exclusion from the market in return for a value transfer, cannot be considered as entirely new or novel and its illegality was foreseeable for the parties.

(3107) Third, there may not be any established precedents specifically in relation to reverse payment settlement agreements, however, the notion that such practices which are aimed at market exclusion in exchange for a value transfer are likely to constitute a restriction of Article 101 or Article 102 of the Treaty is, and was at the time of the events, well established (for the relevant precedents see the case-law cited in

4034 See paragraph (3100).

4035 See paragraph (597).

4036 See paragraph (717).

4037 Concerning Article 102 of the Treaty, the Commission points to the well established case law concerning acquisition of exclusive rights by a dominant company where such transfer of exclusive rights can lead to delays in competitive entry. See Judgment of 6 October 1994, *Tetra Pak v Commission*, T-83/91, ECR, EU:T:1994:246.

4038 Servier referred to the Decision in case 88/501/CEE [IV/31.043 – Tetra Pak I (licence BTG)]. ID10114, p. 654.

4039 Servier referred to Case COMP/38.096 *Clearstream*. ID10114, p. 654.

4040 Servier referred to Case IV/35.613 – *Alpha Flight Service/Aéroports de Paris*. ID10114, p. 654.

4041 Servier referred to COMP/D1/37860 – *Morgan Stanley/Visa International and Visa Europe*. ID10114, p. 654.

4042 Servier referred to COMP/C-2/38.698 – *Cisac*. ID10114, p. 654.

4043 See Judgment of 27 February 2014, *InnoLux v Commission*, T-91/11, ECR, EU:T:2014:92, paragraph 144, and the case-law cited therein.

paragraph (3091)). Unlike in *Clearstream*, in the present case the illegality of the practices was foreseeable for the parties.

(3108) Fourth, in the *Aéroports de Paris* decision (adopted in June 1998) invoked by Servier, the Commission did not impose fines for the following reasons: "*It is necessary to take account of recent changes in competition in the airports sector owing to the full liberalisation of the European Union air industry since April 1997 and the adoption by the Council of Directive 96/97 on the opening-up of the groundhandling market. For these reasons, the Commission does not fine ADP*".[4044] No major liberalisation nor any major Union legislative reform occurred recently in the EU pharmaceutical industry. *Aéroports de Paris* therefore does not assist Servier's argument.

(3109) Fifth, there is no reasonable doubt as to the practices concerned. The contractual parties knew or should have known that the respective agreements had the object and necessary consequence of restricting competition (see paragraph (3065).

(3110) Sixth, there is no wording in the text of the *Cisac* decision invoked by Servier which would support the argument that the fine should not be imposed if the subject matter is legally complex. In any event, the practices in the present case, which were aimed at market exclusion in exchange for a value transfer, cannot be considered, for the purpose of imposition of the fine, as legally complex, and their illegality was foreseeable for the parties.

(3111) Therefore, there is no merit in the argument that no fine should be imposed in the present case in view of the Commission's decisional practice.

10.2.2.6 Legal certainty and legitimate expectations

(3112) Servier argued that the theories advanced by the Statement of Objections are in contradiction with the Commission Technology Transfer Guidelines and therefore the principles of legal certainty and legitimate expectations were breached. [4045]

(3113) As explained above,[4046] the Technology Transfer Guidelines only apply to agreements that transfer technology, such as agreements licensing patent rights, as the provisions they contain are based on a specific balance between the pro-competitive effects of licensing and possible restrictive effects (see point 9 of the Guidelines). The agreements covered by this Decision did not include any enabling transfer of Servier's technology to the generic undertakings concerned for the restricted markets. Moreover, the Technology Transfer Guidelines analyse non-challenge obligations on a stand-alone basis, and not in combination with other elements, such as the existence of payment in consideration for the non-challenge obligation.

(3114) Therefore, the alleged breach of the principles of legal certainty and legitimate expectations does not exist.

10.2.2.7 Clarity of the infringed principles

(3115) Servier argued that a fine can be imposed only if the principles that were infringed were sufficiently clear. In the present case, according to Servier, the criteria that the

4044 Press release of 18 June 1998, "*Commission prohibits discriminatory fees for the provision of ground handling services at Paris airports*", http://europa.eu/rapid/press-release_IP-98-546_en.htm.

4045 ID10114, p. 654-655.

4046 See footnote 1586.

Commission used to condemn the settlement agreements with the value transfer are unclear. [4047]

(3116) As mentioned in paragraph (3091), the notion that such practices which are aimed at market exclusion in exchange for a value transfer are likely to constitute a restriction of Article 101 or Article 102 of the Treaty is, and was at the time of the events, well established. The literal wording of the prohibitions laid down in Articles 101 and 102 of the Treaty [4048] suggests that the practices at stake in this case, namely exclusion from the market in return for a value transfer, infringe Union competition law.

(3117) As explained in paragraph (1113), the assessment of the specific settlement agreements in the present case is clearly structured and is in line with settled case-law. In order to assess the anti-competitive nature of the agreements, regard was given *inter alia* to the content of their provisions, the objectives they seek to attain and the economic and legal context of which they form a part. The Commission first considered whether the parties were actual or potential competitors. The Commission then examined the content of the agreements, including the specific restrictions on the generic companies' behaviour and the nature of the benefit they received in return. In addition, although the parties' intention is not a necessary factor in determining whether an agreement is restrictive, there is nothing prohibiting the Commission or the Union judicature from taking that aspect into account. Thus the anti-competitive nature of an agreement was deduced not only from the content of its clauses but also from the intention of the parties. For each agreement, clear conclusions concerning the infringement of Article 101 and/or 102 of the Treaty were drawn on the basis of the above elements.

(3118) Therefore the infringements in the present case were clearly defined.

10.2.3 The calculation of the fines for Servier

10.2.3.1 General methodology

(3119) In applying the Guidelines on fines, the basic amount results from the sum of a variable amount and – where appropriate – an additional amount. The variable amount results from a proportion of the value of sales of goods or services to which the infringement relates multiplied by the number of years of the company's participation in the infringement. The additional amount is calculated as a proportion of an undertaking's relevant sales in a given year (normally, the last year of the infringement). The resulting basic amount can then be increased or reduced for each undertaking if either aggravating or mitigating circumstances are retained. Servier will receive a fine for each infringement in which it was involved.

(3120) Servier argued in its reply to the Statement of Objections that the fine would be exceptionally severe if the infringements of Articles 101 and 102 of the Treaty were cumulated and different agreements were treated as separate infringements.[4049] As analysed in section 5, Servier entered into separate agreements with five (potential) competitors and each of these agreements infringed Article 101 of the Treaty. As analysed in section 8, the acquisition of technology from Azad and the reverse payment patent settlements also constituted a single and continuous infringement of Article 102 of the Treaty. It follows from Article 23(2) of Regulation (EC)

4047 ID10114, p. 656.
4048 Articles 81 and 82 EC in the relevant period.
4049 ID10114, p. 646. See paragraph 2429.

No 1/2003 and is consistent with the Guidelines on fines that separate fines should be imposed for each infringement. For example, in the Commission Decision of 28 March 2012 in Case No COMP/39.462 - *Freight Forwarding*[4050] four separate infringements were found and four separate fines imposed without any discount for simultaneity for those parties that were involved in more than one cartel. In another Commission's Decision, 2003/2/EC, in Case COMP/E-1/37.512 – *Vitamins,*[4051] upheld by the Courts[4052], there were eight distinct secret market-sharing and price-fixing cartels affecting vitamin products with temporal overlaps within the period September 1989 and February 1999. The company Hoffman-La Roche was an instigator and participated in all the cartels, however it still received a separate fine for each cartel, with no discounts allowed for this fact. Finally, a similar method was used in the recent Commission decision in the case COMP/ AT.39226 – *Lundbeck,* where the pharmaceutical originator company, Lundbeck, was fined for a number of settlement agreements with different generic companies.[4053]

(3121) In the present case the Commission took into consideration the need to avoid a potentially disproportionate outcome resulting from the imposition of multiple fines in parallel and applied a case-specific correction factor (see paragraph (3128)).

(3122) Servier criticised the Statement of Objections as not being sufficiently clear on the calculation of the fines as it was impossible for it to know whether it will receive one or several fines. Servier submitted that there is a contradiction in the wording of the Statement of Objections in this respect.[4054] The Statement of Objections, however, is clear on this issue. The Statement of Objections, which complies with the Commission notice on best practices for the conduct of proceedings concerning Articles 101 and 102 of the Treaty ("Best practices notice"),[4055] stated that "*Servier is to receive a fine for each infringement in which it was involved"*.[4056] This starting point for the calculation of the fine is then complemented by the following statement: "*If appropriate, the Commission may take into consideration the need to avoid a potentially disproportionate outcome resulting from the imposition of multiple fines in parallel and apply a case-specific correction factor"*.[4057] This is indeed the approach taken by the Commission in the present decision (for details on the case-specific correction factor see paragraph (3128) below).

(3123) The Commission applied to Servier the limit set out in Article 23(2) of Regulation No 1/2003.

10.2.3.2 The value of sales

(3124) The basic amount of the fine to be imposed on the undertakings concerned is to be set by reference to the value of sales,[4058] that is, the value of the undertakings' sales

4050 Commission Decision of 28.03.2012, Case COMP/39462 *Freight Forwarding*.

4051 *Vitamins*, Commission Decision 2003/2/EC [2003] OJ L 6/1, 10.1.2003.

4052 See, for instance, Judgment of 15 March 2006, *BASF v Commission*, T-15/02, ECR, EU:T:2006:74.

4053 See, for example, the Commission's press release: "*Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines"*, IP/13/563 of 19 June 2013. Available at: http://europa.eu/rapid/press-release_IP-13-563_en.htm?locale=en.

4054 ID10114, p. 657.

4055 OJ C 308, 20.10. 2011, p. 6.

4056 Statement of Objections, paragraph (2895).

4057 Statement of Objections, paragraph (2908).

4058 See point 12 of the Guidelines on fines.

of goods or services to which the infringement directly or indirectly related in the relevant geographic area in the Union.

(3125) Through the infringements in question Servier protected its perindopril sales against generic competition in the geographic area concerned by each agreement. The lack of generic competition can be associated with a significant welfare loss for the perindopril consumers who for a considerable time could not benefit from a significant reduction of prices. For each infringement, the Commission therefore takes into account Servier's perindopril sales in the respective geographic areas.

(3126) The Commission will normally take into account the sales made by the undertakings during the last full business year of their participation in the infringement.[4059]

(3127) During the last full business year of the infringement in the relevant territories,[4060] Servier achieved the following values of sales:

(a) for the infringement of Article 101 of the Treaty relating to the patent settlement with Niche/Unichem: EUR [400–500 million]*;

(b) for the infringement of Article 101 of the Treaty relating to the patent settlement with Matrix: EUR [400–500 million]*;

(c) for the infringement of Article 101 of the Treaty relating to the patent settlement with Teva: EUR [100–200 million]*;

(d) for the infringement of Article 101 of the Treaty relating to the patent settlement with Krka: EUR [400–500 million]*;

(e) for the infringement of Article 101 of the Treaty relating to the patent settlement with Lupin: EUR [500–600 million]*; and

(f) for the infringement of Article 102 of the Treaty relating to (i) the patent settlements with Niche/Unichem, Matrix, Teva, Krka and Lupin, and (ii) the acquisition of API technology from Azad: EUR [300–400 million]*.[4061]

(3128) The Commission recognises that this Decision establishes that Servier committed a number of infringements of Article 101 and Article 102 of the Treaty which relate to the same product, perindopril, and largely to the same geographic areas and periods of time. Having regard to the foregoing, Servier's role and the nature of the infringements and in view of the need to avoid a potentially disproportionate outcome resulting from the imposition of multiple fines in parallel, the Commission in its discretion decided to apply a correction factor. The correction factor takes two distinct forms. The first type of correction applies to the infringements of Article 101 of the Treaty and on average leads to a decrease of 54.5% in the values of sales subsequently taken into account in the calculation of the variable amount. This correction applies to each of the five infringements of Article 101 of the Treaty and is based on an objective method reflecting the degree of temporal and geographic overlaps between those infringements. The method reduces a part of the annual values of sales taken into account in the calculations to 15% for each additional infringement as far as it is overlapping with at least one other infringement both in

4059 See point 13 of the Guidelines on fines.

4060 See Table 50 for the duration of the infringement and the relevant territories. The last full business year of the infringement is separately established for each of the Member States concerned in view of the relevant end dates.

4061 ID5339.

time and space. The resulting overall reduction calculated for all the infringements is equally reattributed to each of the infringements. The second type of correction applies to the infringement of Article 102 of the Treaty. This is a percentage correction which on average leads to a decrease of 92.9% in the values of sales subsequently taken into account in the calculation of the variable amount. The decrease reflects the degree of a temporal overlap between the infringements of Article 101 and Article 102 of the Treaty. The applicable values of sales for the Article 102 aspect of the case are proportionally reduced to reflect the ratio of (a) the period of the infringement of Article 102 of the Treaty that does not overlap in time with any of the infringements of Article 101 of the Treaty to (b) the entire period of the infringement of Article 102 of the Treaty. Periods (a) and (b) are determined in days. Since the temporal overlaps differ across the geographic areas, the proportional reductions are separately calculated for each of the geographic areas concerned.

10.2.3.3 Determination of the basic amounts of the fines

(3129) The basic amount consists of a variable amount of up to 30% of an undertaking's relevant sales in the Union, depending on the degree of gravity of the infringement and multiplied by the number of years of the undertaking's participation in the infringement, and – where appropriate – an additional amount, which is an additional amount of up to 25% of the value of an undertaking's relevant sales, irrespective of duration.[4062]

10.2.3.3.1 Gravity

(3130) The gravity of the infringement determines the percentage of the value of sales taken into account in setting the fine. In assessing the gravity of the infringement, the Commission has regard to a number of factors, such as the nature of the infringement and the combined market share of all the undertakings concerned, the geographic scope of the infringement and/or whether or not the infringement has been implemented. In this case, these elements, which form part of a non-exhaustive list, are assessed as follows:

(a) Nature:

- the anti-competitive nature and objective of the infringements, in particular the fact that the Commission considers the infringements to constitute market exclusion, which must be regarded as serious infringements of Article 101 of the Treaty. Further, Servier abused its dominant position under Article 102 of the Treaty by means of its single and continuous strategy to delay generic entry by excluding close sources of competition through a combination of the Azad Technology Acquisition and the patent settlement agreements;

(b) Market share:

- Servier at the time of its practices possessed a very high market share of the relevant markets established for the purpose of the present Decision and affected by the infringements of Article 101 and Article 102 of the Treaty;

(c) Geographic scope:

[4062] See points 19 to 26 of the Guidelines on fines.

- the wide geographic scope of the infringements with Niche/Unichem, Matrix and Lupin assessed under Article 101 of the Treaty;

(d) Implementation:

- all of the patent settlement agreements assessed under Article 101 and Article 102 of the Treaty and the acquisition of API technology assessed under Article 102 of the Treaty have been implemented.

(3131) The Commission has taken into account the criteria discussed above in paragraph (3130) namely nature, market share, geographical scope and implementation. It must be recalled that the arrangements constitute a by object restriction of Article 101 of the Treaty and the market exclusion described is considered to be a serious infringement. Moreover, Servier also abused its dominant position under Article 102 of the Treaty. However, even where there could be no doubt as to the illegality of the conduct, the Commission has nevertheless had regard to the specific circumstances of the case, as described in sections 5 and 8. In view of the specific circumstances of this case, the Commission considers that the proportion of the value of sales to be taken into account should be 11% for the infringements with a wide geographic scope (that is to say the infringements with Niche/Unichem, Matrix and Lupin), 10% for the infringements with Krka and Teva and 10% for the abuse of dominant position.

10.2.3.3.2 Duration

(3132) In its assessment of the duration of the infringements the Commission will take into consideration that the agreements lasted at least:[4063]

(a) for the infringement of Article 101 of the Treaty relating to the patent settlement with Niche/Unichem: from 8 February 2005 to 15 September 2008;

(b) for the infringement of Article 101 of the Treaty relating to the patent settlement with Matrix: from 8 February 2005 to 15 September 2008;

(c) for the infringement of Article 101 of the Treaty relating to the patent settlement with Teva: from 13 June 2006 to 6 July 2007;

(d) for the infringement of Article 101 of the Treaty relating to the patent settlement with Krka: from 27 October 2006 to 6 May 2009;

(e) for the infringement of Article 101 of the Treaty relating to the patent settlement with Lupin: from 30 January 2007 to 6 May 2009;

(f) for the infringement of Article 102 of the Treaty relating to (i) the patent settlements with Niche/Unichem, Matrix, Teva, Krka and Lupin,[4064] and (ii) the acquisition of API technology from Azad: from 9 November 2004 to 6 May 2009.

(3133) The dates indicated in the above paragraph are based on the signing dates of the respective agreements and the principal expiry (or patent annulment) dates of the process and crystalline patents in question. They are also subject to a number of exceptions. Apart from the country specific circumstances explained in the previous

4063 See sections 5.8.1 (Niche/Unichem), 5.8.2 (Matrix), 5.8.3 (Teva), 5.8.4 (Krka), 5.8.5 (Lupin) and 8.4.5. (the infringement of Article 102 of the Treaty).

4064 For the distinction of the practices relating to the patent settlements assessed under Article 101 and Article 102 of the Treaty, see paragraph (2931).

sections,[4065] the Commission has adopted a conservative approach and has shortened the basic periods by considering the dates of full scale entries in the UK and the Netherlands given their impact on the sales of Servier's branded product.

(3134) Servier argued that the duration of the infringements was defined only in a general manner in the Statement of Objections and that it was impossible to know for Servier how the Commission will apply the Guidelines on Fines with respect to the duration.[4066] The Commission notes that the Statement of Objections included detailed and specific indications of the duration for each infringement, including territorial specificities.[4067] This argument is therefore without merit. For the sake of clarity and completeness, the duration dates are fully reproduced in Table 50.

Table 50: Start and end dates of the infringements per Member States

Member States	101:Niche/Unichem and Matrix	101: Teva	101: Krka	101: Lupin	102
BE, DK, DE, EE, IE, EL, ES, CY, LU, AT, PT, FI, SE	08/02/2005 15/09/2008	n/a	27/10/2006 06/05/2009	30/01/2007 06/05/2009	n/a
CZ, HU, LT, SK, SI	08/02/2005 15/09/2008	n/a	n/a	30/01/2007 06/05/2009	n/a
BG, RO	01/01/2007 15/09/2008	n/a	01/01/2007 06/05/2009	30/01/2007 06/05/2009	n/a
UK	08/02/2005 06/07/2007	13/06/2006 06/07/2007	27/10/2006 06/07/2007	30/01/2007 06/07/2007	09/11/2004 06/07/2007
NL	08/02/2005 12/12/2007	n/a	27//10/2006 12/12/2007	30/01/2007 12/12/2007	09/11/2004 12/12/2007
FR	08/02/2005 15/09/2008	n/a	27/10/2006 06/05/2009	30/01/2007 16/09/2008	09/11/2004 06/05/2009
PL	08/02/2005 15/09/2008	n/a	n/a	30/01/2007 06/05/2009	09/11/2004 06/05/2009
IT	n/a	n/a	13/02/2009 06/05/2009	13/02/2009 06/05/2009	n/a
LV	01/07/2005 15/09/2008	n/a	n/a	30/01/2007 06/05/2009	n/a
MT	01/03/2007 15/09/2008	n/a	01/03/2007 06/05/2009	01/03/2007 06/05/2009	n/a
HR	n/a	n/a	n/a	n/a	n/a

Sources: see sections 5.8.1 (Niche/Unichem), 5.8.2 (Matrix), 5.8.3 (Teva), 5.8.4 (Krka), 5.8.5 (Lupin) and 8.4.5. (the infringement of Article 102 of the Treaty).

(3135) Servier further argued that the duration of the infringements of Article 101 of the Treaty should take into account the existence of Servier's valid process patents.[4068] This argument is misconceived. The present case concerns restrictive agreements which among others eliminated a possibility of judicial review with respect to the validity, or (non-)infringement of Servier's patents in question. Therefore, for the purpose of the assessment in the present case, the existence of Servier's patents

4065 See sections 5.8.1 (Niche/Unichem), 5.8.2 (Matrix), 5.8.3 (Teva), 5.8.4 (Krka), 5.8.5 (Lupin) and 8.4.5. (the infringement of Article 102 of the Treaty).

4066 ID10114, p.658.

4067 See the Statement of Objections, sections 7.2.3 for the infringement with Niche/Unichem, 7.3.3. for the infringement with Matrix, 7.4.3. for the infringement with Teva, 7.5.4. for the infringement with Krka, 7.6.3. for the infringement with Lupin and 8.3.4. for the infringement of Article 102 of the Treaty.

4068 ID10114, p. 658.

cannot be regarded as a legitimate argument. The agreements had an immediate effect as to the generic counterparts' activities in pursuing a viable and timely independent generic entry.

(3136) Moreover, as far as the present case concerns a restriction by object of Article 101 of the Treaty the duration of the infringement is determined by the duration of the restrictive agreement. What matters is not the validity of the process patents, but the duration of the practices the object of which was to eliminate potential competitors. With regard to the duration of the infringement the Court in the *E.ON-Ruhrgas* judgment stated the following: "*According to settled case-law, even if those undertakings had not implemented the agreement in question but had behaved autonomously after the liberalisation of the markets for gas, that would be irrelevant, because there is no need to take account of the concrete effects of an agreement once it appears that it has as its object the prevention, restriction or distortion of competition within the common market (see Case T-23/99 LR AF 1998 v Commission [2002] ECR II-1705, paragraph 47 and the case-law cited)*".[4069] The start date for the infringements of Article 101 of the Treaty is based on the date of conclusion of the agreement because the restrictions on competitive behaviour of generic competitors were immediately effective as of that date. The end date of the infringements in the present case is determined by the date as of which the generic competitors were able to engage in competitive behaviour.[4070]

(3137) Concerning the duration of the infringement of Article 102 of the Treaty, Servier argued that the duration of the alleged violation of Article 102 of the Treaty is manifestly incorrect in view of the fact that Servier's compound patents expired several years after the alleged start of the infringement in some Member States. Servier further argued that no product could have been launched before the expiry of the SPC and therefore, in view of the E.ON-Ruhrgas case, the practices concerned were not capable of restricting the competition before the expiry of the SPC.[4071] Firstly, the provisions of E.ON-Ruhrgas invoked by Servier [4072] concern the issue of potential competition, not the issue of the duration of the infringement. Secondly, the existence of the SPC alone does not justify the conclusion that generic companies were unable to prepare their entry in the Member States concerned well before the date of the SPC expiry. Generic development times in the case of perindopril were on average 2-3 years and therefore the infringements, where applicable, could have started even before the expiry date of the SPC in question. However, if the SPC expired in a given Member State after generic perindopril had been launched in other Member States, the Commission conservatively assumes that the infringement in such a Member State started on the date of the SPC expiry and not at an earlier date.[4073]

4069 Judgment of 29 June 2012, *E.ON Ruhrgas and E.ON v Commission*, T-360/09, ECR, EU:T:2012:332, paragraph 252.

4070 See paragraphs (2123), (2124), (2125), (2126) and (2127).

4071 ID10114, p. 658.

4072 Points 86-87 and 100-107.

4073 The SPC periods (see Table 2) concern the duration of the infringements of Article 101 and Article 102 of the Treaty in France (see also footnote 3822) and in Italy (see also footnotes 2821, 2825 and 2831, and paragraph (2127)). Regarding France, the Commission takes into account that the generic development times in the case of perindopril were on average 2-3 years and that no generic product had been launched in any other Member State before the SPC expiry. Regarding Italy, in view of the earlier generic entries in other Member States and the existence of accelerated mutual recognition procedures

10.2.3.3.3 Additional amount

(3138) Given that certain infringements consist of horizontal market-exclusion agreements which are restrictions of competition by their very nature, the provisions of the Guidelines on fines should be applied to the additional amount.[4074]

(3139) Taking into account the criteria discussed in paragraph (3130), the basic amount for Servier should include: an additional amount of 11% of the relevant annual value of sales for the first infringement of Article 101 of the Treaty, i.e. the infringement with Niche/Unichem, and an additional amount of 10% of the relevant annual value of sales for the infringement of Article 102 of the Treaty. The imposition of the additional amount only with respect to one out of the five infringements of Article 101 of the Treaty takes into account the specific circumstances of this case and the need to avoid a potentially disproportionate outcome resulting from the imposition of multiple fines in parallel.

10.2.3.3.4 Adjustments to the basic amount: aggravating and mitigating factors

(3140) The Commission may reflect in the fine imposed any aggravating and/or mitigating factors that result in an adjustment of the basic amount. These factors are listed, in a non-exhaustive way, in paragraphs 28 and 29 of the Guidelines on fines.

(3141) Servier argued that the Commission did not comply with the requirements of the Best practices notice as the Statement of Objections did not mention in a sufficiently precise manner that certain facts may give rise to aggravating or mitigating circumstances.[4075]

(3142) The Commission observes that the Statement of Objections stated that the factors listed, in a non-exhaustive way, in paragraphs 28 and 29 of the Guidelines on fines, may result in an adjustment of the basic amount.[4076] However, no aggravating or mitigating factors have been found in the present case.

10.2.3.4 Application of the 10% turnover limit

(3143) Article 23(2) of Regulation (EC) No 1/2003 provides that the fine imposed on each undertaking shall not exceed 10% of its total turnover relating to the business year preceding the date of the Commission decision.

(3144) The basic amounts set out in paragraph (3145) do not exceed 10% of the total turnover of Servier S.A.S., the parent company of the undertaking Servier, in the last full business year.[4077]

10.2.3.5 Conclusion: final amount of fines for Servier

(3145) Therefore the fines to be imposed on Servier S.A.S., Les Laboratoires Servier, Servier Laboratories Limited and Biogaran pursuant to Article 23(2) of Regulation (EC) No 1/2003 should be as follows:

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under which the Member States agree to recognise the validity of the MA issued by another Member State, the starting date is conservatively set on the SPC expiry date.

4074 See point 25 of the Guidelines on fines.

4075 ID10114, p.657 and 658.

4076 Statement of Objections, paragraph (2907).

4077 Based on the period 1 October 2012 to 31 September 2013, see ID10666.

Infringement	**Amount of fine**
Niche/Unichem	Servier S.A.S.; Les Laboratoires Servier; Servier Laboratories Limited and Biogaran, jointly and severally: EUR 131 532 600
Matrix	Servier S.A.S. and Les Laboratoires Servier, jointly and severally: EUR 79 121 700
Teva	Servier S.A.S.; Servier Laboratories Limited and Les Laboratoires Servier, jointly and severally: EUR 4 309 000
Krka	Servier S.A.S. and Les Laboratoires Servier, jointly and severally: EUR 37 661 800
Lupin	Servier S.A.S. and Les Laboratoires Servier, jointly and severally: EUR 37 102 100
Article 102 of the Treaty	Servier S.A.S. and Les Laboratoires Servier jointly and severally: EUR 41 270 000
Total	Servier S.A.S.: EUR 330 997 200 of which jointly and severally with: - Les Laboratoires Servier: EUR 330 997 200 - Servier Laboratories Limited: EUR 135 841 600 - Biogaran: EUR 131 532 600

10.2.4 The calculation of the fines for Niche/Unichem, Matrix, Teva, Krka and Lupin

(3146) The generic undertakings agreed not to sell generic perindopril in the geographic area concerned by each agreement and therefore did not have any sales in the geographic areas concerned. Point 37 of the Guidelines on fines should therefore be applied to the generic undertakings in this case. Point 37 of the Guidelines on fines allows the Commission to depart from the normal methodology of the Guidelines on fines because of the particularities of a given case or the need to achieve deterrence in a particular case.

(3147) Niche and Unichem submitted in their Replies to the Statement of Objections that the calculation of the fine is unclear and contradicts the spirit and letter of the rules to which it is subject, is against the principle of good administration and does not ensure transparency and impartiality of the decision.[4078] Similarly, Teva argued in its Reply to the Statement of Objections that there is a lack of explanation as to the methodology that the Commission intends to apply and that for that reason the Commission did not respect the procedural safeguards provided by the Best practices notice.[4079]

(3148) The Commission's Best practices notice states the following: "*Although under no legal obligation in this respect, in order to increase transparency, the Commission will endeavour to include in the Statement of Objections (using information available) further matters relevant to any subsequent calculation of fines, including the relevant sales figures to be taken into account and the year(s) that will be considered for the value of such sales. […] [T]he parties will be provided with an opportunity to comment*".[4080] In the present case the Commission included in the Statement of Objections, using information available to it, all the matters relevant for the calculation of the fines: the fact that the generic undertakings did not have any sales in the geographic areas concerned in the relevant periods;[4081] the fact that the

4078 ID8722, p. 61 and ID8720, p. 15.
4079 ID9300, p. 164 and 165.
4080 Point 85.
4081 Statement of Objections, paragraph (2909).

Commission therefore intends to apply point 37 of the Guidelines on fines;[4082] the elements that will be taken into account for the assessment of the gravity of each infringement;[4083] the duration of each infringement;[4084] and the amounts of value transferred to the generic undertakings that will be taken into account in order to achieve deterrence.[4085] The parties were subsequently given the opportunity to comment on the elements included in the Statement of Objections. The Commission therefore adhered to its policy as set out under the Best practices notice (which however should not be confused with a legal obligation). There is therefore no violation of the principle of good administration and the transparency and impartiality of the decision is ensured.

(3149) Lupin argued in its Reply to the Statement of Objections that the Commission is departing from the general methodology envisaged by the Guidelines on fines and it is therefore in breach of the principle that it must comply with self-imposed rules.[4086] It is sufficient to state in this respect that the possibility for the Commission to depart from the general methodology is explicitly provided for in point 37 of the Guidelines on fines and therefore the Commission complied with its Best practices notice.

(3150) Lupin further argued that according to the Guidelines on fines the fine must reflect the economic importance of the infringement. Lupin asserts that the Lupin agreement had no effect on the perindopril market, no economic importance and therefore no fine should be imposed on Lupin.[4087] Firstly, this argument is irrelevant in a case such as the present one which involves the finding of a restriction of Article 101 of the Treaty by object. Secondly, it was established already in section 5.6.2.5 that the Lupin Settlement Agreement was likely to entail restrictive effects for competition. This argument therefore cannot be accepted. The Commission takes the following elements into account when calculating the fines for the generic undertakings in this case.

10.2.4.1 Gravity

(3151) When assessing the gravity of each infringement,[4088] the Commission has regard to a number of factors, such as the nature of the infringement, the combined market share of all the undertakings concerned, the geographic scope of the infringement and whether or not the infringement has been implemented. These elements, which form part of a non exhaustive list, are assessed below in this section for each infringement. Normally the gravity of the infringement determines the percentage of the value of sales taken into account when setting the fine. However, in this case by applying point 37 of the Guidelines on fines, the Commission determines the basic amount for Niche/Unichem, Matrix, Teva, Krka and Lupin corresponding to the value transferred to the generic undertaking in each infringement.[4089] This is done without differentiating between the infringements on the basis of various factors of gravity such as nature, market share and geographical scope. However, for the sake of completeness the following is noted:

4082 Statement of Objections, paragraph (2909).
4083 Statement of Objections, paragraph (2911).
4084 Statement of Objections, paragraph (2911).
4085 Statement of Objections, paragraph (2911).
4086 ID9012, p. 106.
4087 ID9012, p. 107.
4088 See Article 23(3) of Regulation No 1/2003.
4089 The values are summarised in paragraph (3162) below.

(a) Nature:

- the anti-competitive nature and objective of the infringement, in particular the fact that market exclusion must be considered a serious infringement of Article 101 of the Treaty;

(b) Market share:

- the fact that each generic undertaking knew or should have known that at the time when it concluded its agreement(s) with Servier, Servier possessed a very high market share of the perindopril market(s) for the geographic area concerned;

(c) Geographic scope:

- the wide geographic scope of the infringements with Niche/Unichem, Matrix and Lupin;

(d) Implementation

- the fact that all of the agreements have been implemented.

(3152) Teva argued that in the absence of generic perindopril sales in the UK in the relevant period, the Commission should rather refer to Teva's sales figures for the period immediately following the infringement which would provide "*the closest proxy*".[4090] According to the Guidelines on fines and the case-law of the Court, in exercising its power to impose fines the Commission enjoys a wide margin of discretion within the limits set by Regulation No 1/2003.[4091]According to Regulation No 1/2003 and the Guidelines on fines, the fine should relate to the following factors: (i) the gravity of the infringement, (ii) its duration, (iii) any aggravating or attenuating circumstances and (iv) the need to achieve deterrence. The Commission, in exercising its margin of discretion, considers that in the present case, given its particularities, the amount of the value transfer received by the generic companies provides important indications as to these factors. The sales figures for the period after the infringement proposed by Teva do not relate to the relevant period of the infringement and the market that existed at that time and therefore cannot be considered as the closest proxy.

(3153) With regard to the nature of the infringement, Niche and Unichem argued that the Niche/Unichem agreement should not be considered as a serious infringement of Article 101 of the Treaty as patent settlement agreements have not previously been the subject of a formal Commission decision.[4092] Similarly, Matrix submitted that it would be disproportionate and unfair to consider Matrix's conduct as a serious infringement of Article 101 of the Treaty due to the novel and unprecedented nature of the Commission's allegations.[4093] As explained in section 10.2.2.4, there may not be any established precedents specifically in relation to reverse payment agreements, however, the notion that such agreements which are aimed at market exclusion in exchange for a value transfer are likely to constitute a restriction of competition under Article 101 of the Treaty is, and was at the time of the events, well established. This argument is therefore without merit.

4090 ID9300, p. 165.
4091 Guidelines on fines, point 2 and the case-law cited therein.
4092 ID8722, p. 62 and ID8720, p. 16.
4093 ID8835, p. 70.

(3154) Teva submitted that its infringement should not be considered as a serious infringement of Article 101 of the Treaty due to: (i) legal uncertainty surrounding the issue of patent settlements in the pharmaceutical sector,[4094] (ii) existence of Servier's valid IP rights and the exclusionary power they entailed,[4095] (iii) specific aspects of the Teva agreement which distinguish it from the other agreements within the scope of the present decision. Teva asserted that unlike the other agreements, the Teva agreement was designed as a bona-fide supply agreement with a view to achieve early entry, Teva refused to forgo its action before the EPO and retained the ability to challenge Servier's '947 patent, and the geographic scope was limited to the UK. [4096]

(3155) As to (i), the Commission refers to paragraph (3153) and section 10.2.2.4 where this issue is discussed in detail. With regard to (ii), it is explained in paragraph (3091) that agreements between competitors are not immune from the application of competition law because they concern IP rights or because their purpose is to put an end to litigation. Concerning the alleged specific aspects raised under (iii), the anti-competitive nature of the Teva agreement was assessed and established already in section 5.4. The possibility to challenge the Servier '947 patent has no bearing on the anti-competitive nature of the agreement and the fact that the agreement amounted to market exclusion of a potential generic competitor. However, the annulment of the '947 patent by the High Court was taken into account for the duration of the infringement.[4097] Finally, the geographic scope of the infringement was taken into account by the Commission,[4098] but it does not alter the conclusion that the market exclusion must be considered a serious infringement of Article 101 of the Treaty .

(3156) With regard to the market share, Niche and Unichem questioned the relevance of this factor and argued that it cannot be inferred that either Niche or Unichem were aware that Servier, as a holder of the relevant patents, may have had a very high market share.[4099] However, the evidence on the file shows that Niche was aware that there was no generic perindopril on the market and that Niche's intention was to agree with Servier on a *"commercial arrangement that will suit Niche and to an extent Servier by keeping other generic versions of perindopril off the market for as long as possible"*.[4100] The fact that the generic undertakings knew or should have known that through the agreements and value transfers Servier extended, or at least maintained, its exclusive position on perindopril is an important factor for the assessment of gravity of the anti-competitive conduct in question.[4101]

(3157) Regarding the geographic scope, Niche and Unichem argued that this factor should not be relied upon as a patent *ipso facto* excludes competition in those countries where it is validly registered.[4102] This argument is misconceived. What matters for the assessment of the gravity is the geographic scope of the anti-competitive agreement that restricted competition, not the scope of the patent. It was already

4094 ID9300, p. 166.
4095 ID9300, p. 166.
4096 ID9300, p. 167.
4097 See section 5.8.3.
4098 See paragraph (3151).
4099 ID8722, p. 63 and ID8720, p. 16.
4100 See paragraphs (489) and (1360).
4101 See point 22 of the Guidelines on fines that refers to the "*combined market share of all the undertakings concerned*" as one of the factors to be taken into account in the assessment of gravity.
4102 ID8722, p. 64 and ID8720, p. 17.

established above that the scope of the Niche/Unichem infringement was Union wide.[4103]

(3158) Finally, with regard to the implementation, Niche and Unichem argued that the fact that the agreement has been implemented only reflects the fundamental rationale of the patent settlement agreement, otherwise costly and uncertain litigation would have continued.[4104] This argument misrepresents Commission's reasoning. This decision does not object to the implementation of the patent settlement agreements in general,[4105] but only the anti-competitive agreements whereby a (potential) competitor is paid off to stay out of the market. In the present case such anticompetitive agreements were not only signed, but also implemented, which is taken into account for the assessment of gravity of the infringements.

10.2.4.2 Duration

(3159) The Commission takes into account the duration of each infringement[4106] as indicated in points (a) to (e) in paragraph (3132) subject to the exceptions described in paragraph (3133). The duration dates are fully reproduced in Table 50.

(3160) Niche and Unichem argued in their Replies to the Statement of Objections that the Commission's assessment of the duration of the Niche/Unichem infringement is not correct, because Niche never agreed not to sell non-infringing perindopril under the settlement agreement.[4107] In other words, it is argued that there is no infringement and therefore no duration. It is sufficient to state in this respect that Niche/Unichem's infringement, including its duration, is already established in section 5.2.

10.2.4.3 Deterrence

(3161) The Commission has taken into account the need to ensure deterrence in each infringement[4108] by using as a basis for the calculation of the fine the value transferred to the generic undertaking in each infringement.

(3162) In applying point 37 of the Guidelines on fines, for the purpose of the calculation of the fine, the following amounts of value transferred to the generic undertaking in each infringement are taken into account and correspond to each generic company's basic amount:

- for Niche/Unichem: EUR 17 161 140;[4109]
- for Matrix: EUR 17 161 140;[4110]
- for Teva: EUR 15 569 395;[4111]

4103 See paragraphs (1405) and (1406).

4104 ID8722, p. 64 and ID8720, p. 17.

4105 See paragraph (1102).

4106 See Article 23(3) of Regulation No 1/2003.

4107 ID8722, p. 64 and ID8720, p. 18.

4108 See also point 31 of the Guidelines on fines.

4109 See sections 4.3.1.4.1 and 5.2. Niche/Unichem received a value transfer of GBP 11.8 million. That amount has been converted into euro at the exchange rate of 0.68760, that is the ECB daily exchange rate for 8 February 2005, i.e. the date of the agreement in question.

4110 See sections 4.3.1.4.2.2 and 5.3. Matrix received a value transfer of GBP 11.8 million. That amount has been converted into euro at the exchange rate of 0.68760, that is the ECB daily exchange rate for 8 February 2005, i.e. the date of the agreement in question.

4111 See sections 4.3.2.5 and 5.4. Teva received in total a value transfer of GBP 10.5 million. That amount has been converted into euro at the exchange rate of 0.67440, that is the ECB monthly exchange rate for

- for Krka: EUR 10 000 000;[4112]
- for Lupin: EUR 40 000 000;[4113]

(3163) Niche and Unichem argued that the Commission should not rely on point 31 of the Guidelines on fines. According to Niche and Unichem there is no need for the "specific deterrence", as Niche entered into a legitimate settlement agreement. In terms of "general deterrence", Niche and Unichem argued that a large fine would not be justified due to legal uncertainty in relation to settlement agreements.[4114] Niche/Unichem's infringement, including the anti-competitive nature of the agreement, was already established above and reference is made to section 5.2. Concerning the alleged legal uncertainty in relation to settlement agreements, as explained in section 10.2.2.4, there may not be any established precedents specifically in relation to reverse payment agreements. However, the notion that such agreements which are aimed at market exclusion in exchange for a value transfer are likely to constitute a restriction of competition under Article 101 of the Treaty is, and was at the time of the events, well established. This argument therefore cannot be accepted.

(3164) Teva argued that the approach proposed by the Commission would result in the final amount that would exceed the level of fines normally imposed for serious infringements of EU competition rules and that would be a breach of the principles of sound administration and proportionality.[4115] Firstly, Teva erroneously based its calculations on perindopril sales achieved by Teva in 2007 and 2008, after the infringement was terminated. This is not appropriate for the reasons explained in paragraph (3152). Secondly, the practices at hand amounted to market exclusion and must be considered a serious infringement of Article 101 of the Treaty, notwithstanding the asserted complexity of the legal situation and the absence of a precedent: these arguments were already rebutted above. Thirdly, it is the purpose of the fines imposed by the Commission to ensure the sufficiently deterrent effect vis-à-vis the undertakings concerned but also to deter other undertakings from engaging in the anti-competitive behaviour.[4116] The Guidelines on fines explicitly envisage the need to consider an increase of the fine in order to exceed the amount of gains improperly made as a result of the infringement[4117] and this is exactly what the Commission has done in the present case.

July 2007, i.e. the month of the last periodic payment received by Teva under the agreement in question.

4112 See sections 4.3.3.6, 4.3.3.7 and 5.5. Krka received a licence that allowed it for risk-free operations as a duopoly seller on seven Central and East European markets (EU7) in exchange for abstaining from market entry efforts in the infringement territories (EU20). Krka valued its presence on the duopoly markets (EU7) for at least EUR 10 million (At the Oral Hearing of 18 April 2013, Krka explained that the opportunity cost of not concluding the Krka Settlement Agreement would amount to *"in 3 years well above €10 mio"* of lost profits (ID9927, p. 3). The profit figures from Krka's three main EU7 markets (Czech Republic, Hungary and Poland) show an aggregated net profit of over EUR 10 million in the period covered by the investigated agreement (ID1307)). The value transferred to Krka is then at least equal to EUR 10 million.

4113 See sections 4.3.4.7 and 5.6.

4114 ID8722, p. 64 and ID8720, p. 18.

4115 ID9300, p. 170.

4116 See Guidelines on fines, point 4.

4117 See Guidelines on fines, point 31.

(3165) Teva also argued that the whole amount of the value transferred, i.e. GBP 10.5 million, should not be considered as *"gains improperly made"*: part of the amount (GBP 5 million) was a compensation for the costs incurred by Teva in entering into the Agreement, including the litigation costs and costs of terminating the Hetero/Alembic arrangements and destroying the existing stocks of the products; the rest of the sum paid by Servier to Teva compensated Teva for the gross margin that Teva would have made as a generic supplier of perindopril if Servier had not breached its contractual obligations.[4118] In view of the Commission's assessment of the precise purpose of the net value transfer, in particular the finding of a clear link between the payment to Teva and its acceptance of the restrictions,[4119] Teva's argument relating to compensation must be dismissed. As already explained above, Teva also errs in its attempt to equalize the amount of fine to *"gains improperly made"*.

10.2.4.4 Aggravating circumstances

(3166) No aggravating circumstances have been found.

10.2.4.5 Mitigating circumstances

(3167) No mitigating circumstances have been found.

(3168) Niche argued in its Reply to the Statement of Objections that the Commission should take into account as mitigating circumstances that Niche effectively cooperated with the Commission outside the scope of the Leniency Notice and beyond its legal obligation to do so.[4120]

(3169) Point 29, fourth indent of the Guidelines on Fines states the following: *"the basic amount may be reduced where the Commission finds that mitigating circumstances exist, such as*: […] *where the undertaking concerned has effectively cooperated with the Commission outside the scope of the Leniency Notice and beyond its legal obligation to do so*". Under this provision the Commission has to assess, in accordance with case-law, whether a reduction of fines is justified due to the fact that the co-operation of the party enabled the Commission to establish the infringements more easily.[4121] The Commission considers the award of such a reduction could only be of an exceptional nature.[4122]

(3170) In the present case, Niche has gone no further than its duty to cooperate during the investigation and dealings with the Commission as specified in Regulation (EC) No 1/2003. Niche has not voluntarily, for example, submitted information that helped the Commission significantly to establish the infringements. Nor can Niche's choice of exercising certain procedural steps without legal representation or not invoking legal professional privilege for some documents be considered as amounting to exceptional circumstances that could justify in the present case granting a reduction of the fine for effective cooperation falling outside the Leniency Notice.

4118 ID9300, p. 171.

4119 See paragraphs (1584)-(1585).

4120 ID8722, p. 65.

4121 Judgment of 6 December 2005, *Brouwerij Haacht v Commission*, T-48/02, ECR, EU:T:2005:436, paragraph 104 and the case law cited therein.

4122 Commission Decision of 20.10.2005, Case COMP/38.281 *Italian Raw Tobacco*, paragraphs 385 ff.

(3171) Niche further submitted that it should benefit from the fact that had it not brought an end to litigation, it would have been driven out of business by Servier.[4123] This argument is, however, not substantiated and amounts to a mere assertion. Moreover, this assertion is at odds with the fact that Niche opted for a patent settlement in exchange for a substantial sum of money instead of continuing the litigation in the United Kingdom, which it was confident of winning.[4124]

(3172) Unichem argued that as a mere signatory to the settlement agreement, with no other role in the infringement, Unichem should benefit from a reduction of the fine as a result of its limited role.[4125] It is recalled that Unichem is held liable as the entity directly participating in the infringement through the negotiation and conclusion of the Niche/Unichem Settlement Agreement and the "Licence and Supply Agreement" with Biogaran. In addition, it is also held liable as the parent company of Niche which exercised decisive influence over Niche.[4126] Moreover, Unichem did not demonstrate that during the period in which it was party to the offending agreement, it actually avoided applying it by adopting competitive conduct in the market as required by the Guidelines on fines.[4127] The argument that Unichem should benefit from its limited role must be therefore rejected.

(3173) Teva argued that the absence of any guidance should be seen as a mitigating circumstance and that the infringement was committed by negligence.[4128] It was already stated above that the notion that such practices which are aimed at market exclusion in exchange for a value transfer are likely to constitute a restriction of Article 101 or Article 102 of the Treaty is, and was at the time of the agreements, well established.[4129] Given the nature of the commitments, which Teva agreed to, Teva was fully aware, or could not have been unaware, that the aim of the agreements in question was its exclusion, at least temporarily, from the market. Teva's argument therefore cannot be accepted.

(3174) Teva further claimed that it should benefit from a reduced fine as its limited participation to the infringement should qualify as a mitigating circumstance.[4130] As acknowledged by Teva itself, the exclusively passive role is not anymore listed among the mitigating circumstances in the 2006 Guidelines on fines. The 2006 Guidelines on fines require instead that in order to benefit from the claimed substantially limited involvement in the infringement, the undertaking must provide evidence and demonstrate that "*during the period in which it was party to the offending agreement, it actually avoided applying it by adopting competitive conduct in the market*".[4131] No such evidence was provided by Teva and its argument therefore cannot be accepted.

(3175) Teva also submitted that it cooperated with the Commission outside its legal obligations to do so as it provided the Commission with submissions that contained particularly responsive information to facilitate the Commission's understanding of

4123 ID8722, p. 65.
4124 See paragraph (1362).
4125 ID8720, p. 18.
4126 See Section 9.3.
4127 See point 29, third indent.
4128 ID9300, p. 168.
4129 See paragraph (3091).
4130 ID9300, p. 168.
4131 Guidelines on fines, point 29, third indent.

the case and its investigation.[4132] Teva, however, did not specify which particular submissions it considered to contain such information. The Commission considers that Teva has gone no further than its duty to cooperate during inspections and subsequent dealings with the Commission as specified in Regulation (EC) No 1/2003. Teva has not voluntarily, for example, submitted information that helped the Commission significantly to establish the infringements and the Commission therefore considers that there are no exceptional circumstances present in this case that could justify granting a reduction of the fine for effective cooperation falling outside the Leniency Notice to Teva.

(3176) Matrix argued that it had only limited involvement in the settlement negotiations as Niche took the leading role in the negotiations and Matrix only became aware of the settlement negotiations late in the process.[4133] The Commission recalls that Matrix signed the settlement agreement in its own right and that it gave up on competing with Servier in return for a substantial cash payment. Moreover, Matrix did not demonstrate that during the period in which it was party to the offending agreement, it actually avoided applying it by adopting competitive conduct in the market as required by the Guidelines on fines.[4134] The argument that Matrix should benefit from its limited role must be therefore rejected.

(3177) Matrix further submitted that it had no prospect of entering the market at the time of the Settlement Agreement and the only realistic option it had was to recoup its investment in the project by entering the Settlement Agreement.[4135] This argument cannot be accepted. The risk of incurring losses is inherent in the process of competition. The fact that an undertaking would be faced with such risk cannot be an excuse for it to engage in practices that restrict competition.

10.2.4.6 Application of the 10% turnover limit

(3178) Article 23(2) of Regulation (EC) No 1/2003 provides that the fine imposed on each undertaking shall not exceed 10% of its total turnover relating to the business year preceding the date of the Commission decision.

Niche/Unichem

(3179) As indicated in section 9.3, Unichem Laboratories Limited and Niche Generics Limited should be held jointly and severally liable. The basic amount set out in paragraph (3162) does exceed 10% of the total turnover of Unichem Laboratories Limited, the parent company of the undertaking Niche/Unichem, in the last full business year.[4136] The final amount of the fine should therefore be reduced to EUR 13 968 773.

Matrix

(3180) The basic amount set out in paragraph (3162) does not exceed 10% of the total turnover of Matrix Laboratories Limited (now Mylan Laboratories Limited) in the last full business year. [4137]

4132 ID9300, p. 169.
4133 ID8835, p. 69.
4134 See point 29, third indent.
4135 ID8835, p. 69 and 70.
4136 Based on the period 1 April 2013 to 31 March 2014, see ID10817.
4137 Based on the period 1 April 2012 to 31 March 2013, see ID10685.

(3181) For Mylan Inc. held liable in its capacity as parent company, account has to be taken of the reduced duration of its liability as determined in section 9.4: from 8 January 2007 until 15 September 2008, namely a period of 617 days.

(3182) The basic amount corresponding to the period of the infringement for which Matrix Laboratories Limited (now Mylan Laboratories Limited) and Mylan Inc. are jointly and severally liable, i.e. EUR 8 045 914 [4138] does not exceed 10% of the total turnover of Mylan Inc., the parent company of the undertaking Matrix, in the last full business year.[4139]

Teva

(3183) As indicated in section 9.5, Teva UK Limited, Teva Pharmaceuticals Europe B.V. and Teva Pharmaceutical Industries Limited should be held jointly and severally liable. The basic amount set out in paragraph (3162) does not exceed 10% of the total turnover of Teva Pharmaceutical Industries Limited, the parent company of the undertaking Teva, in the last full business year.[4140]

Krka

(3184) The basic amount set out in paragraph (3162) does not exceed 10% of the total turnover of Krka, d.d., Novo Mesto, in the last full business year.[4141]

Lupin

(3185) The basic amount set out in paragraph (3162) does not exceed 10% of the total turnover of Lupin Limited, in the last full business year.[4142]

10.2.4.7 Conclusion: final amount of fines for Niche/Unichem, Matrix, Teva, Krka and Lupin

(3186) The final amounts of the fines to be imposed pursuant to Article 23(2) of Regulation (EC) No 1/2003 on Niche/Unichem, Matrix, Teva, Krka and Lupin should be as follows:

4138 The Matrix infringement lasted from 8 February 2005 to 15 September 2008, that is a period of 1,316 days. Mylan exercised decisive influence over Matrix as of 8 January 2007 till the end of the infringement period, that is a period of 617 days. Mylan is found jointly and severally liable for a part of the fine proportional to the period it exercised decisive influence over Matrix, i.e. for EUR 8 045 914 (equal to 617/1316 * EUR 17 161 140).

4139 Based on the period 1 January 2013 to 31 December 2013, see ID10685.

4140 Based on the period 1 January 2013 to 31 December 2013, see ID10663.

4141 Based on the period 1 January 2013 to 31 December 2013, see ID10642.

4142 Based on the period 1 April 2013 to 31 March 2014, see ID10828.

Undertaking	**Amount of fine**
Niche/Unichem	Unichem Laboratories Limited and Niche Generics Limited, jointly and severally: EUR 13 968 773 **Total amount:** EUR 13 968 773
Matrix	Matrix Laboratories Limited (now Mylan Laboratories Limited): EUR 17 161 140 of which jointly and severally with Mylan Inc.: EUR 8 045 914 **Total amount:** EUR 17 161 140
Teva	Teva UK Limited; Teva Pharmaceuticals Europe B.V. and Teva Pharmaceutical Industries Ltd, jointly and severally: EUR 15 569 395 **Total amount:** EUR 15 569 395
Krka	Krka, tovarna zdravil, d.d., Novo mesto: EUR 10 000 000 **Total amount:** EUR 10 000 000
Lupin	Lupin Limited: EUR 40 000 000 **Total amount:** EUR 40 000 000

11 CONCLUSION

(3187) In the light of the considerations set out in this Decision,

(1) Servier S.A.S.; Les Laboratoires Servier; Servier Laboratories Limited; Biogaran; Niche Generics Limited; Unichem Laboratories Limited; Matrix Laboratories Limited (now Mylan Laboratories Limited); Mylan Inc.; Teva UK Limited; Teva Pharmaceuticals Europe B.V.; Teva Pharmaceutical Industries Ltd; Krka, tovarna zdravil, d.d., Novo mesto; and Lupin Limited should be held liable for the infringement of Article 101 of the Treaty, and fines should be imposed on them pursuant to Article 23(2) of Regulation (EC) No 1/2003;

(2) Servier S.A.S. and Les Laboratoires Servier should be held liable for the infringement of Article 102 of the Treaty and fines should be imposed on them pursuant to Article 23(2) of Regulation (EC) No 1/2003.

HAS ADOPTED THIS DECISION:

Article 1

The following undertakings infringed Article 101 of the Treaty by participating in an agreement, for the period of the infringement indicated below, covering all Member States except Italy and Croatia, as follows:

(a) Unichem:

(i) Niche Generics Limited;

(ii) Unichem Laboratories Limited.

(b) Servier:

(i) Servier S.A.S.;

(ii) Les Laboratoires Servier;

(iii) Servier Laboratories Limited;

(iv) Biogaran.

The start date of the infringement was 8 February 2005, except as regards: Latvia, where the infringement started on 1 July 2005; Bulgaria and Romania, where the infringement started on 1 January 2007; and Malta, where the infringement started on 1 March 2007.

The end date of the infringement was 15 September 2008, except as regards: the United Kingdom, where the infringement ended on 6 July 2007; and the Netherlands, where the infringement ended on 12 December 2007.

Article 2

The following undertakings infringed Article 101 of the Treaty by participating in an agreement, for the period of the infringement indicated below, covering all Member States except Italy and Croatia, as follows:

(a) Mylan:

(i) Mylan Laboratories Limited (formerly known as Matrix Laboratories Limited), for the entire period of this infringement;

(ii) Mylan Inc., from 8 January 2007 until the end date of the infringement.

(b) Servier:

(i) Servier S.A.S., for the entire period of this infringement;

(ii) Les Laboratoires Servier, for the entire period of this infringement.

The start date of the infringement was 8 February 2005, except as regards: Latvia, where the infringement started on 1 July 2005; Bulgaria and Romania, where the infringement started on 1 January 2007; and Malta, where the infringement started on 1 March 2007.

The end date of the infringement was 15 September 2008, except as regards: the United Kingdom, where the infringement ended on 6 July 2007; and the Netherlands, where the infringement ended on 12 December 2007.

Article 3

The following undertakings infringed Article 101 of the Treaty by participating, from 13 June 2006 to 6 July 2007, in an agreement covering the United Kingdom:

(a) Teva:

(i) Teva UK Limited;

(ii) Teva Pharmaceuticals Europe B.V.;

(iii) Teva Pharmaceutical Industries Ltd.

(b) Servier:

(i) Servier S.A.S.;

(ii) Les Laboratoires Servier;

(iii) Servier Laboratories Limited.

Article 4

The following undertakings infringed Article 101 of the Treaty by participating, for the period of the infringement indicated below, in three agreements which constitute a single and continuous infringement, covering all Member States except Croatia, the Czech Republic, Hungary, Latvia, Lithuania, Poland, Slovakia and Slovenia:

(a) Krka:

(i) Krka, tovarna zdravil, d.d., Novo mesto.

(b) Servier:

(i) Servier S.A.S.;

(ii) Les Laboratoires Servier.

The start date of the infringement was 27 October 2006, except as regards: Bulgaria and Romania, where the infringement started on 1 January 2007; Malta, where the infringement started on 1 March 2007; and Italy, where the infringement started on 13 February 2009.

The end date of the infringement was 6 May 2009, except as regards: the United Kingdom, where the infringement ended on 6 July 2007; and the Netherlands, where the infringement ended on 12 December 2007.

Article 5

The following undertakings infringed Article 101 of the Treaty by participating, for the period of the infringement indicated below, in an agreement covering all Member States except Croatia:

(a) Lupin:

(i) Lupin Limited.

(b) Servier:

(i) Servier S.A.S.;

(ii) Les Laboratoires Servier.

The start date of the infringement was 30 January 2007, except as regards: Malta, where the infringement started on 1 March 2007; and Italy, where the infringement started on 13 February 2009.

The end date of the infringement was 6 May 2009, except as regards: the United Kingdom, where the infringement ended on 6 July 2007; the Netherlands, where the infringement ended on 12 December 2007; and France, where the infringement ended on 16 September 2008.

Article 6

The following undertakings infringed Article 102 of the Treaty by devising and implementing through a technology acquisition and five reverse payment patent settlement agreements, for the period of the infringement indicated below, an exclusionary strategy which amounted to a single and continuous infringement, covering the perindopril formulation market in France, the Netherlands, Poland and the United Kingdom and the market for perindopril API technology:

(a) Servier:

(i) Servier S.A.S.;

(ii) Les Laboratoires Servier.

The start date of the infringement was 9 November 2004. The end date of the infringement was 6 May 2009, except as regards: the United Kingdom, where the infringement ended on 6 July 2007; and the Netherlands, where the infringement ended on 12 December 2007.

Article 7

1. For the infringement referred to in Article 1, the following fines are imposed:

(a) Niche Generics Limited and Unichem Laboratories Limited, jointly and severally liable: EUR 13 968 773;

(b) Servier S.A.S.; Les Laboratoires Servier; Servier Laboratories Limited, and Biogaran, jointly and severally liable: EUR 131 532 600.

2. For the infringement referred to in Article 2, the following fines are imposed:

   (a) Mylan Laboratories Limited: EUR 17 161 140, of which EUR 8 045 914, jointly and severally liable with Mylan Inc.;

   (b) Servier S.A.S. and Les Laboratoires Servier, jointly and severally liable: EUR 79 121 700.

3. For the infringement referred to in Article 3, the following fines are imposed:

   (a) Teva UK Limited; Teva Pharmaceuticals Europe B.V. and Teva Pharmaceutical Industries Ltd, jointly and severally liable: EUR 15 569 395;

   (b) Servier S.A.S.; Les Laboratoires Servier and Servier Laboratories Limited, jointly and severally liable: EUR 4 309 000.

4. For the infringement referred to in Article 4, the following fines are imposed:

   (a) Krka, tovarna zdravil, d.d., Novo mesto: EUR 10 000 000;

   (b) Servier S.A.S. and Les Laboratoires Servier, jointly and severally liable: EUR 37 661 800.

5. For the infringement referred to in Article 5, the following fines are imposed:

   (a) Lupin Limited: EUR 40 000 000;

   (b) Servier S.A.S. and Les Laboratoires Servier, jointly and severally liable: EUR 37 102 100.

6. For the infringement referred to in Article 6, the following fines are imposed:

   (a) Servier S.A.S.: EUR 41 270 000,

   of which EUR 41 270 000, jointly and severally liable with Les Laboratoires Servier.

The fines shall be credited, in euros, within a period of three months from the date of notification of this Decision to the following bank account held in the name of the European Commission:

BANQUE ET CAISSE D'EPARGNE DE L'ETAT
1–2, Place de Metz
L-1930 Luxembourg

IBAN: LU02 0019 3155 9887 1000
BIC: BCEELULL
Ref.: European Commission – BUFI /AT.39612

After the expiry of this period, interest will automatically be payable at the interest rate applied by the European Central Bank to its main refinancing operations on the first day of the month in which this Decision is adopted, plus 3.5 percentage points.

Where an undertaking referred to in Article 1 lodges an appeal, that undertaking must cover the fine by the due date, either by providing an acceptable financial guarantee, or by making a

provisional payment of the fine in accordance with Article 90 of Commission Delegated Regulation (EU) No 1268/2012[4143].

Article 8

The undertakings listed in Articles 1 to 6 shall refrain from repeating any act or conduct described in Articles 1 to 6, and from any act or conduct having the same or similar object or effect.

Article 9

This Decision is addressed to:

Servier S.A.S. Société par actions simplifiée	50 rue Carnot 92284 Suresnes cedex France
Servier Laboratories Limited Private company limited by shares	Rowley, Wexham Springs Framewood Road, Wexham, Slough SL3 6PJ United Kingdom
Les Laboratoires Servier Société par actions simplifiée	50 rue Carnot 92284 Suresnes cedex France
Biogaran Société par actions simplifiée	15 boulevard Charles de Gaulle 92707 Colombes cedex France
Krka, tovarna zdravil, d.d., Novo mesto	Šmarješka cesta 6 8501 Novo mesto Slovenia

[4143] OJ L 362, 31.12.2012, p. 1.

Lupin Limited	B/4 Laxmi Towers Bandra Kurla Complex Mumbai 400 051 Maharashtra India
Mylan Laboratories Limited	Plot No. 564/A/22 Road No. 92 Jubilee Hills Hyderabad 500 034 Andhra Pradesh India
Mylan Inc.	1000 Mylan Boulevard Canonsburg PA, 15317 United States
Niche Generics Limited	1 The Cam Centre Wilbury Way Hitchin Hertfordshire SG4 0TW United Kingdom
Unichem Laboratories Limited	Unichem Bhavan Prabhat Estate Off S. V. Road Jogeshwari (West) Mumbai – 400 102 India

Teva UK Limited	Ridings Point Whistler Drive Castleford West Yorkshire, WF 10 5HX United Kingdom
Teva Pharmaceuticals Europe B.V.	Piet Hein Building, Piet Heinkade 107 1019 GM Amsterdam The Netherlands
Teva Pharmaceutical Industries Ltd	5 Basel Street P.O. Box 3190 49131 Petach Tikva Israel

This Decision shall be enforceable pursuant to Article 299 of the Treaty.

Done at Brussels, 9 July 2014

For the Commission

Joaquín ALMUNIA
Vice-President

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION