



CASE AT.39226 - LUNDBECK

(Only the English text is authentic)

ANTITRUST PROCEDURE Council Regulation (EC) 1/2003

Article 7 Regulation (EC) 1/2003

Date: 19/06/2013

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Brussels, 19.6.2013
C(2013) 3803 final

COMMISSION DECISION

of 19.6.2013

addressed to

- **Lundbeck Limited**
- **H. Lundbeck A/S**
- **Generics [UK] Limited**
- **Merck KGaA**
- **Arrow Generics Limited**
- **Arrow Group ApS**
- **Resolution Chemicals Limited**
- **Xellia Pharmaceuticals ApS**
- **Zoetis Products LLC**
- **A.L. Industrier AS**
- **Ranbaxy (U.K.) Limited**
- **Ranbaxy Laboratories Limited**

**relating to a proceeding under Article 101 of the Treaty on the Functioning of the
European Union and Article 53 of the EEA Agreement**

AT.39226 - LUNDBECK

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COMMISSION DECISION

of 19.6.2013

addressed to

- Lundbeck Limited
- H. Lundbeck A/S
- Generics [UK] Limited
- Merck KGaA
- Arrow Generics Limited
- Arrow Group ApS
- Resolution Chemicals Limited
- Xellia Pharmaceuticals ApS
- Zoetis Products LLC
- A.L. Industrier AS
- Ranbaxy (U.K.) Limited
- Ranbaxy Laboratories Limited

relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement

AT.39226 - LUNDBECK

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union¹,

Having regard to the Agreement on the European Economic Area,

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 Treaty², and in particular Article 7 and Article 23(2) thereof,

Having regard to the Commission decisions of 7 January 2010 and 24 July 2012 to initiate proceedings in this case,

¹ OJ C 115, 9.5.2008, page 47.

² OJ L 1, 4.1.2003, page 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 Article 101 and 102 TFEU 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 Treaty³,

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

Having regard to the final report of the hearing officer in this case⁴,

Whereas:

1. INTRODUCTION

(1) This Decision concerns six agreements which operated in the years 2002 and 2003 (hereafter also referred to as "the period concerned") between the Danish originator pharmaceutical undertaking Lundbeck on the one hand and each of four generic pharmaceutical undertakings on the other hand. The generic pharmaceutical undertakings concerned by this Decision are:

- Merck: two agreements with Lundbeck, one regarding the United Kingdom (from 24 January 2002 until 1 November 2003), one regarding the EEA excluding the United Kingdom (from 22 October 2002 until 22 October 2003);
- Arrow: two agreements with Lundbeck, one regarding the United Kingdom (from 24 January 2002 until 20 October 2003), one regarding Denmark (from 3 June 2002 until 1 April 2003);
- Alpharma: one agreement with Lundbeck regarding the EEA (from 22 February 2002 until 30 June 2003); and
- Ranbaxy: one agreement with Lundbeck regarding the EEA (from 16 June 2002 until 31 December 2003).

These six agreements will hereafter also be referred to as "the agreements in question", "the agreements covered by this Decision" or "the agreements that are the subject of this Decision."

(2) The product concerned by each of the agreements was the anti-depressant citalopram, whether in the form of an active pharmaceutical ingredient (hereafter also referred to as 'API') or in the form of a medicinal product (hereafter also referred to as 'medicine').⁵

³ OJ L 123, 27.4.2004, page 18.

⁴ OJ

⁵ Article 1 of Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended (OJ L 311, 28.11.2004, pages 67 to 128), defines a 'medicinal product' as "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis." Article 10(2)(b) of the same Directive defines a 'generic medicinal product' as "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal

- (3) At the time the agreements were concluded, Lundbeck's patents and data protection on the citalopram compound and the two original production processes had expired, meaning that Lundbeck no longer had complete blocking power against production and sales of citalopram by generic undertakings. Lundbeck did still have a number of process patents, which gave Lundbeck exclusivity rights on certain (but not all) new ways of producing citalopram to the extent such patents would be found to be valid and infringed. But any undertaking using either the original production processes or any production process not covered by valid Lundbeck process patents could in principle freely enter EEA markets with generic citalopram, provided the product and its production process met regulatory requirements applicable in the EEA at that time.
- (4) Each of the agreements was concluded in the context of at least a potential patent dispute⁶ between Lundbeck and the generic undertaking concerned regarding the (intended) marketing by the generic undertaking of citalopram API or medicine in the geographic area concerned by the agreement. Prior to the agreements concerned, Lundbeck had usually claimed infringement of one or more of its process patents and the generic undertaking concerned had usually claimed non-infringement of the patent(s) concerned or invalidity of the patent(s) Lundbeck invoked. Each of the agreements was concluded before a court ruling on these issues was given, even by way of interim measures, and all except one (Lundbeck's agreement with Alpharma regarding the EEA) were concluded before any litigation had started.
- (5) The Commission wants to emphasise that it is not, of course, as such illegal to settle patent disputes. Patent dispute settlements are, in principle, a generally accepted, legitimate way of ending private disagreements. They can also save courts or competent administrative bodies such as patent offices' time and effort and can therefore be in the public interest. Lundbeck in fact concluded several patent settlements on citalopram that are not the subject of this Decision.
- (6) What is important from the perspective of Union competition law is that each of the agreements covered by this Decision prohibited entry by a potential competitor. Each agreement was characterised by the fact that it contained a transfer of value from Lundbeck to a potential or actual generic competitor, which was related to the latter's agreement not to market generic citalopram in the geographic area concerned for the duration of the agreement. The value which Lundbeck transferred, took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market. The agreements in question did not resolve any patent dispute; they rather postponed the issues raised by potential generic market entry. It was also established that the agreements contained no commitment from Lundbeck to refrain from infringement proceedings if the generic undertaking entered the market with generic citalopram after expiry of the agreement. Finally, the agreements concerned obtained results for Lundbeck that Lundbeck could not have achieved by enforcing its process patents before the national courts: Each of the agreements in question prevented the generic company concerned from selling

product has been demonstrated by appropriate bioavailability studies." See chapter 5 for a further description of the medicinal product in this case, citalopram.

⁶ The term "patent dispute" as used in this Decision refers to a disagreement between two or more parties over a patent and includes the notion of patent litigation as one possible stage of such a dispute.

generic citalopram, irrespective of whether such citalopram would be produced in infringement of Lundbeck's process patents.

- (7) This Decision examines the agreements in question under the competition provisions of Article 101 of the Treaty on the Functioning of the European Union (hereafter also referred to as "the Treaty") and of the corresponding Article 53 of the EEA Agreement. This Decision finds that the agreements in question infringed Article 101 of the Treaty and, where appropriate in light of the geographic scope of the agreement, Article 53 EEA, in that they had the object of restricting competition. As the two agreements between Merck and Lundbeck should be considered a single and continuous infringement, and as the same applies for the two agreements between Arrow and Lundbeck, the Commission finds four separate infringements.

2. PROCEDURE

2.1. The Commission's investigation

- (8) The Commission first became aware of the agreements in question in October 2003 through information from the Danish Competition Authority. As most of the agreements covered the EEA or other parts of the EEA than Denmark, it was agreed at that time with the Danish Competition Authority that the Commission would further examine the legality of the agreements under Union competition law. In consequence, the Danish Competition Authority did not pursue the matter further.
- (9) Between December 2003 and October 2005, while the Commission was pursuing its examination of the agreements in question, it also became aware, *inter alia* through information from the Hungarian Competition Authority, of other behaviour of Lundbeck that in the Commission's view required further examination. As a result, inspections pursuant to Article 20(4) Council Regulation (EC) No 1/2003⁷ took place in October 2005 at the premises of:
- H. Lundbeck A/S in Denmark;
 - Lundbeck Pharmaceuticals Italy S.p.A. (formerly known as VIS Farmaceutici S.p.A.) in Italy;
 - Lundbeck Hungária Kft in Hungary; and
 - [company name]*.
- (10) Based on the Commission's analysis of the documents gathered during the inspections, requests for information were sent in 2006 to:
- the Hungarian Competition Authority in April 2006 pursuant to Article 12 of Council Regulation (EC) No 1/2003;
 - the Danish Competition Authority in June 2006 pursuant to Article 12 of Council Regulation (EC) No 1/2003;
 - [company name]* in July 2006 pursuant to Article 18(2) of Regulation (EC) No 1/2003;

⁷ 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, OJ L 1, 4.1.2003, pages 1 to 25.

* Parts of this text have been edited to ensure that confidential information is not disclosed. Those parts are replaced by a non-confidential summary in square brackets or are shown as [...].

- H. Lundbeck A/S in July 2006 pursuant to Article 18(2) of Regulation (EC) No 1/2003; and
 - the Competition Authorities of the Member States in August 2006 (covering national rules on pricing, reimbursement and substitution).
- (11) Throughout 2007, the replies to these requests for information were examined and preliminary work on establishing the Commission's position in respect of Lundbeck's practices and those of other undertakings involved took place.
- (12) In January 2008, the Commission decided to launch a broad inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003.⁸ This inquiry helped the Commission to obtain a better understanding of the regulatory and economic framework within which originator and generic undertakings operate in the pharmaceutical sector in EEA and, in particular, of possible competition issues in this sector, including with respect to observed delays in the entry of generic medicines to the market. The final report of the sector inquiry was released on 8 July 2009.
- (13) In December 2009, the Commission conducted inspections pursuant to Article 20(4) in Italy at the premises of Lundbeck Italia S.p.A. and [company names]*. These inspections allowed the Commission to exclude from this Decision a settlement concluded between Lundbeck on the one hand and [company names]* on the other hand.
- (14) On 7 January 2010, the Commission opened formal proceedings against Lundbeck. The Commission's press statement indicated:
- "The knowledge acquired during the pharmaceutical sector inquiry..., specifically on ways originator companies use [to] obstruct the entry of generic drugs onto the market, has allowed the Commission to draw conclusions on where Commission action based on competition law could be appropriate and effective. The Commission has decided that the investigation focusing on Lundbeck's conduct should be dealt with as a matter of priority, and as a result has opened proceedings."*⁹
- (15) In 2010 and the first half of 2011, while preparing the current Decision, the Commission sent out a considerable number of requests for information to Lundbeck, the generic companies with which the agreements concerned were concluded, their parent companies and third parties, including notably IMS Health, a data provider in the health sector.
- (16) On 24 July 2012, the Commission opened proceedings against the generic companies that concluded the agreements concerned with Lundbeck and issued a Statement of Objections to Lundbeck and to those generic companies.
- (17) A hearing was held with all parties who had requested a hearing on 14 and 15 March 2013.
- (18) On 12 April 2013, the Commission sent a Letter of Facts to all parties. On 6 May 2013, the Commission sent an additional Letter of Facts to Merck KGaA and A.L. Industriier AS related to chapters 3 and 15 of this Decision.

⁸ Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003 (Case No COMP/D2/39.514).

⁹ IP/10/8 of 7 January 2010.

- (19) The Hearing Officer issued his final report on 17 June 2013.

2.2. The main evidence relied on

- (20) The main evidence relied on is the actual text of the agreements concluded between Lundbeck and each of the generic undertakings concerned, together with documents found during the inspections and replies to requests for information. These documents concern in particular the negotiation, conclusion and implementation of the agreements covered by this Decision.¹⁰
- (21) In order to respond to the Commission's requests for information requesting relevant contemporaneous documents, Lundbeck established a list of "custodians" whose documents were searched by Lundbeck to identify relevant documents. This list of individuals included three [position in Lundbeck]*, three [position in Lundbeck]*, four [position in Lundbeck]*, two [position in Lundbeck]*, one [position in Lundbeck]* and three [position in Lundbeck]* (one of whom was the [position in Lundbeck]*).¹¹ Most of the Lundbeck documents referred to in this Decision either originated with one or more of these senior managers or were sent to one or more of them. Knowledge of the facts identified in this Decision therefore existed at the highest levels of the undertaking Lundbeck.¹² Indeed, the same [position in Lundbeck]* of Lundbeck signed all but one of the six agreements, while the remaining one was signed by a [position in Lundbeck]* of Lundbeck.
- (22) As for the generic companies, participation in the negotiation, conclusion and implementation of the agreements covered by this Decision occurred at the highest levels of the legal entities concluding the agreements. Merck (GUK)'s agreement for the United Kingdom was signed by Merck (GUK)'s [employee function]*. Merck (GUK)'s agreement for other Contracting Parties of the EEA Agreement than the United Kingdom was signed by the [employee function]* of the Merck Generics Group.¹³ Arrow's agreement regarding the United Kingdom was signed by [employee name]*, who was at that time [...] of the two Arrow companies that signed the agreement, Arrow Generics Limited and of Resolution Chemicals Ltd. Arrow's agreement with Denmark was signed by a [employee function]* of Arrow Group A/S, at that time the parent company of the Arrow Group. As for Alpharma, its agreement with Lundbeck was signed by the [employee function]* and the [employee function]* of Alpharma ApS, the legal entity within the Alpharma group that concluded the agreement. For Ranbaxy, the agreement was signed by an [employee function]* of the parent company in India.

3. UNDERTAKINGS SUBJECT TO THE PRESENT PROCEEDINGS

3.1. Introduction

- (23) The undertakings described below in sections 3.2 to 3.6 below are undertakings that are subject to the present proceedings. Section 3.7 below briefly describes certain other market players, which are not subject to these proceedings, but which played a relevant role in the events described in this Decision.

¹⁰ 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.

¹¹ ID 577, page 6.

¹² See also ID 2057.

¹³ ID 1977, page 1.

3.2. Lundbeck

- (24) H. Lundbeck A/S, the parent company of the Lundbeck group of companies, is based in Denmark and is a publicly-traded corporation ("Aktieselskab" or "A/S"). It has been listed on the Copenhagen stock exchange since 1999. About 70% of its shares are owned by the Lundbeck Foundation, while the remaining 30% are traded on the stock exchange.¹⁴ The Lundbeck group of companies as a whole in the period concerned will hereafter be referred to as "Lundbeck".
- (25) Lundbeck, founded in 1915, is a pharmaceutical undertaking specializing in the research, development, manufacturing, marketing, selling and distribution of pharmaceuticals for the treatment of disorders in the central nervous system (CNS), including depression, schizophrenia, Alzheimer's disease, Parkinson's disease, Huntington's disease, epilepsy and insomnia. In the period concerned, CNS medicines represented around 15% of the total spectrum of sales of pharmaceuticals.¹⁵ Lundbeck is a so-called "originator" undertaking, a term used for pharmaceutical undertakings that specialise in developing new medicines and bringing them to the market. In the period concerned, Lundbeck employed around 5 000 people worldwide.¹⁶ At that time Lundbeck was an important global player in the area of medicines for CNS disorders¹⁷.
- (26) Lundbeck concluded the agreements that are the subject of this Decision in 2002 and 2003. In 2002, Lundbeck's sales of citalopram in the EEA amounted to EUR [400-600]* million.¹⁸ This figure represented [80-90]* per cent of Lundbeck's total sales revenue of EUR [400-600]* million for all products and services in that year in the EEA.¹⁹ Lundbeck was therefore, at that time, heavily dependent for its revenues on sales of citalopram. Lundbeck's sales of citalopram in the United Kingdom in 2002 were EUR [40-150]* million²⁰ and those in Denmark in 2002 EUR [0-30]* million.²¹ The total worldwide sales revenue of Lundbeck for all products and services in 2002 was EUR 1 278 million.²² In 2011, the worldwide consolidated turnover for all products and services of H. Lundbeck A/S was EUR 2 148 million.²³
- (27) In the period concerned the undertaking Lundbeck was composed of a considerable number of companies around the world, participating in the group's research and development, manufacturing and sales on a global scale. All of these companies were, directly or indirectly, wholly owned by H. Lundbeck A/S.²⁴ Lundbeck had its own synthesis factories in Denmark, the United Kingdom and Italy. In the period concerned, Lundbeck had sales subsidiaries in virtually all of the then EEA member countries²⁵, selling citalopram mainly under the brand names Cipramil and

¹⁴ Lundbeck website, <http://www.lundbeck.com>.

¹⁵ ID 9, page 656.

¹⁶ ID 1499, page 9.

¹⁷ ID 291, page 22.

¹⁸ ID 972.

¹⁹ ID 972, page 2.

²⁰ ID 983, page 18.

²¹ ID 970, page 20.

²² ID 1499, page 6.

²³ Using an average annual exchange rate for 2011 of 1 EUR = 7.4506 DKK. Source European Central Bank. See ID 4408.

²⁴ ID 841, page 2.

²⁵ ID 1499, page 101.

Seropram²⁶ depending on the Member State. In a few Member States, Lundbeck also sold citalopram in partnership with local or generic pharmaceutical companies. Lundbeck had a co-marketing partnership for the sale of citalopram in Italy with Recordati (selling under the brand name Elopram) and in Spain with Almirall Prodesfarma (selling under the brand name Prisdal). In Denmark, in anticipation of expiry in January 2002 of its patent on the citalopram compound, Lundbeck authorised the company Nycomed to distribute citalopram under the brand name Akarin.²⁷ After expiry of the compound patent, Lundbeck also introduced rebranded versions of its own citalopram in Finland and Sweden.²⁸ In the United Kingdom, as part of the agreements that are the subject of this Decision, Lundbeck allowed the generic undertakings Merck and Ranbaxy to distribute a certain amount of citalopram, to be sold under Lundbeck's brand name Cipramil.²⁹

- (28) H. Lundbeck A/S is the legal entity within the Lundbeck group that signed all except one of the agreements that are the subject of this proceeding. The remaining one was signed by Lundbeck Limited, Lundbeck's 100%-owned United Kingdom sales subsidiary. The worldwide consolidated turnover for all products and services of Lundbeck Limited in 2011 was EUR 53 million.³⁰

3.3. Merck

- (29) The company Generics [UK] Limited (hereafter also referred to as "Merck (GUK)") is a United Kingdom company established in 1981. In the period concerned, Merck (GUK) was an indirect 100% subsidiary of the German company Merck KGaA³¹, the ultimate parent company of the Merck group of companies, including of the Merck Generics Group of companies within which Merck (GUK) functioned. The group of Merck companies as a whole in the period concerned will hereafter be referred to as "Merck".³²
- (30) In the period concerned, Merck (GUK) was engaged in the development, production and marketing of generic pharmaceutical products. Within the Merck Generics Group, Merck (GUK) was not only responsible for marketing generic medicines in the United Kingdom, but acted, in the words of Merck KGaA, as *"the operative lead company for MG's [Merck Generic's] European business... it appears that all material decisions relating to the European business had to 'go through the UK'."*³³ Merck (GUK) also acted as the raw material support group for the entire Merck Generics Group in the EEA.³⁴ In this capacity it bought APIs (including citalopram

²⁶ ID 1053, page 137. This Decision will generally use the non-proprietary name citalopram, also when referring to citalopram sold by Lundbeck.

²⁷ ID 813, page 8.

²⁸ ID 9, page 331.

²⁹ See sections 7.2 and 7.7 respectively.

³⁰ Using an average annual exchange rate for 2011 of 1 EUR = 0.8679 GBP. Source European Central Bank. See ID 4408.

³¹ In the period concerned notably via the legal entities Merck Generics Group B.V., which owned 100% of Generics (UK) Ltd, and via Merck Generics Holding GmbH, which owned 100% of Merck Generics Group B.V. Merck Generics Holding GmbH was 100% owned by Merck KGaA, first indirectly and later directly. See ID 516, pages 11 to 16.

³² The company Generics [UK] Limited as a party to the proceedings will hereafter be referred to as "GUK". The company Merck KGaA as a party to the proceedings will hereafter be referred to as "Merck KGaA".

³³ ID 1707, page 1; ID 5960, page 371.

³⁴ See for instance ID 673, page 95.

API) for the entire Merck Generics Group in the EEA.³⁵ Moreover, as Merck KGaA explained at the Oral Hearing, "*GUK, although being just a sister out of many generic companies, was having almost a full set of business operations and as such was delivering all the services to all its sister companies.*"³⁶ Merck KGaA specified that "*its sister companies*" meant sister companies within the Generics Group.³⁷ Although Merck (GUK) formed part of the Merck Generics Group and the Merck group of companies, Merck (GUK)'s logo remained different from the logo used by other Merck companies, also after Merck had implemented certain corporate identity measures.³⁸ In 2002, Merck (GUK) concluded two of the agreements with Lundbeck that are the subject of this Decision, one concerning the United Kingdom and one concerning the EEA excluding the United Kingdom.

- (31) Merck (GUK)'s worldwide turnover for all products and services in 2002 was EUR 95 million.³⁹ However, Merck (GUK) did not have any sales revenue for citalopram in 2002 in the United Kingdom and hardly any in the rest of the EEA, the geographic areas for which it concluded agreements with Lundbeck, because in these agreements Merck (GUK) agreed not to sell citalopram in those areas.
- (32) In the period concerned, Merck (GUK)'s accounts were consolidated with Merck KGaA's accounts.⁴⁰ Furthermore, on 15 January 2002, Merck KGaA entered into a domination and profit & loss transfer agreement ("*Beherrschungs- und Gewinnabführungsvertrag*") with Merck Generics Holding GmbH.⁴¹
- (33) In October 2007, Merck KGaA sold the Merck Generics business, including all shares in Merck (GUK), to the American company Mylan Inc., the ultimate parent company of the Mylan group of companies (hereafter also collectively referred to as "*Mylan*"). Mylan is a pharmaceutical undertaking focusing on the production and sale of generic medicines. Since its acquisition by Mylan, the company Generics [UK] Limited has continued to exist as a separate legal entity and to be active in the generics business, with its own turnover and assets. In 2010, the worldwide consolidated turnover for all products and services of Generics [UK] Limited was EUR 88 million.⁴²
- (34) In 2011, the worldwide consolidated turnover for all products and services of Merck KGaA was EUR 10.2 billion.⁴³

3.4. Arrow

- (35) The company Arrow Generics Limited is a United Kingdom company established in 2001. Until February 2002, Arrow Generics Limited was a wholly-owned subsidiary

³⁵ See for instance the preferred supplier agreement Merck (GUK) concluded, on behalf of the Merck Generics Group, with the Swiss company Schweizerhall on citalopram from the Indian API producer Natco, ID 670, page 52. See also ID 1509, page 1.

³⁶ Recording of the Oral Hearing of 14 March 2013, ID 6775, at: 5:11-5:12.

³⁷ See ID 6991, page 4.

³⁸ ID 6633, page 56.

³⁹ Using an annual exchange rate for 2002 of 1 EUR = 0.62883 GBP, source European Central Bank.

⁴⁰ See ID 516, pages 11 to 16.

⁴¹ ID 5982.

⁴² See ID 1534, page 1 and ID 3670, page 1 (using an annual exchange rate for 2010 of 1 EUR = 0.85784 GBP, source European Central Bank); at the time of writing, Generics [UK] Limited did not yet have its 2011 revenue figures available in audited form.

⁴³ ID 3828.

of Arrow Group A/S in Denmark. In February 2002, as a result of a new share issue, the percentage ownership by Arrow Group A/S of Arrow Generics Limited was diluted to 76%, with 24% of shares being distributed among individual key staff members of Arrow Generics Limited.⁴⁴

- (36) Arrow Group A/S, which was established in 2000, was in the period concerned also the 100% parent company of Arrow Group sales subsidiaries in France and Sweden and moreover wholly owned the company Resolution Chemicals Ltd, a producer of generic APIs for the Arrow Group of companies.⁴⁵ As of 15 May 2003, Arrow Group A/S became itself wholly-owned by the holding company Arrow International Limited, incorporated in Malta, which in turn at that time became a wholly-owned subsidiary of the company Robin Hood Holdings Limited, also incorporated in Malta. This group structure is still unchanged, with two exceptions: Arrow Group A/S was re-named Arrow Group ApS in August 2003 and Resolution Chemicals Ltd was divested from the Arrow Group in 2009.⁴⁶ The latter is at present an independent company. In 2011, the worldwide consolidated turnover for all products and services of Resolution Chemicals Ltd was EUR 10.2 million.⁴⁷
- (37) In the period concerned, the principal activity of the Arrow group of companies was the development and marketing of generic pharmaceutical products. The Arrow group began trading in 2001. Resolution Chemicals Ltd was at that time engaged in its own project to develop citalopram API.⁴⁸
- (38) In 2002, the Arrow Group concluded, through its United Kingdom subsidiaries Arrow Generics Limited and Resolution Chemicals Ltd, an agreement with Lundbeck for the United Kingdom. Later in the same year the Arrow Group concluded a similar agreement with Lundbeck for Denmark, through the Danish parent company Arrow Group A/S. The group of Arrow companies as a whole in the period concerned will hereafter be referred to as "Arrow".
- (39) In 2002, Arrow's total worldwide sales revenue for all products and services was EUR 70 million.⁴⁹ However, Arrow did not have any sales revenue for citalopram in 2002 in the United Kingdom or Denmark, the countries for which it concluded agreements with Lundbeck because in these agreements Arrow agreed not to sell citalopram in those countries.
- (40) In December 2009, the Arrow Group of companies was acquired by the American company Watson Pharmaceuticals Inc. This did not affect the legal structure within the Arrow group of companies. In 2008, the last full year before the acquisition by Watson, the Arrow Group had a worldwide turnover of around EUR 484 million.⁵⁰ In 2011, the worldwide consolidated turnover for all products and services of Arrow

⁴⁴ In 2009, in preparation for the acquisition by Watson, Robin Hood Holdings Limited took ownership of these shares previously owned by staff.

⁴⁵ ID 1517, pages 1 and 3.

⁴⁶ ID 2601, pages 1 to 7.

⁴⁷ Using an average annual exchange rate for 2011 of 1 EUR = 0.86788 GBP, source European Central Bank. See ID 3673.

⁴⁸ ID 610, page 5.

⁴⁹ Using an annual exchange rate for 2002 of 1 EUR = 0.9456 USD, source European Central Bank. See ID 1517, page 3.

⁵⁰ ID 610, page 14.

Generics Limited was EUR 42 million.⁵¹ In the same year, the worldwide consolidated turnover for all products and services of Arrow Group ApS was EUR 580 million.⁵²

3.5. Alpharma

- (41) Alpharma ApS was a company registered in Denmark. It received its name on 30 November 2000, when the company Dumex-Alpharma ApS, which was already part of the Alpharma group of companies, was re-named into Alpharma ApS.⁵³ In the period concerned, Alpharma ApS owned several other subsidiaries of the Alpharma group of companies, notably in France, Germany, the United Kingdom, the Netherlands, Sweden, Finland, Norway and (as of 3 June 2003) Belgium.⁵⁴ In 2002, Alpharma ApS concluded an agreement with Lundbeck covering the Union and Norway.
- (42) Alpharma ApS was in the period concerned an indirectly wholly-owned subsidiary of Alpharma Inc., a United States company.⁵⁵ Alpharma, Inc., a multinational pharmaceutical company, comprised four business divisions: human generics, branded pharmaceuticals, API manufacture and animal health.⁵⁶ The main activity of the human generics division was the development and sale of generic medicines throughout the world, including in the EEA. Alpharma ApS was primarily active in the human generics division as well as in the API manufacture division.⁵⁷ The Alpharma group of companies as a whole in the period concerned will hereafter be referred to as "Alpharma".
- (43) Alpharma, Inc. was in the period concerned in turn controlled by the Norwegian company A.L. Industrier AS. In 1974, A.L. Industrier AS, at the time operating under a different name, founded a U.S. subsidiary, Alpharma, Inc. (also at the time operating under a different name).⁵⁸ In 1984, A.L. Industrier AS listed Alpharma, Inc.'s Class A-shares on the New York Stock Exchange, while keeping control over all Class B-shares (which granted four voting rights). In 1994, Alpharma, Inc. acquired from A.L. Industrier AS *"the pharmaceutical, animal health, bulk antibiotic*

⁵¹ Using an average annual exchange rate for 2011 of 1 EUR = 1.3920 USD, source European Central Bank. See ID 3823.

⁵² Using an average annual exchange rate for 2011 of 1 EUR = 1.3920 USD, source European Central Bank. See ID 3823.

⁵³ ID 529, page 7.

⁵⁴ In particular through an American company named Alpharma Operating Corporation. See ID 529, pages 7-8, ID 1004, pages 7-9 and 11.

⁵⁵ ID 529, page 1, ID 1004, pages 7-9 and 11.

⁵⁶ ID 746, page 5.

⁵⁷ ID 1220, page 3.

⁵⁸ At that time, A.L. Industrier AS was called Apothekernes Laboratorium A.S. In turn, until 1994, Alpharma, Inc. was called "A. L. Laboratories, Inc." (and for a short time thereafter "A.L. Pharma, Inc."). See Form 8K of 3 October 1994, available at: <http://www.secinfo.com/dM9Ba.b5.htm> In its Form 10K of 30 March 1995, page 2, Alpharma reported: *"The Company was originally organized in 1975 as a wholly-owned subsidiary of Apothekernes Laboratorium A.S, a Norwegian health care company established in 1903. In February 1984, the Company's Class A Common Stock was initially listed on the American Stock Exchange through a public offering and such stock is currently listed on the New York Stock Exchange."* Available at: <http://www.secinfo.com/dM9Ba.ad.htm>

and aquatic animal health businesses" that was still with A.L. Industrier AS.⁵⁹ A.L. Industrier AS explained that when this concentration was negotiated in 1994, it had to be decided which company should be the group parent. Because a United States group parent was considered the best solution, A.L. Industrier AS' board decided to make Alpharma, Inc. *"the actual and real group parent"*. For this reason, Alpharma, Inc. acquired A.L. Industrier AS' businesses, and not the other way around.⁶⁰

However, it is undisputed that from 1994 until the sale by A.L. Industrier AS of Alpharma, Inc. in 2006, A.L. Industrier AS owned all of the outstanding shares of Alpharma, Inc.'s Class B common stock, which gave it the right to ultimately elect a qualified majority of Alpharma, Inc.'s Board of Directors (thus 6 out of 9 directors) and to cast a majority of the votes in any vote of Alpharma, Inc.'s shareholder meetings (the B-shares alone represented around 55% of all votes).⁶¹ Throughout the period concerned, the overall shareholding of A.L. Industrier AS fluctuated between 26,8% and around 23%.⁶²

With respect to the acquisition of A.L. Industrier AS' assets in 1994, Alpharma, Inc. reported in its Form 8K to the U.S. Securities and Exchange Commission (hereinafter "SEC"):

*"The Company [Alpharma, Inc.] is required to account for the acquisition of the Related Norwegian Businesses of A. L. Oslo as a transfer and exchange between companies under common control."*⁶³

(44) Alpharma, Inc. stated in its annual reports for the years 2001-2003:

*"Industrier has the ability to make decisions affecting the Company's capital structure including, in some instances, the issuance of additional indebtedness."*⁶⁴

Alpharma *"... also engages in various transactions with Industrier from time to time, and conflicts of interest are present with respect to the terms of such transactions."*⁶⁵

Among these various transactions, according to Alpharma, Inc.'s annual reports, were A.L. Industrier AS' 1998 purchase of a convertible subordinated note and the 2001 conversion of that note into shares of Class B common stock. Furthermore, Alpharma rendered management services to A.L. Industrier. Finally, in January 2003 Alpharma, Inc. divested its vitamin business to Nopal AS ("Nopal"), a subsidiary of

⁵⁹ See ID 2555, page 3 and Form 8K of 3 October 1994, available at: <http://www.secinfo.com/dM9Ba.b5.htm>

⁶⁰ See ID 6974, pages 1-2.

⁶¹ ID 1599, page 2; ID 2555, pages 4-5, ID 6631, page 3 and ID 2562, page 2 (according to Section 2.6 of Alpharma, Inc.'s bylaws, the *"Vote Required"* is *"...a majority of the voting power represented..."*). B-shares had four voting rights per share, whereas A-shares had only one voting right. See also Form 10K of 30 March 1995, available at: <http://www.secinfo.com/dM9Ba.ad.htm>. See also ID 6974, page 7, where A.L. Industrier AS pointed out that board members of Alpharma, Inc. are formally suggested and nominated by Alpharma, Inc. A.L. Industrier AS voted on those suggestions. See further the references in footnote 62.

⁶² ID 4921, page 3; see also ID 1599, page 2 and ID 2555, page 4. Before Alpharma concluded the agreement with Lundbeck, on 31 December 2001, the Norwegian company A.L. Industrier AS owned all of the outstanding shares of Alpharma Inc.'s Class B common stock (11.872.897 shares), and 39.293.180 shares of Class A common stock, amounting in total to 26,8% of the common stock of Alpharma Inc.

⁶³ Form 8K of 3 October 1994, page 2, available at: <http://www.secinfo.com/dM9Ba.b5.htm>

⁶⁴ E.g., Form 10K for 2001, available at: <http://www.secinfo.com/dM9Ba.3b.htm>

⁶⁵ E.g., Form 10K for 2001, available at: <http://www.secinfo.com/dM9Ba.3b.htm>

A.L. Industrier AS, for approximately \$3.3 million. In connection with this sale, AlphaPharma, Inc. entered also into a supply agreement with Nopal pursuant to which it would supply Nopal with certain vitamin products, and two distribution agreements pursuant to which both companies would continue to distribute certain of each other's products.⁶⁶ According to AlphaPharma, Inc.'s Form 10K for 2003:

*"The divestiture was a transaction between companies under common control..."*⁶⁷

For the period 2000 to 2003, A.L. Industrier AS provided the Commission with an overview and summary of all discussions at A.L. Industrier AS' board meetings of AlphaPharma, Inc.'s business.⁶⁸ The minutes of the board meetings of A.L. Industrier reveal that AlphaPharma Inc. business activities were from time to time reported to the board of A.L. Industrier (see for instance the minutes of the boards of 22 August 2002 and 13 November 2003). However, A.L. Industrier AS generally discussed AlphaPharma, Inc.'s business affairs only after the latter had already taken business decisions, based on AlphaPharma, Inc.'s press releases.⁶⁹ The board meeting minutes do not mention any discussion, or approval, of the sale of AlphaPharma, Inc.'s vitamin business to Nopal and the contracts concluded in this context between AlphaPharma, Inc. and Nopal.

However, the minutes show that A.L. Industrier AS was involved in the decision-making process concerning the envisaged acquisition of the United States/Australia Company Faulding by AlphaPharma Inc. in 2000. In this case A.L. Industrier AS' board issued instructions to AlphaPharma, Inc.'s board already before a decision on the acquisition had been taken. The acquisition would have required a capital increase through the issuance of new stock. Subsequently, A.L. Industrier AS could have lost control over AlphaPharma, Inc. A.L. Industrier AS' board thus decided on 15 June 2000: *"the board decided to instruct the board members of AlphaPharma Inc appointed by the B-shares to consult the board of A.L. Industrier before they decided to issue so many A shares that A.L Industrier lost the majority vote"*.⁷⁰ However, with respect to the acquisition itself, [employee function]* made clear that *"it was the board of directors of AlphaPharma Inc that are to decide about the projects"*.⁷¹

- (45) Important personal links existed in the period of the infringement between AlphaPharma, Inc. and A.L. Industrier AS, because [...] * "[...]" *⁷²

Moreover, the then [employee function]* of A.L. Industrier AS was at the same time [...] * of AlphaPharma ApS.⁷³

- (46) [employee function]* of A.L. Industrier AS and of AlphaPharma, Inc. [...] *. In 1994, AlphaPharma, Inc. reported to the U.S. Securities and Exchange Commission:

⁶⁶ Form 10K for 2001, available at: <http://www.secinfo.com/dM9Ba.2e.htm>; "As required of all related party transactions, the sale was determined to be fair to the holders Class A Common Stock by the Company's Audit and Corporate Governance Committee."

⁶⁷ Form 10K for 2003, available at: <http://www.secinfo.com/dM9Ba.11w.htm>

⁶⁸ See ID 6788, pages 11-21.

⁶⁹ See in particular the discussions of A.L. Industrier AS' board of 21 August 2003 (the discussion of a new strategic plan of AlphaPharma, Inc.

⁷⁰ Office translation by A.L. Industrier AS. See ID 6788, page 13; further discussions took place beginning of 2001, see page 14.

⁷¹ ID 6788, page 14.

⁷² Form 10K for the year 2003, available at: <http://www.secinfo.com/dM9Ba.11w.htm>

⁷³ ID 1601, page 119 and ID 2555, page 6.

"In addition, [employee function]* [...]."⁷⁴

"As a result, A.L. Industrier, and ultimately [...]*, [...]*."⁷⁵

Although [...]* shares, which were considered to be [...]* pursuant to Norwegian law, were considerably lower and did not reach those 50,8%, through proxy or agreement, [...]* nevertheless [...]*.

The following table summarises [...]*, and [...]*:⁷⁶

[...]*

These figures show that following the restructuring of the pharmaceutical businesses of A.L. Industrier AS and Alpharma, Inc. in 1994, where [...]*, in each and every year following the year 1994 until the expiry of the agreement between Alpharma and Lundbeck on 30 June 2003⁷⁷, [...]*.⁷⁸

- (47) In November 2003, the board of A.L. Industrier AS discussed a law firm memorandum about the [...]*. It stated that as [employee function]* of Alpharma, [employee function]* had at any point in time the obligation to [...]*. It indicated that [...]*.⁷⁹ In fact, with respect to the potential financing of Alpharma, Inc.'s acquisition in 2001, [employee function]* could not participate in [...]*, because of [...]* being [employee function]* also of Alpharma, Inc.⁸⁰
- (48) Alpharma explained that on 6 June 2002, it adopted a Contract Policy according to which certain strategic commercial decisions, including all investments over USD 5 million (or USD 7.5 million if the contract was of a type regularly entered into by Alpharma), had to be approved by the Board of Directors of Alpharma, Inc. the majority of which was, as mentioned, appointed by A.L. Industrier AS and which was [...]*.⁸¹ Furthermore, Alpharma *"also located a document which appears to be the version of the Alpharma Contract Policy adopted in 1998 [...], although it cannot be certain as the Contract Policy does not specify its date of issue"*. That Contract Policy contained rules similar to the 2002 Contract Policy.⁸² A.L. Industrier AS admitted that a Contract Policy was issued on 6 June 2002 (after the agreement with Lundbeck had been concluded), but claimed that the 1998 Contract Policy as submitted by Alpharma, Inc. was not dated, and thus A.L. Industrier AS did not know and it would not be clear whether the 1998 Contract Policy was ever approved by Alpharma, Inc.'s Board of Directors.⁸³ The 1998 Contract Policy would have been applicable, when Alpharma concluded the agreement with Lundbeck on 22 February 2002.

⁷⁴ Form 8K of 3 October 1994, available at: <http://www.secinfo.com/dM9Ba.b5.htm>

⁷⁵ Form 10Ks for the years 2000-2003, available at: <http://www.secinfo.com/dM9Ba.4f89c.4.htm>; <http://www.secinfo.com/dM9Ba.3b.htm>; <http://www.secinfo.com/dM9Ba.2e.htm>; <http://www.secinfo.com/dM9Ba.11w.htm>

⁷⁶ ID 6863 and 6864, pages 9-10; ID 6793, page 92 (note that the table in ID 6793 was partially amended by the one in ID 6864, page 27).

⁷⁷ The shareholder meeting of 30 June 2003 is excluded, because the agreement expired on that date.

⁷⁸ ID 6864, page 27.

⁷⁹ ID 6788, pages 20-21.

⁸⁰ ID 6788, page 15.

⁸¹ ID 1601, pages 245-246. ID 6559, pages 57-68.

⁸² ID 6560, page 11.

⁸³ ID 6788, page 7.

- (49) The financial accounts of Alpharma Inc. were in the period concerned consolidated into the financial accounts of A.L. Industrier AS.⁸⁴ A.L. Industrier AS still exists as a company. Its worldwide consolidated turnover for all products and services in 2011 was EUR 151 000.⁸⁵
- (50) On 19 December 2005, Alpharma Inc. sold its worldwide human generics division to the generic pharmaceuticals company Actavis Group hf, established in Iceland. This sale included Alpharma's rights to marketing authorisations for generic citalopram in the EEA, Alpharma's supply agreement for generic citalopram with Tiefenbacher as well as assets of Alpharma ApS.⁸⁶ Through this acquisition, Actavis took over Alpharma's sales of generic citalopram in the EEA. This acquisition did not, however, include the legal entities Alpharma ApS or Alpharma Inc, which remained part of the Alpharma group. As Xellia Pharmaceuticals ApS later informed the Commission: *"Alpharma ApS was not sold by Alpharma [Inc.] as the company was also used for other Alpharma divisions including the Alpharma API Division."*⁸⁷
- (51) As part of a subsequent divestment by Alpharma Inc. of its API manufacture division, ownership of Alpharma ApS changed on 31 March 2008 when the company was acquired by a bidder group of companies headed by the company Otnortopco AS with the financial backing of certain investment funds managed by the international investment group 3i. Following the acquisition, Alpharma ApS was renamed Axellia Pharmaceuticals ApS. For trade mark reasons, this name was changed into Xellia Pharmaceuticals ApS in 2010.⁸⁸ The company has remained a separate legal entity since then, active mainly in the manufacture of APIs.⁸⁹ Its worldwide consolidated turnover for all products and services for 2011 was [...]*.⁹⁰
- (52) Alpharma Inc. itself, with its remaining business divisions of branded pharmaceuticals and animal health, was acquired by King Pharmaceuticals, Inc., a United States company, on 29 December 2008.⁹¹ In April 2010, Alpharma Inc. was changed into a limited liability company and in line with that its name became Alpharma, LLC.⁹² In February 2011, the King Pharmaceuticals Group was acquired by Pfizer Inc, another United States pharmaceutical company.⁹³ Alpharma, LLC initially remained a separate legal entity within the Pfizer group of companies.⁹⁴ However, on 15 April 2013, Alpharma, LLC changed its name to Zoetis Products LLC as part of re-structuring by Pfizer that consolidated Pfizer's animal health businesses under a new publicly listed company Zoetis Inc.⁹⁵ The worldwide

⁸⁴ ID 2555, page 8.

⁸⁵ Using an average annual exchange rate for 2011 of 1 EUR = NOK 7.79337. Source European Central Bank. See ID 3553, page 1.

⁸⁶ ID 1220, pages 2, 8, 11 and 12.

⁸⁷ ID 1220, page 2.

⁸⁸ ID 1220, page 8.

⁸⁹ ID 529, page 2, ID 1220, pages 1, 7 and 8.

⁹⁰ Using an annual exchange rate for 2011 of 1 EUR = 7.4506 DKK. Source European Central Bank. See ID 3578.

⁹¹ ID 529, page 1, ID 416, page 2.

⁹² ID 1005, page 22.

⁹³ ID 3950 and <http://www.businesswire.com/news/home/20110301006102/en/Pfizer-Completes-Acquisition-King-Pharmaceuticals>.

⁹⁴ ID 529, page 5 and ID 3950.

⁹⁵ ID 6984.

consolidated turnover for all products and services of Alpharma, LLC (since April 2013: Zoetis Products LLC) for 2011 was [...]*.⁹⁶

3.6. Ranbaxy

- (53) Ranbaxy Laboratories Limited is an Indian company specialising in the development and production of a wide range of generic APIs and generic medicines. The company was established in 1961 and was listed on the stock market in 1973. Ranbaxy not only sells API to other companies but also sells generic medicines worldwide through its own sales subsidiaries. In the period concerned, Ranbaxy had sales subsidiaries in the United Kingdom, Germany, France, Ireland and the Netherlands. The United Kingdom sales subsidiary, also addressed by this Decision, is called Ranbaxy (U.K.) Limited (hereafter also referred to as "Ranbaxy (UK)" or "Ranbaxy (UK) Ltd"). In 2011, the worldwide consolidated turnover for all products and services of Ranbaxy (U.K.) Limited was EUR 22 million.⁹⁷ Ranbaxy has also had a European headquarters in the United Kingdom, Ranbaxy Europe Limited.⁹⁸ In 2011, the world-wide consolidated turnover for all products and services of Ranbaxy Laboratories Limited was EUR 1 568 million.⁹⁹ The Ranbaxy group of companies as a whole in the period concerned will hereafter be referred to as "Ranbaxy".
- (54) In June 2008, Ranbaxy entered into an alliance with Daiichi Sankyo Company Limited, a Japanese pharmaceutical company specialising in innovative medicines. Since then, Ranbaxy has been a member of the Daiichi Sankyo Group, but has kept its own legal personality, assets and turnover.

3.7. Other market players

- Norpharma
- (55) As early as October 1998, a small Italian API producer, Norpharma S.p.A. (hereafter also referred to as "Norpharma"), was engaged in the development of a process to manufacture generic citalopram, different from Lundbeck's processes. In October 1999, Lundbeck purchased the patent applications of Norpharma for the process in question.¹⁰⁰
- VIS
- (56) The company VIS Farmaceutici S.p.A. (hereafter also referred to as "VIS"), located in Padua, Italy, was another small producer of APIs. In the late 1990s, VIS cooperated with the German company Tiefenbacher (see recital (57) below) in developing generic citalopram for marketing in the EEA. In October 2000, Lundbeck purchased VIS and withdrew its Drug Master File from Tiefenbacher's application for a marketing authorisation for generic citalopram.
- Tiefenbacher

⁹⁶ See ID 3950 and ID 4201, page 1 (using an average annual exchange rate for 2011 of 1 EUR = 1.392 USD, source European Central Bank).

⁹⁷ Using an average annual exchange rate for 2011 of 1 EUR = 0.86788 GBP, Source European Central Bank. See ID 3646.

⁹⁸ ID 587, pages 3 to 5.

⁹⁹ Using an average annual exchange rate for 2011 of 1 EUR = 64.8859 INR, Source European Central Bank. See ID 3632.

¹⁰⁰ See recital (174) below.

- (57) The company Alfred E. Tiefenbacher GmbH & Co. (hereafter also referred to as "Tiefenbacher"), located in Hamburg, Germany, was established in 1963. In the period concerned Tiefenbacher had around 70 employees and an annual turnover of around EUR 250 million. At that time, Tiefenbacher's business was - and still is - to represent foreign producers of APIs and thus to form a link between producers of active ingredients, often located outside the EEA, and generic companies in the EEA interested in selling medicines using the active ingredient concerned. In this capacity, Tiefenbacher also developed drug registration files and obtained marketing authorisations in Contracting Parties of the EEA Agreement for new generic medicines with a view to allowing the marketing of such new generic medicines as soon as possible after the compound patent for the active ingredient in the EEA had expired. Tiefenbacher commercialised the marketing authorisations it obtained to interested generic companies, the latter normally being committing to buy for a certain period the product concerned via Tiefenbacher from the API producer(s) which Tiefenbacher represented.¹⁰¹ Tiefenbacher often used two alternative API suppliers to ensure a steady supply. In the case of citalopram, after VIS had been eliminated as a supplier, Tiefenbacher used the Indian API producers Cipla and Matrix.¹⁰²
- (58) With respect to citalopram, Tiefenbacher was the first company to obtain a marketing authorisation for generic citalopram in the EEA. This happened in September 2001 in the Netherlands.¹⁰³ The marketing authorisation stated Matrix and Cipla as suppliers of the citalopram.¹⁰⁴ Subsequently, in the course of 2002, Tiefenbacher obtained, through the mutual recognition process, similar marketing authorisations in Belgium, Denmark, Finland, Germany, Norway, Sweden and the United Kingdom.¹⁰⁵ Based on API supplies by Cipla and Matrix, Tiefenbacher commercialised these marketing authorisations to a number of companies interested in selling generic citalopram in the EEA. These companies could obtain the API from Cipla or Matrix, either in the form of bulk or in the form of tablets prepared by the company Omega Farma in Iceland.
- Omega Farma
- (59) The company Omega Farma ehf (hereafter also referred to as "Omega Farma"), located in Iceland, was used by Tiefenbacher for the production of citalopram tablets.¹⁰⁶ Lundbeck did not have any patents on citalopram in Iceland, thus allowing Omega to obtain a marketing authorisation for citalopram there already in January 2001.¹⁰⁷ In 2005 Omega Farma ehf was acquired by the generic pharmaceutical undertaking Actavis.¹⁰⁸

¹⁰¹ ID 291, pages 1-2.

¹⁰² ID 291, page 4.

¹⁰³ ID 280, page 3. In the United Kingdom, however, Merck (GUK) was the first generic undertaking to obtain a marketing authorisation on 9 January 2002 (based on Natco API). See recital (259) below.

¹⁰⁴ ID 1713, page 1.

¹⁰⁵ ID 301.

¹⁰⁶ See for instance Arrow's contract with Tiefenbacher, ID 619, page 2.

¹⁰⁷ ID 9, pages 96-97, 230.

¹⁰⁸ ID 746, page 8.

- Cipla
- (60) The company Cipla Limited (hereafter also referred to as "Cipla") was established in India in 1935. It is active in the production and sale of generic APIs and medicines. In the period concerned, it was involved in the development and manufacture of generic citalopram for Tiefenbacher.
- Matrix
- (61) Matrix Laboratories Limited (hereafter also referred to as "Matrix") is an Indian company active in the production and sale of generic APIs and medicines. The company was acquired in 2006 by Mylan. In the period concerned, Matrix was involved in the development and manufacture of generic citalopram for Tiefenbacher.
- Natco
- (62) The company Natco Pharma Limited (hereafter also referred to as "Natco") was established in India in 1981. It is active in the production and sale of generic APIs and medicines.¹⁰⁹ In the period concerned, it was involved in the development and manufacture of generic citalopram for Merck.¹¹⁰
- Lagap
- (63) The United Kingdom company Lagap Pharmaceuticals Limited (hereafter also referred to as "Lagap"), a subsidiary of Sandoz (the generic business of the Novartis group of companies), was in the period concerned a supplier in the United Kingdom of generic citalopram sourced from Matrix (via Tiefenbacher). After it had entered the United Kingdom market with Matrix citalopram in October 2002, Lundbeck launched litigation against Lagap before the United Kingdom courts for infringing Lundbeck's process patents, notably Lundbeck's recently obtained crystallisation patent.¹¹¹ Following a court-ordered inspection of Matrix's premises and process technology, the litigation was settled on 13 October 2003. In the settlement Lundbeck granted a non-exclusive royalty-free licence to Lagap to use Lundbeck's crystallisation patent in the EEA. The settlement led Lundbeck to terminate most of its agreements with other companies, as a result of which much fuller generic competition could take place.

4. THE REGULATORY FRAMEWORK

4.1. Patents

- (64) 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.¹¹² In order to ensure sufficient compensation to the inventor for the innovative work which is the subject of the patent, patent law gives the innovator an

¹⁰⁹ ID 581, page 3.

¹¹⁰ See sections 7.2 and 7.3 below.

¹¹¹ See recitals (152) to (165) below.

¹¹² 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).

exclusive right to the commercial exploitation of the invention for a certain period of time. Commercial exploitation includes the originator's production and marketing of products based on the invention and the originator's granting of licences to third parties allowing the latter to use the invention, usually in exchange for royalties.

- (65) A national patent applies only in the States in which it has been granted. At the time of events, European patents granted by the European Patent Office (EPO) were split after grant into a bundle of national patents, and had to be validated in each State (designated by the applicant) before they can be enforced there. Enforcement of patents took place through an infringement procedure in the national court system, which, depending on the Member State, could be a general court or a court specialised in intellectual property issues. An example of the latter is the Patents Court of the Chancery Division in the High Court of Justice in the United Kingdom.
- (66) In the EEA, patent protection may be obtained for up to 20 years from the filing date.¹¹³ Because the long period that elapses between the filing of an application for a basic patent for a new medicinal product and authorisation to place the medicinal product on the market made the period of effective protection under the basic patent insufficient to cover the investment put into the research, the European legislator created in 1992 a supplementary protection certificate (also called 'SPC') that extended with a maximum of five years the patent protection of products that are protected by a basic patent in the territory of a Member State and that are subject, prior to being placed on the market as a medicinal product, to a marketing authorisation.¹¹⁴ Through this extended period of protection, the European legislator encouraged research into new medicinal products in the Union.
- (67) During the period of patent exclusivity, from the moment the patent holder (also called 'originator' in the pharmaceutical industry) has obtained a marketing authorisation for a medicinal product until the expiry of the SPC (or of the patent if no SPC was granted), corresponding in practice to a maximum period of fifteen years¹¹⁵, the patent holder may be able to charge a price for the medicine resulting from the invention that is higher, often far higher, than its marginal cost of production. This allows the originator company to recoup the significant investment

¹¹³ 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 European Patent Convention (EPC) provides that the term of a European patent is 20 years from the date of filing of the application.

¹¹⁴ The extension applies subject to the limitations in Articles 4 and 5 of 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). Article 1 of this Regulation defined 'product' as "*the active ingredient or combination of active ingredients of a medicinal product*." For the definition of 'medicinal product', see footnote 5 above. After the period concerned by this Decision, Regulation No 1768/92 has been 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 of 16.6.2009, pages 1 to 10). Article 13(2) of this Regulation provides that the duration of the certificate may not exceed five years from the date on which it takes effect. See also footnote 115 below.

¹¹⁵ 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 of 16.6.2009, pages 1 to 10) explicitly provides for an overall maximum period of exclusivity of 15 years from the time the medicinal product first obtains authorisation to be placed on the market in the Union (see recital 9 of the Regulation). Under 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) the maximum period of exclusivity was, in practice, the same. See also European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 131-132.

it makes in research and development of new medicines (not just the particular product that is being successfully marketed, but also numerous projects that never reach the marketing stage). The end of this period reflects the assessment by the legislator that this is the point in time where the cost to society of continued patent protection, in the form of extra profits to the originator company from its exclusive position, starts exceeding the benefits to society.

- (68) Once the SPC period has expired and the active ingredient is no longer protected, that active ingredient can in principle be used by third parties, so-called 'generic companies', to produce and sell so-called 'generic' medicines containing the identical active ingredient in question. It should be noted, in this respect, that the original patent application covering the compound must also indicate how the invention can be reproduced¹¹⁶, that is to say in the case of active ingredients how the active ingredient can be produced. The right of society (competitors) to freely reproduce the invention after patent expiry is precisely what society gains in exchange for guaranteeing the inventor an initial period of exclusive use. Patent protection for the original production method of the active ingredient therefore normally expires at the same time as the protection for the active ingredient itself. From that moment on, the market is in principle open for entry of generic versions of the active ingredient concerned.
- (69) When originator companies have been able, as explained, to charge during the period of patent protection medicine prices far higher than the marginal cost of production and such medicines reach significant sales, typically a highly dynamic process of generic competition starts some time before expiry of the original patent application, which takes the form of a "race" between different generic undertakings to (be the first to) enter the market.¹¹⁷ In fact, the earlier a generic undertaking comes to the market, the higher its profit margins will be. As concerns citalopram, Merck (GUK), Arrow, Alpharma and, to a lesser extent, Ranbaxy participated in this competitive process and were seeking to enter the market as soon as possible with their generic version of citalopram. These are the generic undertakings with which Lundbeck concluded the agreements covered by this Decision.
- (70) As the Commission has analysed in its sector inquiry into the pharmaceutical sector, generic entry into a pharmaceutical market *"can have a profound effect as it changes the market from one in which only one firm could sell the product(s) concerned (possibly via licensees) into one where more sources of supply become available for the product. The most direct effect is likely to be on the average price level of the product(s) concerned and the sales volumes of the originator."*¹¹⁸ The Commission found in its report that one year after generic entry, on average the prices for its sample of 75 major products had fallen by almost 20% and by about 25% after two years¹¹⁹. The Commission also found for the same sample of 75 major products that

¹¹⁶ EPC Article 83: The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. See also Article 29 TRIPS.

¹¹⁷ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 559: *"The value sales of the originator drug prior to loss of exclusivity [...] seem to be a clear driver of generic entry."*

¹¹⁸ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 98.

¹¹⁹ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 99.

within one year after generic entry, generic companies had acquired on average a market share by volume of 30%, and of 45% after two years.¹²⁰

- (71) As long as patent protection for the compound (molecule) exists, it will normally not be possible for a generic company to enter the market with a medicine containing the compound concerned without causing an infringement of the compound patent. However, even after the compound patent has expired, intellectual property obstacles for generic companies can still arise, in particular if patents, usually belonging to the originator company, are still in force that cover inventive, more efficient production methods of producing the compound which itself is no longer patent protected. It may be the case, for instance, that the production method disclosed in the original patent application is sufficient to reproduce the active ingredient in a laboratory, but is unsuitable to industrial production on a large scale. In that case, the originator company may have obtained additional process patents in developing an efficient industrial production method for the active ingredient. If a production method were still under patent protection and such a production method were used by a generic company to produce the compound that was no longer patent protected, the generic company would still be committing a patent infringement of the process concerned and as a result could be legally stopped from making or selling the product resulting from that process. However, this does not mean that market entry is not possible. 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.*"¹²¹ The same can be said of process patents, in cases where an active substance can be produced by different processes.¹²²
- (72) The generic company is thus free to develop still another production method that is not patent protected. If a generic company succeeds in inventing a new production process it may apply for a patent for that process.¹²³ Much of the development work of generic producers of APIs is therefore focused on compounds that are close to patent expiry. Such work tries to reproduce the original production process for such an active ingredient and to render it more efficient, where necessary, or to "invent around" other existing process patents of the originator company concerned. Whether or not a generic challenger has managed to reproduce the original production process without infringing process patents that are still in force or invented around such patents may depend on complex patent law questions and can easily become the subject of a dispute with the originator. Such disputes are common in the pharmaceutical sector and part of the competitive process for generic entry.
- (73) Alternatively, the generic company may challenge before the national patent office, the EPO or the national courts the validity of a process patent, claiming, for instance, that it does not represent a true invention. Such challenges are an inherent part of the competitive process between originator and generic companies as well and are useful to society in potentially eliminating unmerited patents that form an unjustified

¹²⁰ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 108.

¹²¹ Case T-321/05, *AstraZeneca v Commission*, judgment of 1.7.2010, paragraph 607.

¹²² As will be explained in section 6.3 below, this was the case for citalopram.

¹²³ Regarding citalopram see, for example, ID 1024, page 83, where Merck (GUK) reported: "*several published process patents were identified assigned to Sumika, Cipla, Ranbaxy, Orion and NATCO.*" For Norpharma see recital (174) below.

obstacle to effective competition in the market for the compound concerned. The generic company may also seek a ruling from the court that it is not infringing the patent(s) concerned. In the United Kingdom, this is referred to as a "clearing the way" procedure if the procedure is undertaken before actual marketing of the generic product starts.¹²⁴

- (74) When a generic company launches - or is about to launch - a generic product on the national market in a situation where the patent holder still holds a number of process patents, the patent holder may react by initiating an action before the national court for infringement of one or more of those process patents against the generic company concerned as well as possibly against other companies involved in the production and marketing of the product. Such a generic product launch is called "at risk", as it is at risk of being challenged as a patent infringement before the court by the patent holder. When a generic challenger is being challenged in court, this does not mean that the generic company is indeed infringing the patent holder's process patents. The patent holder often has only insufficient knowledge about the exact API production process used, and therefore has difficulty to know when it launches litigation whether the generic company is in reality infringing its patent rights. The outcome of court proceedings is therefore generally difficult to predict and uncertain.
- (75) In an infringement proceeding, the originator company may ask for an interim injunction to prevent (further) damage to its commercial interests. In deciding whether to grant an interim injunction, the judge will duly take into account the interest of the originator company in preventing commercial harm from infringement of its patent. But, before ordering an interim injunction, the judge may and normally will also satisfy itself that the applicant is the right holder and that the applicant has provided reasonably available evidence that its right is being infringed, or that such infringement is imminent.¹²⁵ If the interim injunction is granted, the judge will order that the generic company must stop marketing its product until the main proceeding has been decided. In the main proceeding, the originator company may, apart from a finding of infringement, also ask for damages. As for the defending generic party, apart from arguing that the invoked patent has not been infringed, it can - and often does - also make a counterclaim that the invoked patent is invalid. If the defending generic party was unlawfully excluded from the market, it may also ask for damages. The judge will then decide, first, whether interim measures are justified and secondly, in the main proceeding, whether the patent is valid and whether it has been infringed.
- (76) The Commission's report on the sector inquiry into the pharmaceutical sector found for the period between 2000 and 2007 that generic companies won 62% of all patent litigation cases that resulted in a ruling.¹²⁶ For process patents, the corresponding figure was 74%.¹²⁷ Out of all litigation cases in which a final judgment was given on

¹²⁴ "Clearing the way" may also refer to steps that a generic company can take to avoid a preliminary injunction, see footnote 312 below.

¹²⁵ See Corrigendum to Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights, Article 9 (OJ L 195, 02.06.2004, pages 16 to 26).

¹²⁶ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 11.

¹²⁷ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 238.

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%.¹²⁸ For litigations 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.¹²⁹

When a patent right is litigated, it may therefore be more difficult to predict the outcome than in the case of rights to tangible property, such as a piece of land or a car, for two main reasons:

The first main reason relates to the very nature of a patent right: A patent is only merited if an invention has been made which is new, involves a genuine inventive step and is capable of industrial application.¹³⁰

The requirement of novelty means that the claimed invention should not form part of the "state of the art", which includes everything already made available previously to the public anywhere in the world. A 2011 "Study on the quality of the patent system in Europe" commissioned by DG MARKT found that in 68% of the cases, "*the prior art reported by the patent examiner was accurate and complete*".¹³¹ A particular issue is that in the EEA there is at present no mandatory requirement per se for the applicant to disclose knowledge of prior art. However, the EPO may request the applicant to provide information on prior art taken into consideration in the examination of similar patent applications before other Patent Offices. If the applicant fails to provide the information, the application is deemed to be withdrawn.¹³²

The requirement of inventive step means that, having regard to the state of the art, the claimed invention should not be obvious to a person skilled in the art. In order to assess inventive step in an objective and predictable manner, the EPO has developed a well-defined procedure the so-called "problem-and-solution approach". This approach provides objective criteria for characterising the invention in terms of a technical problem and its solution when assessing whether an inventive step is present.

The requirement of industrial application means that an invention can be made or used in any kind of industry, including agriculture. This requirement aims to distinguish between aesthetical and scientific inventions, that is to say that only inventions that have a technical character are eligible for patent protection. In addition industrial applicability requires that the invention can be manufactured and does not violate physical laws.

Secondly, the process for examining patent applications is essentially an *ex parte* process, i.e. a process between the applicant and the patent office. Although third parties - such as actual or potential competitors - have an opportunity to make written observations before the patent office makes a decision on the patent application which might be taken into consideration, if justified, by the examiners, third parties

¹²⁸ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 237.

¹²⁹ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 237.

¹³⁰ Article 52(1) EPC.

¹³¹ See page 46. See: http://ec.europa.eu/internal_market/indprop/docs/patent/patqual02032011_en.pdf

¹³² Article 124 EPC and rule 141 of the implementing regulations of the European Patent Convention

do not have the right to discuss those observations with the patent office or the applicant before a decision on the application is taken. At this stage, expert witnesses of third parties cannot be heard. However, after the patent has been granted, any third party can formally oppose it within a given time period. Such opposition (followed if necessary by an appeal) may, normally several years later, lead to a decision of the patent office to revoke the patent. Such revocation will apply *ab initio*, meaning that legally speaking the patent is annulled from the very beginning and is deemed to have never existed. Oppositions may also lead to either a narrowing of the claims in the patent or the rejection of the opposition – the patent is then maintained as it is. The opposition division decision might also be challenged by the parties before the Board of Appeals.

According to the statistics published by the EPO in its Annual Report 2002, the EPO granted on average over the years 33.8% of all patents applied for, while less than 7% of those patents were challenged.¹³³ However, of the patents challenged through opposition before the EPO in 2002, 35.4% were revoked and 37.9% were amended. Only 26.7% of challenged patents remained intact.¹³⁴ It should be noted that even patents confirmed by the EPO, whether in amended form or not, may still be held invalid by national courts, even if this happens only rarely.

- (77) Once granted, patents are assumed to be valid and they can be invoked by patent holders against third parties, including before national courts – whether or not there is a disagreements on the validity of the patent. The General Court held in *AstraZeneca*:

*"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."*¹³⁵

- (78) This assumption of validity of patents does not mean, however, that a generic company which believes that it does not infringe any patent or which believes that the patent in question is invalid would not have be able to try to sell its product in the market. Indeed, in deciding whether to grant a marketing authorisation to a generic company for a particular medicinal product, the marketing authorisation bodies in the EEA are not allowed to take the patent status of that product into account.¹³⁶ Moreover, when a patent is invoked against entry of a generic company, that generic company is free to challenge the validity of such patent. In court, the assumption of validity allocates the burden of proof:.. Thus, while an originator company claiming before a court that a patent has been infringed in principle bears the burden of proving the infringement¹³⁷, a generic company (counter-)claiming that a patent is

¹³³ This means that roughly 2.4% of the initial patent applications will be opposed if they become a granted patent.

¹³⁴ EPO, Annual Report for the year 2002, page 16.

¹³⁵ Case T-321/05, *AstraZeneca AB and AstraZeneca plc v Commission*, judgment of 1 July 2010, paragraph 362.

¹³⁶ For a further description of the procedure for marketing authorisation, see section 4.2 below.

¹³⁷ Lundbeck pointed out in its reply to the Statement of Objections that *"Article 34 TRIPS recognizes the difficulty of enforcing process patents. It requires TRIPS contracting parties to provide for a reversal of the burden of proof in litigation concerning the alleged infringement of process patents, meaning that the generic company must, under certain circumstances, demonstrate that it did not infringe a process*

invalid bears the burden of proving that. If a counterclaim for invalidity has been lodged at the same court where an infringement action is pending, the judge in question will examine without bias based on the substance whether the patent is truly valid and has indeed been infringed.

- (79) Patent disputes can also lead to a settlement between the parties, whether before or after patent litigation has started. A settlement seeks an amicable resolution of the dispute between the parties with a view to avoiding (further) costly litigation and the risk of a potentially adverse ruling (for either party) by the court. A patent settlement between an originator company and a generic company could, for instance, in the light of each party's assessment of the chance that the court will hold the patent (in)valid or (not) infringed, agree on an entry date for the generic product at any point in time between immediate entry and entry at the expiry of the patent protection of the invoked patent(s). Such an agreement may in many cases be pro-competitive enabling the generic company to enter the market prior to the lapse of the patent. In the case of process patents which generic companies are constantly trying to invent around, normally one or the other generic manufacturer will succeed sooner rather than later in finding a way to manufacture the product in a non-infringing manner.¹³⁸ This means that a settlement involving process patents may well see an agreed entry date for the generic company concerned a considerable time before the lapse of the patent. Moreover, in the case of process patents, the generic company entering into such a settlement may want to make unilateral termination of the agreement possible as soon as other generic companies freely enter the market. A settlement may also include a licence from the originator company to the generic company authorising the latter to use the invention, with or without royalties.
- (80) These types of settlements are to be distinguished from the agreements covered by this Decision, in which the parties did not resolve or terminate any patent dispute and did not agree on any entry date for the generic company but rather agreed on a period in which the generic company would be excluded from the generic market, without any guarantee of unrestricted market entry thereafter, in exchange for a considerable sum of money from the originator company. As Lundbeck wrote to the Commission: *"Lundbeck's settlements did not remove uncertainty over whether a generic's challenge would eventually succeed, because they did not finally resolve the dispute"* and *"Lundbeck's agreements did not...ultimately decide when any generic company could enter the market."*¹³⁹ Indeed, the agreements covered by this Decision

patent. However, Article 34 of the TRIPS gives contracting parties the option – which most EEA countries have exercised in their national implementing measures – to subordinate the reversal of the burden of proof to the condition that the patented process concerns the production of an entirely new product. Therefore, in practice, this reversal of the burden of proof often does not apply in favour of patent holders, which makes proof of infringement very difficult." (ID 5394, page 29).

¹³⁸ Lundbeck wrote to the Commission: "More fundamentally, in the context of process patents, any company can produce the underlying compound through non-infringing means." See ID 1683, page 21. In its reply to the Statement of Objections, Lundbeck added that, in practice, proof of infringement of a process patent is "very difficult". "Furthermore", according to Lundbeck, "...the difficulty in enforcing a particular process patent, as opposed to a product patent, lies in the potentially endless alternatives to that process, which means that the originator will have to investigate every single claim of a generic that it has now produced the same product by means of a non-infringing process. And by fudging slightly with a given process, the generic can at least initially claim it now has a new, non-infringing process..." (ID 5394, page 29).

¹³⁹ ID 1683, pages 3 and 2. See also, for instance, recital (519) below.

postponed the issue of potential generic market entry, thus effectively extending, at least in respect of the generic companies concerned, the period of exclusivity for Lundbeck well beyond the expiry of the original compound and original process patents. The agreements in question did not settle any patent dispute and should not, therefore, strictly speaking be called "settlements".

- (81) In Case 65/86, *Bayer AG and Maschinenfabrik Hennecke v Heinz Süllhöfer*, the Court of Justice held that an agreement does not fall outside the scope of Article 101 of the Treaty simply because it is a settlement agreement or an agreement related to IP rights. The Court of Justice held that "[i]n its prohibition of certain 'agreements' between undertakings, Article 85(1) [now 101(1) 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."¹⁴⁰ Thus, while companies in principle have the right to settle their patent disputes, just as they have the right in principle to conclude other kinds of agreements, even if they are actual or potential competitors, in doing so they must respect Union competition law.
- (82) In its inquiry into the pharmaceutical sector, the Commission found that in the European Union more than 200 patent settlements had been concluded between 2000 and June 2008, covering 49 medicines. In slightly over 20 of these settlements, that is to say in around 10% of all agreements, the agreement provided for a direct payment from the originator company to the generic company and for a restriction on the generic company's ability to market the product in question.¹⁴¹ In respect of this latter type of agreement, the Commission noted in its sector inquiry report:
- "Agreements that are designed to keep competitors out of the market may also run afoul of EC competition law. Settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies are an example of such potentially anticompetitive agreements, in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets."*¹⁴²
- (83) The present Decision concerns the concrete application of Union competition law, *in casu* Article 101 of the Treaty, to a number of agreements "that limit generic entry and include a value transfer from an originator company to one or more generic companies..."¹⁴³

4.2. Marketing authorisation

- (84) With a view to safeguarding public health, no medicinal product for human use, whether a product of an originator company or of a generic company, may be placed

¹⁴⁰ Case 65/86, *Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Süllhöfer*, [1988] ECR 5249, paragraph 15.

¹⁴¹ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 12-13.

¹⁴² European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 20.

¹⁴³ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 20.

on a market in the EEA unless a marketing authorisation has been issued for it.¹⁴⁴ A marketing authorisation is a permit granted by the responsible health authorities to a pharmaceutical company, authorising the sale of a given pharmaceutical product in the territory concerned. The pharmaceutical company must apply for a marketing authorisation, providing data concerning the medicinal product, including its name, pharmaceutical form, indications, dosage and adverse reactions as well as documenting the product's pharmaceutical quality, safety and efficacy. Obtaining a marketing authorisation involves therefore submitting the results of a certain number of pre-clinical toxicological and pharmacological tests as well as clinical trials, which together allow an assessment of the safety and efficacy of the medicine.

- (85) In the period concerned by this Decision, the years 2002 and 2003, generic companies obtained for their generic medicines national authorisations, which were issued by the competent authorities of the Member States and covered their own territory.¹⁴⁵ Directive 2001/83 provided that a Member State had to complete the procedure for granting a marketing authorisation within a maximum of 210 days of the submission of a valid application.¹⁴⁶ A national authorisation could be recognised by other Member States by using the mutual recognition procedure (MRP).¹⁴⁷ A decision on whether to recognise the marketing authorisation granted by another Member State (the so-called Reference Member State) had to take place within 90 days after the receipt of that other Member State's assessment report (which in turn had to be prepared within 90 days).¹⁴⁸ Finally, following this recognition, it would

¹⁴⁴ Recital 2 and Article 6 of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, OJ L 311, 28.11.2001, page 67 (hereafter also referred to as "Directive 2001/83").

¹⁴⁵ See European Commission, DG Competition: Report on the Pharmaceutical Sector Inquiry, 8 July 2009, page 134. Norway, Iceland and Liechtenstein have, through the EEA Agreement of 1994, adopted the 'acquis communautaire' on medicinal products. They are parties to the Union's marketing authorisation procedures, with the only exception that legally binding acts adopted at Union level do not directly confer rights and obligations but first have to be transposed into legally binding acts in the respective countries. Marketing authorisations granted by Member States are eligible for mutual recognition in Norway, Iceland and Liechtenstein, just as marketing authorisations granted by Norway, Iceland and Liechtenstein are eligible for mutual recognition by Member States of the Union. See European Commission, DG Competition: Report on the Pharmaceutical Sector Inquiry, 8 July 2009, page 134, footnote 274.

¹⁴⁶ See Article 17 of Directive 2001/83/EC. This period began to run on the day the authorities accepted that the application was valid. As long as the application was incomplete or incorrect, the period did not start.

¹⁴⁷ See European Commission, DG Competition: Report on the Pharmaceutical Sector Inquiry, 8 July 2009, pages 134 and 146-147. See also Articles 10 and 18 of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, OJ L 311, 28.11.2001, page 67. As for the so-called centralised procedure (where a single application is made at Union level) and the decentralised procedure (where identical applications are made to a number of Member States and a single Member State among them acts as reference Member State and prepares the assessment), these came into operation for generic products only in 2005. These two procedures did not, therefore, play a role in the facts concerned by this Decision. See also 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.

¹⁴⁸ Articles 28 and 29 of Directive 2001/83 provided that in the mutual recognition procedure, a Member State had to either recognise the marketing authorisation granted by another Member State, within 90 days of the receipt of the assessment report of that other Member State, or within that period indicate its reasons for believing that the granting of a marketing authorisation would pose a public health risk.

normally take a couple of weeks for a national marketing authorisation to be granted (the so-called "national phase").¹⁴⁹ Thus, in the period concerned, generic companies wanting to sell in the EEA could either make several national applications (which were formally independent of each other), whether simultaneously or consecutively¹⁵⁰, or could use the mutual recognition procedure. In the latter case, they would make an application to a single Member State first, the so-called reference Member State. If the application was correct from the beginning, generic companies could obtain a marketing authorisation in the Reference Member State within around 7 months. This could be followed by marketing authorisations in other Contracting Parties of the EEA Agreement, normally within at most an additional 7 months if no objections arose, bringing the total to 14 months if all went well.¹⁵¹ If the applicant made several simultaneous applications to different national marketing authorisation bodies, it could, in principle, obtain several marketing authorisations after 7 months, although Member States had the right to suspend examination if they noted that an application was already under active consideration in another Member State.¹⁵² How much longer the procedure would actually take would depend on the number of deficiencies in the application and the speed with which the applicant acted to correct those. According to Lundbeck, a full process including mutual recognition could "*in reality*" take 25 months or more.¹⁵³

- (86) Once a generic undertaking had obtained a marketing authorisation, it could apply for a type I variation to that marketing authorisation to cover any future amendments

According to the European Generic Medicines Association (EGA), the later decentralised procedure involves the other Member States in an earlier stage of the evaluation than under the mutual recognition procedure in an effort to minimise disagreements. See the EGA webpage on "authorisation" <http://www.egagenerics.com/gen-authorisation.htm>.

¹⁴⁹ Compare Article 34(3) of the original Directive 2001/83 and Article 28(5) of Directive 2001/83 as amended. Article 28 of the original Directive 2001/83, which applied at the time of events, was silent on the period in which the national marketing authorisation had to be issued in the case of recognition. According to Arrow, "*There is no specific deadline for the national phase...this period varies significantly from one CMS [Concerned Member State] to another and in the UK can vary from several weeks to several months.*" See ID 6082, page 31. According to a contemporaneous Lundbeck document: "...normally MCA [the United Kingdom Medicines Control Agency] issues within 14 days..." See ID 904, page 281. In its reply to the Statement of Objections, Lundbeck pointed out that there were instances where Member States in practice did not comply with the various deadlines; see ID 5394, page 51.

¹⁵⁰ Article 17(2) of Directive 2001/83 provided that where a Member State noted that an application for a marketing authorisation was already under active examination in another Member State, it could suspend its own examination in order to await the assessment report prepared by the other Member State.

¹⁵¹ Of course, as mentioned, to the extent that an application was incomplete or incorrect, delays could be incurred. Moreover, if one or more of the other Member States considered that granting a marketing authorisation entailed a risk to public health, Directive 2001/83 foresaw if necessary a procedure leading to a binding decision at EC level.

¹⁵² See Article 17(2) of Directive 2001/83. For an example, see recital (558) below, where Ranbaxy stated: "*We will file now for UK & Germany, where we have our own subs – expect registration in 8 months.*"

¹⁵³ Lundbeck stated in its reply to the Statement of Objections: "*Thus, at the time of the Agreements, obtaining an MA in one single EEA country would theoretically have taken a generic at the very least seven months. In reality, obtaining an MA took often much longer, up to 18 months, depending on the time needed by the applicant to submit all required additional information and respond to the queries of the relevant authority. Obtaining an MA in more than one EEA country [through the mutual recognition process] would have taken at the very least 14 months, but could in reality have taken more than 25 months.*" See ID 5394, page 52; ID 6814, page 18.

to the manufacturing process of its approved API supplier. Based on a previously submitted Drug Master File of another API supplier, a generic undertaking with a marketing authorisation could also apply for a type II variation to its marketing authorisation in order to switch to that different API supplier. According to a March/April 2002 publication of the United Kingdom Medicines Control Agency in the United Kingdom, the Agency processed all type II variations within 90 days from the acknowledgement letter (and 85% within 60 days), resulting either in an approval or a request for supplementary information. For type I variations, the corresponding figures were 100% in 30 days and 84% in 20 days.¹⁵⁴ Whether an applicant actually obtained approval within these time periods depended on the completeness and accuracy of the information supplied to the agency.¹⁵⁵

- (87) With respect to generic medicines which contain the same API as the originator product and are "essentially similar" to that product, the same Directive 2001/83 as well as pre-existing national legislation provided that once a certain period of data exclusivity for the pre-clinical toxicological and pharmacological tests and clinical trials originally performed by the originator company had expired, generic companies were allowed to submit an abridged application for a marketing authorisation, relying for this purpose on the data concerned as originally submitted by the originator company. In the period concerned by this Decision, this period of data exclusivity was six or ten years, depending on the Member State.¹⁵⁶ For most compounds, the period of data exclusivity would normally have expired before the patent protection (including the SPC period) for the compound expired. This was also the case for Lundbeck's citalopram.¹⁵⁷ In such cases, as soon as the patent protection (including SPC) for the compound had expired, generic companies were in principle able to enter EEA markets immediately based on an abridged application for marketing authorisation, which could already have been filed before expiry of the patent protection.¹⁵⁸ The public authorities in charge of granting marketing authorisations could not take into account the patent status of the originator medicine in their decision whether to grant a marketing authorisation to a generic undertaking

¹⁵⁴ ID 1910, page 16.

¹⁵⁵ For example, on 7 May 2002, Tiefenbacher filed in the Netherlands, the Reference Member State, for a Type I variation to its marketing authorisation to cover Matrix's "*patent free extraction method for purification of Citalopram*". This application was completed positively on 16 July 2002, two months and nine days later. See ID 1718, page 1. A filing for Cipla's "*patent free purification method*" was ready for filing on 24 September 2002. According to Tiefenbacher, this application was also approved around two months after filing, see ID 1713, page 1. With respect to type II variations, Ranbaxy stated to Lundbeck: "*We are discussing with a partner for Northern Europe, who will be able to bring our product to the market in 3-4 months*". See recital (558) below. In its reply to the Statement of Objections, Lundbeck claimed that a type II variation would require more time, that is to say "*...at least nine to 12 months...*" See ID 5394, page 246. However, the example Lundbeck mentioned involved the creation and submission of new stability data by the API producer, taking at least six months. If a Drug Master File had already been submitted by the API producer, this delay could be avoided. See footnote 369 below, referred to in Lundbeck's reply to the Statement of Objections, page 246, footnote 974. See also ID 280, page 6.

¹⁵⁶ A period of ten years was used by Belgium, Germany, France, Italy, the Netherlands, Sweden, the United Kingdom and Luxembourg. A period of six years was used by Austria, Denmark, Finland, Ireland, Portugal, Spain, Greece, Norway, Liechtenstein and Iceland. See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 143, footnote 326.

¹⁵⁷ See recitals (109) to (111) below.

¹⁵⁸ For instance, Merck (GUK) obtained its marketing authorisation in the United Kingdom four days after Lundbeck's compound patent had expired there. See recital (259) below.

and such marketing authorisations could already be applied for and obtained before expiry of the compound patent exclusivity period for the medicine concerned. Once the generic undertaking had received a marketing authorisation, it was therefore entitled to market the product in the Member State concerned, even if it could subsequently be required by a court order to cease marketing because of the court's assessment of (the likelihood of) patent infringement.

4.3. Pricing, reimbursement and substitution

- (88) In the period concerned, the setting of price and reimbursement levels of medicines was regulated at Member State level, with each Member State of the EEA following its own policy in this respect. In general, however, it can be said that Member States of the EEA shared three common objectives: (1) patients in need should have access to the necessary medicines; (2) health budgets should remain under control; and (3) incentives for further innovation in medical treatment should exist. Differences between Member States existed mainly in the extent to which they emphasised one or the other of these three objectives, with some Member States with important originator pharmaceutical industries giving a relatively greater weight to the stimulation of innovation.¹⁵⁹
- (89) In several Member States, notably Germany and the United Kingdom, companies were in principle free in the period concerned to set the initial price of new medicines.¹⁶⁰ In other Member States, the initial price of new medicines was the subject of negotiation with or approval by the public authorities. Even when set by the public authorities, the price of a new medicine tends to be much higher than the marginal cost of producing that medicine, as the – normally very significant – R&D expenses of the innovator company need to be covered and a stimulus needs to be given for further innovation. Where a new medicine fulfils a new medical need, uses a new mode of action or shows a stronger performance or fewer side effects than already existing medicines, the producer is in principle in a strong negotiating position to ask a high price, as public authorities will want to ensure that patients have access to that medicine. Where a new medicine has similar therapeutic effects as already existing medicines and no particular advantages over existing medicines, the public authorities may apply "therapeutic reference pricing" and grant the new medicine the same price as the other already existing medicines within the same therapeutic reference group.¹⁶¹
- (90) In all Member States in the period concerned, reimbursement levels for patients were set by the public authorities, whether at 100% of the price level or at a lower percentage. Even in Member States which leave the pricing of new medicines free, the reimbursement level of a medicine, if lower than 100%, tends to exert a moderating influence on its price, as patients may no longer be willing to buy a certain medicine if they have to pay too much for it directly out of their own pocket (the so-called "co-payment"). The setting of reimbursement levels is subject to the same considerations as the setting of the initial price.

¹⁵⁹ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 149.

¹⁶⁰ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 151. See also ID 1053, page 73 (Germany), ID 1072, page 1 (United Kingdom).

¹⁶¹ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 153. The same may apply to the reimbursement level, see recital (90) below.

- (91) In the period concerned, a number of Member States compared the price requested by the producer to the prices of the same medicine in a selection of other Member States (so-called "reference pricing"). As prices set in one Member State can thus become a reference point for subsequent price determinations in other Member States, traditionally the United Kingdom and Germany have been "early launch" countries as they allow companies to freely set the price of a new medicine.¹⁶² The same system of reference pricing may work to gradually decrease the prices of medicines over the years, in the sense that any price decrease applied in one Member State (for instance for general budget reasons or because another, more effective medicine has in the meantime entered the market) will indirectly come to affect price levels in other Member States that use the Member State concerned as reference Member State. This in turn may have further ripple effects on yet other Member States.
- (92) Because of the above mechanisms, a normal price development for a new medicine is that immediately after its market launch the price (adjusted for inflation) of the medicine is at its highest, at a level far above its marginal cost of production. In subsequent years that price level may either remain stable or gradually go down somewhat, while still remaining at a much higher level than the marginal cost of production. This situation will normally continue for the entire period over which the medicine continues to enjoy patent protection (including the SPC period). While a certain degree of competition may exist with other originator medicines that have the same or a similar therapeutic function, such competition will be much less on price than on the qualitative aspects of the different medicines. This is the more so as other originator products will also tend to be sold at prices far above marginal costs as long as they are still patent-protected. Even if one medicine were considerably cheaper than another one with a different active ingredient, physicians will normally not change the active ingredient they deem appropriate for their patient simply because a different medicine may be cheaper. Nor will patients normally prefer a medicine with an active ingredient that may be less appropriate for their health concern, simply because their co-payment might be lower.
- (93) However, once patent protection for the compound has expired and generic competition for the same active ingredient becomes possible, genuine alternatives for the same medicine appear and genuine price competition for that medicine therefore becomes possible, not only between generic companies and the originator company, but also among generic companies. Furthermore, at this point in time, public authorities will tend to put more emphasis on budget control and broad access for patients to the medicine concerned than on continued stimulation of innovation. After all, the basic principle underlying patent protection is that the originator company concerned is sufficiently rewarded for its innovation by the commercial exclusivity it enjoys during the period of patent protection (including SPC protection). Once the period of exclusivity is over, the invention becomes generally and freely accessible to the public. At that time therefore, when generic companies start to enter the market, lower prices for the medicine concerned will normally result, not only from price competition of - and between - generic companies, but

¹⁶² European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 151-152.

also from certain mechanisms public authorities will tend to apply to reduce the reimbursement cost of the medicine concerned for the public health budget.

- (94) Such budget control measures may exist in imposed reductions in the price or reimbursement level of (a) medicines with APIs that are no longer patent protected (including the originator product) or (b) generic medicines (excluding the originator product). Budget control measures may also exist in stimuli to shift demand from the (normally more expensive) originator product to the (normally cheaper) generic product, or even to the cheapest generic product on the market. This can be accomplished by issuing prescription guidelines to the medical profession, with a view to physicians prescribing more often a generic product than the originator product, or by issuing recommendations or binding rules to pharmacists to always substitute a generic product (or even the cheapest generic product) for a prescribed originator product, unless the physician has indicated on the prescription that the originator product is necessary for medical reasons.
- (95) Most Member States applied one or more types of budget control measures after generic entry in the period concerned by this Decision. Based on information from Lundbeck, a non-exhaustive list of examples of such measures in the period concerned is:
- Austria: *"If a generic entered, a new price for the innovative product was negotiated"*¹⁶³
 - Belgium: *"When an INN has become generic, a cluster based on the same active substance is created with a set reference price. The latter has evolved by law over the years from minimal reduction of 16% to minimal reduction of 30% relative to the price of the branded drug."*¹⁶⁴
 - Denmark: *"The reimbursement price was set as the lowest average European price for a product within the same medicinal group, or the Danish price, whichever was lower....Generic entry lowered the average price used to calculate the reimbursement price..."*¹⁶⁵
*"Since 1997, the pharmacies must substitute a generic for a branded product if the price difference is between DKK 5-20, depending on the price of the product, unless the doctor has specifically noted "no substitution" on the prescription or if the patient requests the original product."*¹⁶⁶
 - Finland: *"Every time that the PPB [Pharmaceutical Pricing Board] has made a decision on citalopram reimbursement price, it has used the lowest price available to define the price level (i.e., the generic price). When reimbursement status is applied for a new generic product, the generic company in most cases (if not always) applies a price that is 40% lower in comparison to the original product as this way the product in question will be promptly included into the reimbursement and reference price system."*¹⁶⁷

¹⁶³ ID 1053, page 21.

¹⁶⁴ ID 1053, page 33.

¹⁶⁵ ID 1053, pages 42-43.

¹⁶⁶ ID 1053, page 44.

¹⁶⁷ ID 1053, page 55.

*"Mandatory generic substitution was introduced in Finland following the entry into force of the Act on the Amendment of the Medicines Act (80/2003) on April 1, 2003."*¹⁶⁸

- France: *"The price of generic medicine is linked to the price of branded medicinal products. The price of the generic is usually 55% lower than the original price of the branded medicinal product. When the first generic enters the market, the price of the branded drug should be decreased by 15%."*¹⁶⁹

*"Since 1999, pharmacists have a right to substitute medicinal products listed on the directory (repertoire). Every year, a substitution percentage for each generic group and one that applies to all groups is set. This percentage has increased from 35% in 2000 to 80% in 2010."*¹⁷⁰

- Germany: *"The requirement [for pharmacies] to dispense one of the three least expensive drugs has existed since 2002."*¹⁷¹
- Italy: *"Law 549/1995 provided that generics should have a price 20% less than the reference product."*¹⁷²

*"The entry of a generic determines the application of the reference price system pursuant Law 405/2001, whereby a product is reimbursed within the limit of the lowest price of the products having the same composition an[d] dosage form ("reference price")."*¹⁷³

*"Law 405/2001 provides that the pharmacist should dispense the product having the lowest price unless the prescriber expressly writes a non-substitution clause or the patient request the prescribed product and pays the difference."*¹⁷⁴

- Netherlands: *"Generic entry may have impacted the prices, since the maximum prices set pursuant to the WGP [Wet geneesmiddelenprijzen] have been amended as a result of generic entry in the reference countries, which led to different G-Standard [official list of suggested retail sales prices] prices and wholesaler prices."*¹⁷⁵
- Norway: *"Generic substitution regulation was introduced on March 1, 2003. Under the substitution rules, the pharmacist can offer a generic substitute if the Department of Health and Social Affairs has determined that the product can be used as a substitute. The National Insurance Fund reimburses the full price paid by the patient for the generic substitute. If the patient however prefers the branded medicinal product, he has to bear the additional costs. The prescriber can refuse substitution for the patient."*¹⁷⁶

¹⁶⁸ ID 1053, page 57.
¹⁶⁹ ID 1053, page 68.
¹⁷⁰ ID 1053, page 70.
¹⁷¹ ID 1053, page 78.
¹⁷² ID 1053, page 101.
¹⁷³ ID 1053, page 98.
¹⁷⁴ ID 1053, page 100.
¹⁷⁵ ID 1053, page 126.
¹⁷⁶ ID 1053, page 108.

- Sweden: *"When generic products enter the market, the pharmacies are required to substitute prescription medicine with a lower-priced identical product."*¹⁷⁷
- United Kingdom: *"Generic products are subject to reimbursement tariffs, which are set by the government and aim to reflect the actual acquisition cost of a generic, rather than the list price of the branded product."*¹⁷⁸

*"The physician decides whether to write a prescription for branded or generic citalopram/escitalopram. In the U.K., 80% of prescriptions are for generic products. If a prescription is for a generic, the pharmacist can choose which product."*¹⁷⁹

- (96) Because generic entry tends to strongly intensify or even initiate price competition for the medicine concerned¹⁸⁰ and because the above-mentioned budget control mechanisms will tend to further reduce prices for that medicine and to shift demand to generic versions of it, consumers will benefit from often considerably lower prices for the medicine concerned. The Commission's inquiry into the pharmaceutical sector found that, on average, the price at which generic companies entered the market was 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after entry, prices of generic medicines were on average 40% below the former originator price.¹⁸¹ This average additional price decrease over two years was also the result of an increased number of generic entrants, as shown by the sector inquiry.¹⁸² The number of generic entrants is therefore important for competition. Financial benefits for consumers from generic entry result directly for patients from lower co-payments (in those Member States which use co-payments) and indirectly from reduced financial pressure on public or private health insurance budgets and

¹⁷⁷ ID 1053, page 117.

¹⁷⁸ ID 1072, page 6.

¹⁷⁹ ID 1072, page 8. In the United Kingdom, national guidelines for physicians strongly encouraged generic substitution. This mechanism was so effective that already in 2002 citalopram was prescribed generically by doctors in 90% of the cases, although no generic citalopram was yet available. Only the remaining 10% of prescriptions were written for Lundbeck's branded Cipramil. See Department of Health (2003) – "Prescription Cost Analysis: England 2002", http://www.dh.gov.uk/en/Publicationsandstatistics/Statistics/StatisticalWorkAreas/Statisticalhealthcare/DH_4000027

¹⁸⁰ In the United Kingdom, for instance, wholesalers and pharmacists had the incentive to seek out the cheapest generic citalopram available, as *"pharmacies are financed by the payments from the NHS. The NHS pays the pharmacy the wholesale price for any drugs dispensed, with a deduction of an estimated discount given by the wholesaler [clawback]. If the discount given to the pharmacy was in fact larger than estimated by the authorities, the pharmacy may keep the difference. Pharmacies are therefore keen to obtain products from the wholesalers as cheaply as possible."* (ID 1489, page 103). If enough generic companies were on the market, selling sufficient supplies of citalopram, this would have triggered a rapid downward price spiral, as indeed happened after October 2003 (see recital ((209) below for more details on the evolution of generic prices in the United Kingdom). The United Kingdom health system would also have benefited from lower citalopram prices, firstly by clawing back some of the discounts obtained by the pharmacists, through a discount recovery scheme, and secondly by lowering the reimbursement tariff for citalopram.

¹⁸¹ European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 9 and 85 to 116.

¹⁸² European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 107 and 572. Competition may be more intense over time, when generic entrants rely on different APIs that are produced by different production processes with different marginal costs of production as this may increase the scope of price competition among generic entrants.

premiums (to the benefit of all consumers, not just the patients concerned). Actions that delay generic entry will prevent such benefits from arising.

5. THE PRODUCT: CITALOPRAM

5.1. Product characteristics

- (97) Citalopram is the international non-proprietary name (INN) of an antidepressant molecule which inhibits the reuptake of the neurotransmitter serotonin in the brain. According to Lundbeck's annual report for the year 2002, *"Depression involves an imbalance in serotonin metabolism in the brain. Serotonin acts as a signaling compound by transmitting nerve impulses from one nerve ending to another; too little serotonin can trigger depression. Antidepressants such as citalopram... increase the amount of serotonin in the synapse between the nerve endings, by preventing the compound from being taken up into the neurones. An antidepressant using this mode of action is called an SSRI (selective serotonin reuptake inhibitor)."*¹⁸³
- (98) In the EEA, Lundbeck marketed citalopram as tablets of 10mg, 20mg and 40mg in packs of different tablets counts and as an oral, liquid 40mg formulation. For hospitals, an injection/infusion mode of delivery was also marketed. Citalopram received approval in the EEA for the following medical indications: major depressive disorder, prevention of the recurrence of the depressive episode, the depressive phase of bipolar disorder¹⁸⁴ and anxiety disorders¹⁸⁵, particularly panic disorder with or without agoraphobia.¹⁸⁶ Citalopram was also recommended in co-morbid conditions with dementia or Alzheimer's for the elderly.¹⁸⁷ For these indications, citalopram was prescribed by general practitioners in primary care, as well as by specialists, mainly psychiatrists and neurologists, both in hospitals and in private practices. Citalopram's more common side-effects included insomnia, dry mouth, nausea, sleepiness and increased sweating.¹⁸⁸
- (99) In principle, as long as an anti-depressant has been found to be sufficiently effective and well-tolerated, physicians are unlikely to switch patients to another active ingredient in the course of the treatment.¹⁸⁹ This will be true even if another active

¹⁸³ ID 1499, page 23.

¹⁸⁴ ID 9, page 498.

¹⁸⁵ ID 1499, page 26: "Anxiety can be divided into different indications, but the best known are generalised anxiety disorder, social anxiety disorder, panic disorder, obsessive compulsive disorder (OCD), and post-traumatic stress disorder (PTSD)."

¹⁸⁶ ID 1055.

¹⁸⁷ ID 1497, page 28.

¹⁸⁸ ID 1055.

¹⁸⁹ See for instance the following publications:

- Folia Pharmacotherapeutica (2000) - "Place des antidépresseurs dans la prise en charge de la dépression en première ligne chez l'adulte", <http://www.cbip.be/Folia/index.cfm?FoliaWelk=F27F01B> ;
- DGPPN, BÄK, KBV, AWMF, AkdÄ, BptK, BApK, DAGSHG, DEGAM, DGPM, DGPs, DGRW (2009) – "S3-Leitlinie/Nationale VersorgungsLeitlinie Unipolare Depression Langfassung", http://www.versorgungsleitlinien.de/themen/depression/pdf/s3_nvl_depression_lang.pdf;
- AFSSAPS (2005) – "Bon usage des antidépresseurs au cours des troubles dépressifs chez l'adulte ", <http://www.afssaps.fr/content/download/6201/60125/version/3/file/map.pdf>;
- Health Service Executive (2006) – "Guidelines for the Management of Depression and Anxiety Disorders in Primary Care", http://www.icgp.ie/assets/77/77D7A752-C0BD-63AC-448B59552E2A469E_document/GuidelinesontheManagementofDepression.pdf;

ingredient may be considerably cheaper. After an initial period, patients therefore normally remain "loyal" to the anti-depressant medicine they have been prescribed. It is, however, normally possible for a physician to switch existing patients from the originator product to a generic product containing the same active ingredient (unless for instance the patient does not tolerate a different coating used in the generic pill, which, however, is rare) and it is certainly possible for a physician to prescribe a new patient a generic antidepressant instead of the originator product. Given that escitalopram is the S-enantiomer part of citalopram (which also contains the stereoisomer R-citalopram), it may also be possible to switch existing patients from citalopram to the successor product escitalopram, in particular if the patient did not tolerate or respond to citalopram well.¹⁹⁰ It would, in any case, certainly be possible for a physician to prescribe a new patient escitalopram instead of citalopram.¹⁹¹

5.2. Citalopram within the antidepressant universe

- (100) The European Pharmaceutical Market Research Association (EphMRA) maintains¹⁹² a classification of molecules, in which citalopram belongs to the anatomic therapeutic group of Selective Serotonin Reuptake Inhibitors (SSRIs) within the broader N6A group of antidepressants.¹⁹³

- Agenzia del Farmaco (2001) – "La depressione e gli antidepressivi", http://www.agenziafarmaco.gov.it/wscs_render_attachment_by_id/111.50560.11503794810969ea7.pdf?id=111.50565.1150379481285;

- Nederlands Huisartsen Genootschap (2003) – "Depressieve stoornis M44 (oktober 2003)", http://nhg.artsennet.nl/kenniscentrum/k_richtlijnen/k_nhgstandaarden/Samenvattingskaartje-NHGStandaard/M44_svk.htm;

- National Institute for Clinical Excellence (2004) – "Depression – Management of depression in primary and secondary care", Clinical Guideline 23, <http://www.nice.org.uk/nicemedia/live/10957/29592/29592.pdf>.

In reply to the Statement of Objections (see ID 5394, footnote 249), Lundbeck pointed out that guidelines recommended switching only when a medicine failed.

¹⁹⁰ See recital (108) below, mentioning elderly patients with tolerance problems in particular. See also recitals (139) and (140). When applying for a marketing authorisation for escitalopram in Sweden, Lundbeck "initially submitted an application under the Note for Guidance on Clinical investigation of chiral active substances [...] which made it] possible to refer (or bridge) to data for the racemate [that is to say citalopram] if it can be justified that the data will also be relevant for the enantiomer [escitalopram]." See ID 6814, page 20. In other words, Lundbeck considered that it could rely for escitalopram on certain of the pre-clinical data originally submitted for the registration of citalopram based on bridging studies (abridged application) ("pharmaceutical studies have demonstrated that the pharmacological activity of citalopram resides only in the S-enantiomer"; ID 6815, page 2). This was, however, rejected by the Swedish authorities. See also ID 5394, page 238.

¹⁹¹ See recital (196) below, where a contemporaneous document of Lundbeck is quoted as saying: "Cipralex (escitalopram) is planned to be launched in April 2002. The aim will be to convert the remaining part of the citalopram franchise to escitalopram as fast as possible, with strong focus on the first three months after launch. This implies a cannibalisation of the citalopram business, the effect of which is a reduction of citalopram sales of 65% in total on E [expected] 2001."

¹⁹² This classification is used by IMS Health (IMS), a provider of health data services, as a basis for the data provided by it (http://www.whoec.no/atc_ddd_methodology/the_ephmra_classification_system/). Data and other information from IMS, which are cited or used in this Decision, were obtained by the Commission pursuant to requests for information based on Article 18(2) of Council Regulation 1/2003. IMS has not acted as an advisor, expert, or consultant in connection with this report or, more generally, in connection with the investigation. Further references to IMS in this text should be understood in the same way.

¹⁹³ See IMS data.

- (101) The antidepressant universe, as listed by the EphMRA classification in the N6A group¹⁹⁴, contains one hundred twenty molecules. These molecules are further grouped, by their therapeutic indications, in:
- N6A2 – Herbal antidepressants;
 - N6A3 – mood stabilizers;
 - N6A4 – SSRI antidepressants, including citalopram;
 - N6A5 – SNRI antidepressants;
 - N6A9 – other antidepressants.
- (102) As Lundbeck mentioned in its annual report for the year 2001: "*Drugs for treatment of depression can be divided into two generations. The first generation comprises the so-called tricyclic antidepressants and monoaminoxidase inhibitors (MAOIs). The Selective Serotonin Reuptake Inhibitors (SSRIs) are by far the largest and most important group of the latest generation of antidepressants.*"¹⁹⁵
- (103) Historically, some of the molecules in group N6A9, referred to hereafter as MAOIs, were the first antidepressants, introduced in the 1950s. They targeted all monoamine neurotransmitters (serotonine, dopamine, norepinephrine, amongst others.). They were considered very effective in treating depression, but had a significant risk profile, as they interacted with other substances, sometimes resulting in the patient's death.
- (104) The next group in time of antidepressants to be used were tricyclic antidepressants (or TCAs), thus named because of their molecular structure. They began to be launched in the EEA in the 1960s and were considered to be almost as effective as MAOIs, but less dangerous for the patients. However, overdoses with TCAs were still likely to be lethal. TCAs also belong to the N6A9 class. Together, MAOIs and TCAs were referred to in the industry as "first generation antidepressants".
- (105) The 1990s saw the market entry and increasing popularity of new, second-generation anti-depressant medicines: most selective serotonin reuptake inhibitors (SSRIs) entered the EEA markets in the early 1990s¹⁹⁶, followed by serotonin-norepinephrine reuptake inhibitors (SNRIs) in the second half of the decade¹⁹⁷. SSRIs and SNRIs were as effective as TCAs, but safer to use, and thus by the end of the decade, largely replaced the TCAs: "*The main reasons for the massive shift from TCAs, which formerly dominated the pharmacotherapy of depression, to SSRIs and SNRIs are the adverse effect burden of TCAs and their lethality in overdose. An overdose with a TCA is more than 5 times as likely as an overdose with an SSRI to result in death.*"¹⁹⁸ Throughout the 1990s and early 2000s, the antidepressant market as a whole grew strongly, with more patients being treated with second-generation products for more indications and over longer periods of treatment.

¹⁹⁴ [See IMS data.](#)

¹⁹⁵ ID 1498, page 16.

¹⁹⁶ Some, like fluoxetine and citalopram, already entered one or more national markets in the EEA in the late 1980s. See ID 1053, pages 137-138.

¹⁹⁷ ID 1053, page 137.

¹⁹⁸ Bodkin, J.A., Gören, J.L. (2007) - Not Obsolete: Continuing Roles for TCAs and MAOIs, *Psychiatric Times*, Vol 24, No 10.

- (106) In the course of the 1990s, SSRIs became the most popular type of anti-depressant. Lundbeck's reports show that, between 1999 and 2005, sales of second generation antidepressants (SSRIs and SNRIs), including citalopram, grew strongly.¹⁹⁹ Lundbeck remarked in its annual report for the year 2001 that *"SSRIs are by far the largest and most important group of the latest generation of antidepressants."*²⁰⁰ Indeed, in several of the EEA Member States, SSRIs (including citalopram) were officially recommended as the first-line treatment for depression, anxiety and bipolar disorder by medical guidelines.²⁰¹ For example, in the United Kingdom: *"When an antidepressive is to be prescribed in routine care, it should be a SSRI, because SSRIs are as effective as tricyclic antidepressants and are less likely to be discontinued because of side effects."*²⁰² As Lundbeck remarked in its annual report for the year 1999: *"Because SSRIs have fewer side effects, they can be used to treat patients with chronic depression over longer periods of time – in some cases, for the rest of the patient's life."*²⁰³
- (107) The main difference between SSRIs and SNRIs is that SSRIs inhibit the reuptake of a single neurotransmitter - serotonin at the neuronal level – and belong to the N6A4 group, while SNRIs act upon the levels of two neurotransmitters - serotonin and norepinephrine - and belong to the N6A5 group. The most popular SNRI was venlafaxine (Wyeth's brand Effexor), which was launched in the EEA in 1994. While it had apparently better efficacy than SSRIs, it was considered primarily a second-line treatment²⁰⁴ because of the high number of side-effects.²⁰⁵ In addition, other classes such as NRIs²⁰⁶ (norepinephrine reuptake inhibitors) and TeCAs (tetracyclic antidepressants) also appeared, but sales data seem to indicate that they were less popular than SSRIs and SNRIs.
- (108) Aside from citalopram, other SSRIs sold in the period concerned in the Member States of the EEA included fluoxetine (Eli Lilly's brand Prozac), fluvoxamine (Solvay's brand Fevarin), paroxetine (GSK's brand Seroxat) and sertraline (Pfizer's brand Zoloft). In 1995 Lundbeck stated: *"Five important unique selling points are*

¹⁹⁹ In Europe, a Lundbeck management report (ID 814 page 6) show that in 1998 and 1999, SSRIs and SNRIs had a market share of over 65% of the total N6A market. In 2001, according to Lundbeck's annual report (ID 1498 page 19), SSRIs alone had reached over 85% of the N6A market. This trend continued in 2002, when, according to a Lundbeck document (ID 3416 page 27), SSRIs alone accounted for 90% of the N6A market. In 2003 (ID 3417 page 29), the share of SSRIs and SNRIs in the N6A market remained above 70%, going down to over 60% in 2005 (ID 3415 page 40). At the same time, the N6A market as a whole had a strong potential for growth. The Lundbeck yearly report 2001 shows (ID 1498 page 18) that between 1999 and 2000 the antidepressant market grew 18%. In 2003, the market could still grow nearly 15% a year (ID 3416 page 36).

²⁰⁰ ID 1498, page 16.

²⁰¹ In many Member States, health agencies and independent bodies provided prescription guidelines, providing guidance to physicians (particularly general practitioners) on how to deal with depressed or anxious patients, reviewing the efficacy and side-effects of a wide array of medicines as well as laying down the recommended duration for the treatment and eventual treatment alternatives.

²⁰² National Institute for Clinical Excellence (2004) – "Depression – Management of depression in primary and secondary care", Clinical Guideline 23, <http://www.nice.org.uk/nicemedia/live/10957/29592/29592.pdf>, page. 7. This edition of the United Kingdom medical guidelines was in force until 2007.

²⁰³ ID 1497, page 28.

²⁰⁴ For instance if initial treatment with a SSRI had failed to produce the desired results.

²⁰⁵ ID 9, page 30.

²⁰⁶ NRIs include mirtazapine (Organon's brand Remeron) and reboxetine (Pfizer's brand Edronax/Davedax), and were launched in the second half of the 1990s (ID 1053, page 138).

*used on the market: Cipramil is the most selective SSRI, it is well tolerated, has simple kinetics without active metabolites, it is not likely to interact with other drugs because of its minor influence on the metabolic enzyme systems of the liver, and it is easy to administer, only once a day. These advantages over other SSRIs are especially important as regards elderly patients. This group of patients often has problems of tolerance and frequently receives other medication concurrently with antidepressant treatment. In addition, they need a simple medication scheme."*²⁰⁷ As of 2002, Lundbeck launched in EEA markets a successor SSRI to citalopram, called escitalopram, which is the S-enantiomer of citalopram. In 2004 Lundbeck described escitalopram as "*more than just the active enantiomer of citalopram. The originally thought "inactive" part of citalopram, R-citalopram, has been shown to counteract S-citalopram and has consequently masked the full efficacy potential of S-citalopram.*"²⁰⁸

5.3. Lundbeck's patent rights on citalopram

- (109) Lundbeck's earliest citalopram patent, filed in 1977 in Denmark (DK 143275) covered the pharmaceutical compound of citalopram and two processes to produce citalopram, referred to by Lundbeck as the cyanation 2002-1 process and the alkylation 2002-2.²⁰⁹ Patents for the product or the processes were granted in most Western European countries between 1977 and 1985. In certain countries at that time, notably Austria, Denmark, Finland, the Netherlands, Norway and Sweden, patents could only be granted for processes for preparing pharmaceutical products, not for the pharmaceutical compound itself.²¹⁰ In these countries, only the original processes for producing citalopram were protected, thus offering only indirect protection for the compound.²¹¹ In principle, if an API producer managed to develop an industrially efficient non-infringing process, market entry of generic citalopram in those countries would be possible as soon as data exclusivity had expired at the latest on 30 January 1999²¹² and the necessary marketing authorisations had been obtained. Lundbeck expected that this would be the case by the year 2000.²¹³
- (110) The same was in principle possible in some other countries in the EEA where Lundbeck neither had any patent protection for the citalopram compound nor for the manufacturing processes. This was the case notably in Greece, Italy, Luxemburg and Portugal.²¹⁴
- (111) In Germany, due to the absence of an SPC²¹⁵, protection on the compound expired already in December 1994. Nevertheless, in this Member State the citalopram compound was still protected to the extent that it enjoyed data protection until 30

²⁰⁷ ID 163, page 982.

²⁰⁸ ID 9, page 30; for 2007 see also ID 5394, page 80.

²⁰⁹ ID 823, page 3 and ID 5394, pages 34-35. The year refers to the date of expiry of patent protection in most countries in the EEA.

²¹⁰ ID 9, page 300. See also ID 869, page 27.

²¹¹ ID 869, page 27.

²¹² ID 280, page 1. In certain Member States, such as Denmark, data protection had already expired on 30 January 1995, depending on whether they granted six or ten years of data protection. See also ID 1053, page 166.

²¹³ ID 9, page 304.

²¹⁴ ID 9, page 36.

²¹⁵ ID 280, page 1.

January 1999.²¹⁶ In Spain patent protection expired in February 1998.²¹⁷ In Sweden, patent protection on the original process expired in December 2001; in Belgium (compound), Denmark (original process), Finland (original process), France (compound), Ireland (compound), the Netherlands (original process), Norway (original process) and the United Kingdom (compound) in January 2002; and in Austria (compound) in April 2003.²¹⁸ These periods include the extended protection offered by SPCs.

- (112) By the mid-1980s, Lundbeck had developed a new and more efficient process for purifying citalopram, referred to by Lundbeck as the diol process, which allowed Lundbeck to manufacture citalopram efficiently on an industrial scale.²¹⁹ In 1985, Lundbeck obtained patent protection in the EEA for this process under patent number EP 0171943²²⁰ (and in those countries where this was allowed also for the intermediate produced by the process).²²¹ These patents expired in 2005.²²² From approximately 1986 to 2003, Lundbeck used this process to manufacture citalopram.²²³
- (113) On 13 March 2000, two years before the expiry of the original citalopram patent covering the compound and cyanation and alkylation processes, Lundbeck filed a priority patent application²²⁴ for the so-called crystallisation patent in Denmark, covering a process for the preparation of purified salts of citalopram through crystallisation of the base.²²⁵ An application was made under the Patent Co-operation Treaty (PCT) of the World Intellectual Property Organisation (WIPO) in April 2000 (WO 01/68627: Crystalline base of citalopram). The international filing date was in February 2001 and the patent application was published in September 2001. A number of national patents or utility models were granted in the EEA, starting with a utility model (basically a 6-year patent granted without examination) in the Netherlands on 6 November 2000.²²⁶ The national United Kingdom patent

²¹⁶ Germany was among those countries that granted 10 years of data exclusivity under Directive 2001/83. See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 143.

²¹⁷ ID 9, page 36. Spain was among those countries that granted 6 years of data exclusivity under Directive 2001/83. See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 143.

²¹⁸ ID 9, page 36. See also ID 869, page 23 and ID 9, page 300.

²¹⁹ ID 280, page 1, ID 282, pages 1 to 9 and ID 5394, page 36.

²²⁰ ID 5394, page 36.

²²¹ In Austria, Portugal and Spain, the patent covered the process only. In all other Contracting Parties to the EEA Agreement where Lundbeck registered the patent, it also covered the intermediate. See ID 869, page 28.

²²² ID 869, page 28.

²²³ See ID 823, page 4, footnote 3 and ID 5394, page 36.

²²⁴ The priority application is the first patent filing in any country for the invention concerned. Under the Paris Convention for the Protection of Industrial Property, if within 12 months following the first application in any of the member states to the Convention an applicant makes further patent applications for the same invention in other member states, then, for the purpose of the patent examination, these subsequent applications will be regarded as if they had been made on the date of the first application (the "priority date"). See Sector Inquiry Report, footnote 218.

²²⁵ See ID 823, pages 3-4 and ID 5394, page 36.

²²⁶ Information based on Espacenet (NL1016435) and register.octrooicentrum.nl (1016435). See also ID 847, page 62. This Dutch utility model was granted without examination for a period of 6 years, see ID 4817, page 140 and ID 4817, pages 175, 194 and 219. Amongst others, an Austrian utility model was

application was published on 4 July 2001 and granted on 30 January 2002²²⁷ (GB 2 357 762²²⁸), followed by several other European countries in the first half of 2002.²²⁹ A European patent application was applied for by Lundbeck on 28 February 2001, published by the EPO on 9 January 2002 and granted on 4 September 2002 (EP 1 169 314 and national equivalents).²³⁰ [...] *²³¹

- (114) The crystallisation patent and other process patents which Lundbeck filed close to the expiry of the compound patent are described further below in section 6.3. That section provides additional information on Lundbeck's process patents in connection with its strategy against generic entry, including Lundbeck's objective to create a 'window of opportunity' for the introduction of escitalopram. These process patents created considerable uncertainty for potential generic entrants and were at the heart of the generic companies' struggle for market entry.
- (115) In the 1980s, Lundbeck also started the development of a successor product to citalopram that would be patent-protected for an additional number of years. This product became escitalopram, the S-enantiomer of citalopram. Patent protection for the escitalopram compound, with priority date of 14 June 1988²³², was accepted in most European countries in 1989, albeit not in Denmark (where the application was rejected) and in Finland, Greece, Norway, Portugal and Spain (where compound protection was not possible at that time). The corresponding process patent was granted in all European countries applied for. Patent protection for escitalopram expires in most European countries in June 2014 (including SPC).²³³

5.4. Lundbeck marketing of citalopram in the EEA

- (116) Lundbeck first filed a patent application for the citalopram compound in 1977 in Denmark. However, the original production processes it had developed as part of the original invention worked in the laboratory, but were not well suited to economically produce a pure product on an industrial scale. It was only in 1985 that Lundbeck developed the more efficient diol manufacturing process and prepared to market citalopram as a medicine. Lundbeck obtained its first marketing authorisation in the EEA in January 1989 (in Denmark).²³⁴ The product was launched in Northern Europe at the beginning of the 1990s, but introduced in the larger EEA markets only in 1994-1996.²³⁵ In Germany, for instance, the single largest market in the EEA in

²²⁷ published on 25 June 2001 (AT004364 (U1)) and two German utility models on 31 August 2000 (DE 20007303 (U1)) and on 8 August 2002 (DE 20121240 (U1)). Information based on Espacenet.

²²⁸ Information based on Espacenet. See also ID 723, page 19. Lundbeck's information in ID 5394, footnote 77, that the application for the crystallisation patent was published in the United Kingdom on 7 January 2001 appears incorrect.

²²⁹ ID 610, pages 9 and 28.

²³⁰ For instance, the patent for Denmark was granted on 11 February 2002, the patent for Sweden was granted on 16 April 2002. See ID 846, page 46. For the patent situation in Germany, see footnotes 226 and 390.

²³¹ Information based on Espacenet. See also ID 1713, page 1 and ID 2773, pages 1 to 4.

²³² See ID 823, pages 3-4 and ID 5394, page 37.

²³³ ID 280, page 1, ID 286, pages 1 to 17.

²³⁴ ID 844, page 8.

²³⁵ ID 823, page 3, ID 673, page 26, ID 621, page 3.

According to one study, additional safety data had to be provided to obtain marketing authorisation in those larger markets in the EEA. See ID 9, page 370.

terms of number of inhabitants, citalopram was not approved for marketing until June 1996.²³⁶

- (117) By 1993, four years after citalopram's first market introduction in Denmark in 1989, Lundbeck had become fully aware of the enormous commercial potential of citalopram for the company. In its Strategic Plan for 1993 Lundbeck wrote:

*"CIPRAMIL, although still in the introductory phase, is by far the most important Lundbeck product, accounting for 65% of the antidepressant business and 22% of total turnover in 1993. CIPRAMIL is marketed with great success in Denmark, Finland, Switzerland, Greece, Luxembourg, Austria, Belgium and Sweden. It is expected that half of Lundbeck's turnover in 1997 will come from the sales of CIPRAMIL and that its sales will have grown with about 800% by the year 2000."*²³⁷

- (118) By 1996, Lundbeck's sales of citalopram in the EEA (at EUR [50-150]* million) had come to represent [50-60]* % of the undertaking's effective total sales in the EEA. By 2002, Lundbeck's sales of citalopram in the EEA (at EUR [400-600]* million) represented [80-90]*% of the undertaking's effective total sales in the EEA.²³⁸

- (119) At the same time, the product was also highly profitable for Lundbeck:

*"As the CIPRAMIL profit per daily dosis is often five times as large as the profit per daily dosis of older products, and as the potential market volume is up to three times the volume for the old tricyclic antidepressants, the majority of Lundbeck's marketing activities aim to ensure CIPRAMIL's market penetration."*²³⁹

- (120) Thus, while in 1993 Lundbeck's profit before tax (on revenue from all products) had been 7%, by 2002 this had grown to 22%, largely due to booming sales of citalopram.²⁴⁰ Lundbeck internally referred to citalopram as its "golden egg".²⁴¹

- (121) As already mentioned, citalopram was promoted by Lundbeck as the SSRI with the least side-effects, having the least interactions with other medicines, and easiest to administer. A Lundbeck document from 2000 stated that *"since the launch of citalopram in Denmark for a good ten years, the main argument in the marketing has been that citalopram is the most selective SSRI."*²⁴² In 2001, Lundbeck reported that *"Citalopram is the fastest growing product within the SSRIs."*²⁴³

- (122) The first marketing authorisation for escitalopram, Lundbeck's successor product to citalopram, was granted in December 2001 (in Sweden). Due to delays in approval, Lundbeck did not meet its original objective of launching escitalopram in the first Member State by May 2001.²⁴⁴ The Swedish approval was the basis for a mutual

²³⁶ Marketing authorisations for citalopram were issued in France in December 1994 and in the United Kingdom in March 1995. See ID 280, page 1, ID 283, pages 1-2.

²³⁷ ID 163, page 981.

²³⁸ ID 972.

²³⁹ ID 163, page 982.

²⁴⁰ ID 1499, page 60.

²⁴¹ ID 230, page 193.

²⁴² ID 9, page 587.

²⁴³ ID 1498, page 18.

²⁴⁴ ID 163, page 447. Lundbeck had expected that escitalopram would be launched in Sweden already in May 2001. See ID 9, page 675. See also ID 815, page 45. Lundbeck informed the Commission that it had filed an abridged application based on Article 10(1) of Directive 2001/83 considering that Lundbeck could rely on the pre-clinical data originally submitted for the registration of citalopram. The

recognition procedure by the other Member States.²⁴⁵ By May 2002, Austria, Belgium, Denmark, France, Ireland, Luxembourg, Norway, Sweden and the United Kingdom had approved escitalopram for the treatment of depression and panic disorder. However, Lundbeck had to withdraw its application in Finland, Germany, Greece, Italy, Portugal and Spain after these national authorities raised public health concerns.²⁴⁶ By December 2002, escitalopram had also obtained marketing authorisations in Finland, Germany, Italy, Portugal and Spain.²⁴⁷ Lundbeck introduced escitalopram in most EEA markets between April 2002 (Sweden) and April 2003 (Belgium). Escitalopram was launched in the United Kingdom in June 2002.²⁴⁸ Lundbeck markets escitalopram in the EEA mainly under the brand names Cipralext, Seroplext and Sipralext.

6. LUNDBECK'S STRATEGY AGAINST GENERIC ENTRY INTO THE CITALOPRAM MARKET²⁴⁹

6.1. Lundbeck's overall strategy against generic entry on citalopram

(123) Because Lundbeck had managed to introduce citalopram, first patented in 1976, in the larger European markets only by the mid-1990s, the available time for Lundbeck to fully exploit the product commercially before patent expiry of the compound, by January 2002 for a number of European countries and earlier for certain other European countries²⁵⁰, was comparatively short.

(124) As early as 1997, therefore, Lundbeck started planning for possible generic entry in the coming years. An internal planning document of 14 February 1997 on Cipramil sales forecasts for the coming years stated:

*"We are assuming that Citalopram generics will gain 40-70% of total substance volume in year five after introduction (at a 40% price discount to the original) (emphasis in the original)."*²⁵¹

Later on, the document stated: *"The negative impact of generic citalopram on Lundbeck's own original sales will vary by market according to independent variables such as reimbursement, generic substitution regulations, the existence of a generic environment or suppliers..., the current & expected volume share of generics for the total pharma market..., profit margins, etc. Lundbeck's share of Citalopram substance following patent expiry is forecast as shown in **figure 6**. The end-point for the volume market share of Citalopram substance is assumed to be year 5 after patent expiry. The end-points for UK, Germany, Italy & Spain (realistic scenario)*

Swedish authority, however, required the submission of all the pre-clinical and clinical data requested under the normal procedure. See ID 5394, page 238.

²⁴⁵ ID 280, page 2, ID 287, pages 1 to 2.

²⁴⁶ ID 5394, footnote 930.

²⁴⁷ ID 1499, pages 10-11. Cipralext was launched in Spain only in April 2004. See ID 163, page 141.

²⁴⁸ ID 1499, page 10.

²⁴⁹ The Commission's factual description in this chapter of Lundbeck's strategy against generic entry into the citalopram market does not prejudice the question of the legality of those practices of Lundbeck which are not legally assessed in this Decision.

²⁵⁰ See section 5.3 above.

²⁵¹ ID 9, page 282.

are assumptions taken from IMS who forecast that original fluoxetine²⁵² will keep only 30%, 40%, 50% and 60% respectively of substance sales; generics will gain the remainder at a price/day 40% lower than the original. Historic experience from the patent expiry of fluoxetine shows that in Finland, [two countries outside EEA] & Denmark generics have gained a 25-30% volume share of total substance in the first year after patent expiry. In Finland, 4 years after patent expiry original fluoxetine only has 30% of substance volume [emphasis in the original].²⁵³

Figure 6 of this document showed the following:

countries	impact	scenario	year 0	1	2	3	4	5+
DK, UK, IRE, NL, [not EEA]	VERY HIGH	PESSIMISTIC	[90-100]*%	[65-75]*%	[40-50]*%	[30-40]*%	[20-30]*%	[15-25]*%
		REALISTIC	[90-100]*%	[65-75]*%	[45-55]*%	[35-45]*%	[25-35]*%	[25-35]*%
		OPTIMISTIC	[90-100]*%	[75-85]*%	[60-70]*%	[55-65]*%	[50-60]*%	[45-55]*%
F, S, SF, N, D, B, A, GR, [not EEA]	HIGH	PESSIMISTIC	[90-100]*%	[65-75]*%	[40-50]*%	[30-40]*%	[25-35]*%	[20-30]*%
		REALISTIC	[90-100]*%	[70-80]*%	[50-60]*%	[45-55]*%	[40-50]*%	[35-45]*%
		OPTIMISTIC	[90-100]*%	[80-90]*%	[65-75]*%	[60-70]*%	[55-65]*%	[55-65]*%
ITALY	MED	PESSIMISTIC	[90-100]*%	[70-80]*%	[55-65]*%	[45-55]*%	[40-50]*%	[35-45]*%
		REALISTIC	[90-100]*%	[75-85]*%	[60-70]*%	[55-65]*%	[50-60]*%	[45-55]*%
		OPTIMISTIC	[90-100]*%	[80-90]*%	[65-75]*%	[60-70]*%	[55-65]*%	[55-65]*%
SPAIN	LOW	PESSIMISTIC	[90-100]*%	[70-80]*%	[55-65]*%	[45-55]*%	[40-50]*%	[35-45]*%
		REALISTIC	[90-100]*%	[80-90]*%	[65-75]*%	[60-70]*%	[55-70]*%	[55-65]*%
		OPTIMISTIC	[90-100]*%	[80-90]*%	[75-85]*%	[70-80]*%	[65-75]*%	[65-75]*%

Source: ID 9, page 290.

²⁵² Fluoxetine (best known under its brand name Prozac) is another anti-depressant in the SSRI class. In this document, Lundbeck uses the development in generic sales of fluoxetine which IMS expected to occur in the years following patent expiry of fluoxetine as a proxy for the expected development of generic sales of citalopram after patent expiry of citalopram.

²⁵³ ID 9, page 284. See also ID 9, page 303.

Note: These figures assumed that Lundbeck would maintain its price for Lundbeck citalopram at the original level and would not launch its own generic product.²⁵⁴

- (125) By the end of 1997, Lundbeck identified the following "sales risk and uncertainty" in its Budget and Activity Plan for 1998 :

"With an attractive, worldwide SSRI market estimated at a value of more than DKK 30bn [over EUR 4 billion]²⁵⁵ in 1996, generic SSRI competition poses a major threat to Lundbeck.

*About 60% of Lundbeck's 1998 turnover is expected to come from CIPRAMIL. It is to be foreseen that generic competition will limit CIPRAMIL's growth rate in the antidepressant market in the years to come."*²⁵⁶

Consequently, Lundbeck listed as one of the company's key expectations for 1998: *"Implement generic strategy for citalopram."*²⁵⁷

- (126) The following year, in its Budget and Activity Plan 1999 of November 1998, Lundbeck listed for this expectation of "Implement a generic strategy for citalopram" the following "results achieved":

*"Initial steps have been taken towards cooperation with generic manufacturers and towards the establishment of local co-marketing agreements with generic companies in order to postpone generic competition on a short-term basis. S-citalopram is considered to be the long-term weapon against generic competition, and the development has been accelerated accordingly."*²⁵⁸

- (127) Later on in the same report, Lundbeck provided more specifics on this strategy:

"Generic citalopram represents a serious risk to Lundbeck because CIPRAMIL accounts for a high percentage of Lundbeck's turnover in all markets and is essential to the company's continued growth. Generic competition is foreseen on markets where the product patent has expired or where generic suppliers may invent a new manufacturing process. In some EU markets the patent has already expired. However, Lundbeck expects only minimal generic competition on CIPRAMIL in Europe before year 2000.

Lundbeck currently strives to identify potential generic chemical manufacturers of citalopram. The aim is to reach agreements with such manufacturers that will postpone or stop the manufacturing of generic citalopram in the short-term, such as:

- *Lundbeck outsources individual steps in the citalopram manufacturing process to the generic manufacturer under a secrecy agreement*
- *Lundbeck purchases the rights to the generic manufacturer's production method*

²⁵⁴ ID 9, page 284.

²⁵⁵ Using an exchange rate of 7.45 DKK to one EUR.

²⁵⁶ ID 163, page 640.

²⁵⁷ ID 163, page 635.

²⁵⁸ ID 163, page 599. An example of a local co-marketing agreement as referred to in this statement is the agreement Lundbeck concluded in 1999 with Nycomed authorising Nycomed to launch a generic version of Lundbeck citalopram in Denmark before expiry of Lundbeck's compound patent there.

- *Lundbeck purchases large quantities of citalopram from the generic manufacturer*

Another defensive strategy is to strike up alliances with some of the important generic marketers. Such alliances must be formed when launch of hostile generics is imminent and will ensure that Lundbeck receives a part of the profits made by the generics.

The development of S-citalopram is the strategic measure which will enable Lundbeck to protect the income from its antidepressant portfolio in the long term."²⁵⁹

- (128) In a report to its Board of Directors of 8 February 1999, Lundbeck wrote:

*"When generic citalopram is launched on a market, there is enormous price competition with the maker of the original product to begin with, until a sort of equilibrium is attained where the generic producers are satisfied with their market share."*²⁶⁰

- (129) Lundbeck's "Goal, Activity and Budget Plan 2000" of December 1999 stated:

*"During the nineties Lundbeck has seen substantial growth in sales, primarily due to Cipramil and geographical expansion. Cipramil will continue to be the main driver behind Lundbeck's sales in the coming years. However, generic citalopram is expected to have appeared on the market in several countries by the end of 2000. But because of Lundbeck's 2002 patent in some major markets and the limited tradition for generics in southern Europe, sales should nevertheless increase in both 2000 and 2001. By 2002, however, generics are expected to have captured a substantial share of Cipramil sales. The launch of Lu 26-054 [Cipralex, escitalopram] is foreseen to prevent a decrease in sales."*²⁶¹

- (130) An undated internal Lundbeck strategic analysis stated under "Assumptions":

"Priority number one is to keep the market price of citalopram as high as possible before launch of Cipralex. Th[is] because of price as a competitive advantage on Cipralex, but first and foremost the threat of an influence on the reimbursement price.

*Priority number two is not to lose more sales to generics than we have to."*²⁶²

- (131) A Lundbeck Business Development document with the title "Generic citalopram update 22 11 02" stated:

"It is like a poker game

- *We have been dealt a mediocre hand – no aces, a couple of queens and some small uneven cards*
- *But we have a large pile of \$\$\$ at our side*
- *We call it – "the art of playing a losing hand **slowly**"*

Our strategy

²⁵⁹ ID 163, page 601.

²⁶⁰ ID 9, page 316.

²⁶¹ ID 163, page 550.

²⁶² ID 903, page 150.

- *Our objective : To create a window of opportunity for the Cipralex switch*
- *Focus on EU and particularly the northern European markets – the generic markets*
- *Three main tactics:*
 - *Influencing the authorities*
 - *Patent defence, mainly process patents*
 - *Deal making".*²⁶³

Lundbeck defined "window of opportunity" as "time difference from Cipralex launch to generic entry [on citalopram]." ²⁶⁴

(132) The same "Generic citalopram update 22 11 2002" also stated:

"Value of delayed generic entry

- *Besides the value of "sales not lost to generics"*
- *Additional value from impact on*
 - *Cipralex price*
 - *Cipralex penetration!*
 - *Staff morale.*"²⁶⁵

(133) From these quotes above it may be deduced that by 1997²⁶⁶ Lundbeck had concluded that generic entry on citalopram, which it deemed realistically possible as of the year 2000 in a number of European countries²⁶⁷, represented the greatest threat to the company's future profitability, given the company's strong dependence on sales of citalopram. By the end of 1998, Lundbeck had come to consider the earliest possible market launch of its successor product escitalopram as the company's most important strategy to ensure continued high turnover and profitability for the company in the future.²⁶⁸ Ideally, the market launch of escitalopram would take place before generic entry on citalopram, thus creating a "window of opportunity" for Lundbeck to switch a maximum of new patients to escitalopram. Lundbeck apparently believed that patients that had started taking escitalopram were unlikely to switch in the course of their treatment to generic citalopram, given that Lundbeck marketed escitalopram as being a different and better product than citalopram.²⁶⁹ Every month gained in enlarging this window of opportunity was therefore of significant commercial value to Lundbeck. The worst case scenario for Lundbeck would arise if massive generic entry on citalopram took place long before escitalopram was launched in the market.

²⁶³ ID 847, pages 50-51. Emphasis in the original. As concerns Lundbeck's view of this document see footnote 1479 below. See also ID 904, page 290, Concerning Lundbeck's general strategy dated 11 December 2001 to aggressively defend itself against any breach of patent rights, see ID 815, page 85.

²⁶⁴ ID 163, page 251.

²⁶⁵ ID 847, page 75.

²⁶⁶ See recital (124) above.

²⁶⁷ See recitals (127) to (129) above. See also ID 847, page 52, which indicates that Lundbeck expected generic entry to occur in a number of Contracting Parties to the EEA Agreement as early as the beginning of the fourth quarter of 1999.

²⁶⁸ See recital (126) above.

²⁶⁹ See recital (108) above. See also section 6.2 below.

In that case, there could be significant negative consequences for Lundbeck's turnover and profitability on citalopram (and therefore for the turnover and profitability of the company as a whole), for the price and reimbursement level of escitalopram²⁷⁰ and for Lundbeck's chances to gain a large customer base for escitalopram (and therefore for the future turnover and profitability of the company as a whole). It thus became very important for Lundbeck to delay as much as possible the entry of generic citalopram in European markets.

(134) The sections below will describe in greater detail, based on contemporaneous documents, several policies Lundbeck pursued as part of its strategic defence against generic entry on citalopram.²⁷¹ Such policies will be described to the extent that they were relevant for the agreements which are the subject of this Decision. These policies were:

- Creating a window of opportunity for escitalopram;
- Patenting processes to manufacture citalopram;
- Intervening in marketing authorisation procedures for generic citalopram;
- Eliminating the competitive threat of upcoming citalopram API producers;
- Persuading generic suppliers to stop their efforts to enter the citalopram market.

In order to understand the rationale behind Lundbeck's agreements as covered in this Decision and to evaluate their legality under Union competition law it is important to realise how these agreements fitted into Lundbeck's overall strategy against generic entry.

6.2. Creating a window of opportunity for escitalopram

(135) Already in its Strategic Plan for 1993 Lundbeck considered:

*"In 1994 it will be decided whether Lundbeck should initiate development of the enantiomer to replace the CIPRAMIL (citalopram) racemate whether for safety reasons (registration authority requirements) or for patent reasons, or both."*²⁷²

(136) A document prepared for a H. Lundbeck A/S Board meeting of 24 April 1998 stated:

²⁷⁰ See section 4.3 above. See also section 6.2 below.

²⁷¹ In its reply to the Statement of Objections, Lundbeck claimed that the Commission "*mischaracterize[s] Lundbeck's actions by focusing on isolated statements in selected documents rather than on the relevant facts and the evidence.*" See ID 5394, page 76. The Commission notes that many of the contemporaneous statements reported in this chapter 6 originate in documents that were distributed to the board of directors of H. Lundbeck A/S. The quotes mentioned in this chapter speak for themselves and constitute facts and evidence regarding the intentions of Lundbeck. Lundbeck did not supply the Commission with quotes from contemporaneous documents that would significantly contradict the policy statements reported in this chapter, which together lead to the conclusion that Lundbeck did everything it could to delay generic entry on citalopram, its most important product by far. At most, quotes reported by Lundbeck in its reply to the Statement of Objections complemented the intentions of Lundbeck, in the sense, for instance, that Lundbeck's acquisition of VIS served not only to avoid generic competition from citalopram products manufactured with the production process of VIS, but also to obtain additional production capacity for Lundbeck's own citalopram. The Commission simply notes, in this respect, that of course the one does not exclude the other.

²⁷² ID 163, page 999.

*"The two developing projects: "[...]" and "S-Citalopram" have been evaluated to see if they could be included as part of a generic strategy. [...] The projects should therefore alone serve the purpose to prevent or slow down generic companies in introducing Citalopram or slow down the loss of market share to the generic competitors."*²⁷³

The same document stated:

*"The S-Citalopram project can lead to the launch of a patent protected product in year 2002. When this happens, Lundbeck's protection against generic competition will be prolonged until 2012 or later in the UK, Ireland, Belgium, Netherlands and France. On top of this a shift from Citalopram controlled release to S-Citalopram will further secure Lundbeck's market share in the other countries where generic competition already exists."*²⁷⁴

According to Lundbeck, a decision to initiate the development of escitalopram for the European market was taken in 1998.²⁷⁵

- (137) Lundbeck's Budget and Activity Plan 1999 of November 1998 stated:

"The enantiomer of citalopram, S-citalopram, is expected to become Lundbeck's most important defence against generic competition on the citalopram racemate. The enantiomer has certain therapeutic advantages over the racemate and will be protected by product patents until year 2012 as well as by clinical data protection.

*The development of S-citalopram will be accelerated...Submission of the registration file is scheduled for year 2001 with subsequent launch in year 2002."*²⁷⁶

- (138) A Lundbeck document of 24 September 1999 listing the company's goals and their status of implementation stated as the company's third goal (after profitability and strengthening citalopram's commercial position):

"Speed up the development of S-citalopram"

The business rationale given for this goal was:

*"Launching a new version of citalopram will prolong Cipramil's [citalopram's] lifetime and minimise losses caused by generic competition".*²⁷⁷

- (139) Lundbeck's "Goal, Activity and Budget Plan 2001" of December 2000 stated in the Executive Summary:

"The major challenges in the medium-term will be to:

- *Successfully switch patients from Cipramil/ Celexa [citalopram] to escitalopram"*²⁷⁸

Later on in the same document, Lundbeck wrote:

*"The immediate goal after launch will be to switch loyal Citalopram prescribers into loyal escitalopram prescribers."*²⁷⁹

²⁷³ ID 9, page 100.

²⁷⁴ ID 9, page 100.

²⁷⁵ ID 5394, page 81.

²⁷⁶ ID 163, page 601.

²⁷⁷ ID 9, page 599.

²⁷⁸ ID 9, page 654.

- (140) Lundbeck's "Goal, Activity and Budget Plan 2002" of December 2001 stated:
- "Launch and promotion of Cipralex (escitalopram) have the highest priority in Lundbeck in 2002. The citalopram franchise should be converted into escitalopram to the largest possible degree....*
- ...
- The continued growth of Cipramil is pivotal for an optimal market penetration of Cipralex (escitalopram) once introduced, and an effective strategy to counter generic erosion of Cipramil sales is of utmost importance in maintaining Cipramil's sales base."*²⁸⁰
- (141) Handwritten notes to a Lundbeck strategy presentation probably dated early 2003 stated:
- "Lundbeck fight generics to create a window of opportunity to switch to escitalopram."*²⁸¹
- (142) The situation in Spain illustrates well the importance to Lundbeck of delaying generic entry of citalopram in order to obtain a higher price for escitalopram. A Lundbeck Business Development document with the title "*Generic citalopram update 04 09 2002*" stated with respect to the Spanish market:
- "We are trying to obtain an injunction against Tifi [Tiefenbacher] – Cipla & Matrix. If successful the generic will not be included in the reference price list. Important for the Cipralex price."*²⁸²
- (143) A later Lundbeck document of December 2003 shows that the arrival of the first generic citalopram on the market in Spain led the authorities, firstly, to establish a reference group with a price for citalopram (including for Lundbeck) which was 29% lower than Lundbeck's previous price for citalopram. Secondly, with respect to escitalopram, where Lundbeck had originally hoped to get a price of [5-15]*% above the previous price for Lundbeck citalopram, the introduction of lower-priced generic citalopram led the Spanish authorities to offer Lundbeck the generic reference price (the one 29% lower) also for escitalopram. Lundbeck hoped at that time it could negotiate up to a price equal to the previous price for citalopram (but not any longer [5-15]*% higher).²⁸³

6.3. Patenting processes to manufacture citalopram

- (144) Between 1997 and 1999, with the expiry of patent protection for the citalopram compound in many European countries looming, Lundbeck launched an avalanche of patent applications for all processes for manufacturing citalopram Lundbeck was able to identify. A Lundbeck press release of 16 May 2000 stated that "*The manufacture of citalopram ... is protected by numerous process patents, which cover all known production methods.*"²⁸⁴ At least seven patent families for processes for manufacturing citalopram were filed. According to Lundbeck, "*The purpose of these*

²⁷⁹ ID 9, page 663.

²⁸⁰ ID 163, page 375.

²⁸¹ ID 844, page 45.

²⁸² ID 904, page 274.

²⁸³ ID 9, pages 723 to 726. See also ID 9, page 722.

²⁸⁴ ID 8, page 521, translation from Danish. See also ID 5394, footnote 257.

*patent applications is to protect alternative methods and thereby to prevent that generic companies circumvent the above-mentioned process patents".*²⁸⁵

- (145) A Lundbeck Business Development document with the title "*Generic citalopram update 22 11 2002*" stated:

"Process patent defence

- *From 1997 we patented some 30 different citalopram processes*
- *In addition, we have some use patents on citalopram within special indications.*"²⁸⁶

- (146) Lundbeck also filed patents for different intermediates of citalopram (including 5-cyanophthalide and 5-carboxyphthalide), as well as for particle sizes, processes to make tablets, and different formulations of citalopram.

- (147) According to information from GUK, in the period from July 2000 to January 2002 – the 18 months before the expiration of Lundbeck's compound and basic processes patent in a number of Contracting Parties of the EEA Agreement²⁸⁷ – Lundbeck applied for 14 new process and related patents for citalopram, of which it withdrew or allowed to lapse eight before December 2006.²⁸⁸ These new process patents Lundbeck was obtaining made it more difficult for generic competitors to produce citalopram, once the compound patent had expired, without potentially infringing one or the other Lundbeck patent (application) on different production methods. The uncertainty this created for potential generic competitors was further increased by the fact that several of Lundbeck's patent applications had not been granted or even published yet shortly before expiry of the compound patent.²⁸⁹

- (148) Lundbeck used its process patents in an effort to deter API producers from producing generic citalopram. In an internal e-mail entitled "*India visit postponed*" of 12 January 2001, Lundbeck wrote:

"This week we have been sending out a "warning" letter with a listing of all our citalopram process patents and other related IP rights. This letter has been sent to

²⁸⁵ ID 869, page 28. These "above-mentioned process patents" were the Lundbeck patents covering the diol process, which Lundbeck had been using in its production of citalopram since the mid-1980s, see recital (112) above. Lundbeck wrote in its third quarter 2002 financial statement: "*Lundbeck is still convinced that citalopram is protected against generic competition beyond the date of expiry of the original compound patent via, among other things, a large number of process patents*" (ID 610, page 7).

²⁸⁶ ID 847, page 56.

²⁸⁷ In January 2002, Lundbeck's last national patents in Contracting Parties of the EEA Agreement on the citalopram compound and original process expired, with the exception of Austria, where the original process expired in April 2003. See ID 9, page 300.

²⁸⁸ ID 1013, page 3.

²⁸⁹ See ID 673, pages 96 to 99, including a list of Lundbeck patents and patent applications Lundbeck sent to API producers and certain generic suppliers in January 2001. In a number of instances the list indicates "*Unpublished application*" or "*To be published soon.*" See also recital (1113) below, where Ranbaxy mentions the risk that claims may be amended before the patent is granted. As another example, Tiefenbacher wrote to Arrow on 28 January 2002, after Lundbeck's patent covering the compound and the two original production processes had expired in most European countries and generic entry had in principle become possible: "*As you know Lundbeck is still publishing a lot of patents and nobody can give guarantees. We are currently checking the situation regarding one patent...It's even not clear whether the application came through or not and – if so – which claims came through or not.*" See ID 631, page 3.

companies which we believe are involved with citalopram, and amongst others the letter has been sent to Natco, Max, Herero, Cipla, Ranbaxy-Vorin, Dai-ichi, Sun and RPG Life Science."²⁹⁰ This letter also mentioned the crystallisation patent as granted as a utility model in the Netherlands.²⁹¹

- (149) According to Lundbeck, Lundbeck's *"enemies"* labelled the crystallisation patent *"high school chemistry"* and considered that it was not novel.²⁹² Lundbeck itself admitted: "[...]"²⁹³ This process patent immediately became Lundbeck's main legal weapon to fight generic market entry in the EEA with infringement litigation.²⁹⁴ According to Lundbeck, use of the original cyanation 2002-1 process or the original alkylation 2002-2 process left chloro- and bromo-impurities that crystallisation of the free base of citalopram could reduce in a very efficient and cost-effective manner to levels below regulatory requirements in the EEA. It is this patent in particular that was at issue in the disputes and litigations with generic companies that led to most of the agreements that are the subject of this Decision, as Lundbeck argued that generic citalopram offered for sale in the EEA had been purified by the API producers concerned through crystallisation of the free base.
- (150) Indeed, in its reply to the Statement of Objections, Lundbeck went so far as to argue that *"No commercially viable processes, apart from the Crystallization Patent and the other processes patented by Lundbeck, existed at the time."*²⁹⁵ However, earlier in the proceedings before the Commission, Lundbeck had stated to the Commission:

"In early 2002, (just after expiry of the Citalopram Product Patent), Generics were preparing to enter the market. They could have entered the market using the Cyanation and Alkylation method, or any other method the Generics could invent (e.g. the Matrix "Washing Method" or Sumika's process). But: the method identified in the Crystallization of Free Base Patent was a more efficient method to achieve

²⁹⁰ ID 681, page 111.

²⁹¹ See recital (248) below.

²⁹² ID 847, page 62. On 12 February 2002, Merck (GUK) stated in an internal e-mail: *"I can't believe that this patent has been granted in the UK... the examiner must have not bothered to object properly (as the crystalline free base has been disclosed in the prior art)."* (ID 673, page 326). Merck added on 25 February 2002: *"the patent is considered to be weak. Thus some generic companies try to invalidate the patent and work together with Tiefenbacher..."* (See ID 675, page 25) Considering these assessments, it is not clear why Merck KGaA argued, in reply to the Statement of Objections, that the possibility that the patent would be revoked, if challenged, was not "distinct" but only "theoretical". (See ID 5960, pages 121-122.)

²⁹³ ID 904, page 251.

²⁹⁴ A generic citalopram update of Lundbeck of 28 June 2002 called the crystallisation patent *"Currently the most important patent."* See ID 848, page 18. According to Ranbaxy in its reply to the Statement of Objections, *"Lundbeck's claim was very broad because any process whereby citalopram base in solution was treated with a reagent and yielded even an infinitesimally small amount of crystalline citalopram would be a target for an infringement attack"* (ID 5176, page 23).

²⁹⁵ ID 5394, page 39; ID 6814, page 4. In its reply to the Statement of Objections, Lundbeck argued infringement of the crystallisation patent, at least initially, by Natco (API supplier to Merck (GUK), Cipla (API supplier to Arrow and Alpharma) and Matrix (potential alternative supplier to Arrow and Alpharma). As for Ranbaxy, Lundbeck at the time mainly argued infringement of two other process patents, namely Lundbeck's iodo and amide process patents (European patents EP 1159274 and EP 1015416 respectively), as reflected in the agreement with Ranbaxy. See recital (564) below. Similarly, in its reply to the Statement of Objections Merck KGaA claimed (without producing further evidence) that it was *"impossible or at least extremely difficult to avoid"* the crystallisation patent. See ID 5960, pages 11, 12 and 26. It moreover claimed that Lundbeck invoked patent EP 1015416 also against Merck (GUK). See ID 5960, page 151.

commercial volumes of sufficient quality quickly. The Crystallization Patent could not prevent generic competition – non-infringing processes to produce citalopram existed, although these were less efficient. The Generics opted to infringe Lundbeck's Crystallization of Free Base Patent in order to boost their potential profits (emphasis in the original)"²⁹⁶

Therefore, according to Lundbeck, "...generic entrants could have produced citalopram by using the process described in Lundbeck's original compound patent filed in 1977, albeit with a different and potentially less efficient method of purification, or they could have invested to invent an entirely new process. The Crystallization of Free Base Process, however, was a significant improvement over other known processes used to manufacture pure citalopram, enabling more efficient production, and several of the early suppliers of generic citalopram thus chose the lower-cost option of infringing Lundbeck's Crystallization of Free Base patent."²⁹⁷

Lundbeck had also earlier explained to the Commission that "In the 2002-2004 timeframe, there were several processes available to produce citalopram. Instead of using one of the several processes available, generics freely chose to use the process described in the Crystallization patent because it was more efficient than the other processes" and had listed the following processes which generic companies could have chosen to use in the period 2002-2004 instead of (allegedly) infringing the crystallisation patent:

- the original cyanation and alkylation processes;
- the Matrix washing method;
- Sekhsaria's process;
- Sumika's process;
- other process, including processes of the API producers Max Pharma, Natco and Cipla, which these API producers claimed to be non-infringing.²⁹⁸

Moreover, on 2 March 2002, Lundbeck's patent experts concluded: "SPE has shown that it is possible to make an active pharmaceutical ingredient (API) that very probably does not require crystallisation of the free base".²⁹⁹

Consistent with these latter explanations is also a contemporaneous statement of 9 November 2002 that Lundbeck's Senior Vice President gave to the press: "It would

²⁹⁶ ID 1944, page 16.

²⁹⁷ ID 823, page 4. See also ID 723, page 19.

²⁹⁸ ID 2773, pages 14 and 15. Regarding this list, Lundbeck clarified: "Given the number of potential processes to produce citalopram, it is not possible to provide an exhaustive list." In reply to the Letter of Facts, Lundbeck pointed out that it did not intend to imply that all these processes would have been available already at the beginning of 2002. With respect to Sumika, Lundbeck claimed that the process became available only in 2004. Regarding Max, Lundbeck alleged that "Lundbeck had already established that [... Max] infringed the Crystallisation patent" and that Max's citalopram would have only become available in 2004, although it was being advertised with a regulatory file and registration already in February 2003. See ID 6814, pages 24-27.

²⁹⁹ ID 681, page 113 (translation from Danish, emphasis in the original). For the relevant context of this statement see further recital (281) below. "SPE" was a research unit within Lundbeck, which according to Lundbeck had developed an alternative process for the preparation of citalopram (for laboratory purposes); the process had been patented by Lundbeck in 1997. See ID 6814, page 27.

*be naïve to think that it is **not** possible for producers of generic copies to produce Cipramil without breaking our patent.*"³⁰⁰

- (151) With respect to Lundbeck's crystallisation patent, it should be noted that as published in September 2001, Lundbeck's PCT patent application WO 01/68627 also contained several claims to the crystalline base of citalopram itself with a purity of more than 99.8% as well as claims to pharmaceutical compositions. After the application had entered into the regional phase, the EPO communicated to Lundbeck on 10 January 2002 that these claims lacked novelty. As requested by the EPO, Lundbeck deleted these claims from the patent application and decided to pursue the claims regarding the crystalline base of citalopram separately in a divisional application. Lundbeck did later manage to obtain from the EPO a product patent on the crystalline base of citalopram itself (EP 1 227 088). This patent was opposed before the EPO and subsequently revoked by the EPO in 2007.³⁰¹ Crystallisation patents applied for at a national level, including GB patent 2357762 in the United Kingdom, also contained claims relating to the crystalline base of citalopram itself and to pharmaceutical compositions.³⁰² The claims regarding the crystalline base of citalopram in particular led to considerable uncertainty on the part of API suppliers and generic companies, because, if valid, they meant that irrespective of whether the precise method of production, the creation of highly pure crystalline base of citalopram could in itself amount to a patent infringement.³⁰³ In January 2001, Lundbeck sent a warning letter to API suppliers and generic companies which it suspected of wanting to sell generic citalopram. This letter listed the Dutch utility model 1016435 which covered not only a process to purify citalopram through crystallisation of the free base, but also, in the words of Lundbeck in the letter: *"The crystalline base of citalopram is claimed *pr. se.*"*³⁰⁴

³⁰⁰ ID 1789, page 6.

³⁰¹ See ID 307, page 2 and Espacenet.

³⁰² It appears that the British patent GB 2357762 was granted including the product claims and pharmaceutical composition claims. Source: Espacenet and United Kingdom Intellectual Property Office IPsum online databases. In its reply to the Commission's Letter of Facts of 12 April 2013, Lundbeck stated: *"With respect to the UK patent, there were simply no opposition claims filed, and therefore the patent remained in force in unamended form."* See ID 6814, page 28. There is no indication in the file that Ranbaxy opposed the British patent, as it had intended in March 2002. See recital (555) below. In the Netherlands, utility model 1017413, granted on 13 September 2001 and similar in nature to utility model 1016435 already granted in November 2000 (see recital (113) above) was challenged by a generic company (different from the ones subject to this Decision) before the Industrial Property Office. In the proceedings, Lundbeck stated that it wished to limit the patent rights to the method claims only. The Office advised in a ruling of 5 September 2002 that only the process claims 3 to 5 (out of a total of 16 claims, of which three related to the crystalline base of citalopram and three more to pharmaceutical compositions) could be maintained in the two patents and then only if they were reformulated to significantly narrow the scope of the claims. See ID 5409. In the United Kingdom, Ranbaxy intended to oppose the product claims in the crystallisation patent, but apparently no longer pursued this after having reached its agreement with Lundbeck.

³⁰³ For examples, see recitals (382) and (505) and (555). This meant that the United Kingdom patent was on the one hand more likely to be infringed than without these claims, but on the other hand also more likely to be found at least partially invalid. Merck KGaA argued in its reply to the Statement of Objections that the wide scope of the crystallisation patent took several API producers by surprise. (ID 5960, page 11).

³⁰⁴ See, for example, ID 903, pages 66-68. The letter stated: *"Lundbeck has used substantial resources in investigating new processes for the manufacture of citalopram. Lundbeck has, of course, protected such new processes in addition to the earlier patented processes). Accordingly, we now have a large*

- (152) In the United Kingdom the crystallisation patent was most notably invoked by Lundbeck in court in October 2002 against the generic company Lagap, after Lagap had started to distribute in the United Kingdom citalopram sourced from Matrix in the United Kingdom.³⁰⁵ On 15 March 2002, Lundbeck had sent a warning letter to Lagap informing Lagap about Lundbeck's patents, which it intended to enforce.³⁰⁶ Having obtained a marketing authorisation on 1 August 2002³⁰⁷, and prior to entering the United Kingdom market, in September 2002, Lagap sent an independent expert to inspect Matrix's manufacturing process at Matrix's manufacturing facility in India for four days. The expert reported that the inspected process, which used a washing method to purify citalopram³⁰⁸, did not involve crystallisation and was, in his opinion, able to operate on an industrial scale. He found that Matrix had the facilities, equipment and raw materials to conduct the process at an industrial scale. In light of this report, Lagap informed Lundbeck on 9 October 2002 that it intended to enter the United Kingdom and started selling Matrix citalopram in the United Kingdom on 11 October 2002.³⁰⁹ In that context, Lagap also provided Lundbeck with a full process description for Matrix's method of production and the report prepared by its expert. Lundbeck, however, issued legal proceedings on 14 October 2002 and sought directions in respect of an application for an interim injunction.³¹⁰ Lagap in turn challenged the patent's validity, denied infringement and stated to the press that it *"had every confidence that it would win"*.³¹¹
- (153) At a hearing for directions before the United Kingdom patent judge in charge of the case, on 18 October 2002, the judge remarked that Lundbeck's expert should view Matrix's production facility to confirm what Lagap's expert had seen before any application for an interim injunction was to be heard. The judge told Lundbeck: *"If your expert goes out and sees what [Lagap's expert] did, and is satisfied in the same way, you had better turn on your toes. If [Lagap's expert]'s report is right, then that*

portfolio of patents and other intellectual property rights relating to the preparation of the compound including special know-how useful to obtain the required purity, formulation of the compound and crystal forms of the compound".

³⁰⁵ On 26 July 2002, Lagap, a United Kingdom subsidiary of the pharmaceutical undertaking Sandoz (in turn part of the Novartis group), had received a United Kingdom marketing authorisation for the distribution of citalopram tablets of 10, 20 and 40 mg, see ID 682, pages 4-5. A Lundbeck document of 14 October 2002 stated: *"Lagab [sic] (Novartis) launched with Matrix in the UK Friday 11 Oct – it seems as if they are only selling to retail pharmacists and not yet to wholesalers – the price is relatively high £12.40 – Lundbeck has requested an injunction to-day – probably a November hearing."* See ID 846, page 34. On 7 March 2003, Lundbeck reported the following press article to its Board of Directors: *"Lagap has sold a generic version of Citalopram in the UK since October 2002. The latest information we have is that Lagap's generic Citalopram is priced on a par with branded Citalopram from Lundbeck. According to our information, Lagap has not been very aggressive in its marketing and thereby not gained much sales. The reason for this cautious behaviour is that if Lagap loses the court case – so far set for October 2003 – it will be fined a penalty according to the damage Lundbeck has suffered. Lagap has not been willing to comment on its position in the UK."* See ID 891, page 36.

³⁰⁶ See ID 5394, page 59.

³⁰⁷ ID 1239.

³⁰⁸ Matrix made a patent application under the PCT for its washing method, see ID 640, page 2.

³⁰⁹ ID 5394, page 68.

³¹⁰ ID 239, pages 497-523 (501-502); ID 234, pages 34 to 36 (which states as entry date 9 October), and ID 5394, pages 68-69 and 206. That Lundbeck had at least considered the idea of concluding an agreement instead of litigating with Lagap is shown by recital (203) below, where a contemporaneous Lundbeck document is quoted as saying: *"May [2002]? MAs [marketing authorisations] for Lagab (Novartis) and Ratiopharm Lu [Lundbeck] requests injunction or settles."* See ID 847, page 4.

³¹¹ ID 1789, page 36.

will be the end of the case."³¹² With the consent of Matrix³¹³, an inspection by Lundbeck of Matrix' production facility in India took place in November 2002, during which the main proceeding was stayed.³¹⁴ In the course of these investigations, Matrix admitted that it had used base crystallisation to manufacture citalopram from December 2000 to July 2001 (when Lundbeck's United Kingdom patent application was published and allegedly without having exported such product to the EEA), but claimed that it had been using the non-infringing process since September 2001 (including for product that had been exported as of March 2002 to the EEA).³¹⁵

³¹² ID 234, page 37. On 23 October 2001, the same judge had issued an interim injunction in the United Kingdom proceedings *Smithkline Beecham PLA v Generics (UK) Limited* ((2002) 25(1) I.P.D. 25005 Official Transcript) (also referred to as the Paroxetine case) against GUK because it had failed to do the necessary "for clearing the way": *"The defendants could, so soon as they settled upon the product they were intending to sell, have caused the litigation to start. They could have done a number of things: First, they could have launched a petition for the revocation of the patent and started a claim for a declaration of non-infringement. Or, since there are certain difficulties with the latter (for example onus of proof goes the other way round), they could simply have said to the patentees, "We intend (we are not saying when but it is a settled intention) to launch our product within the next five years. If you intend to sue us, sue us now". If they had taken such a course, having settled upon the product they intended to sell, the whole of this dispute would have been got out of the way before their date of intended launch. [...] They knew perfectly well the issue of infringement was likely to arise. If they wanted to be sure of their position they could and would have made sure that all their experimental data was properly in place and vouched for by an independent expert. And they would have presented this evidence to the patentees. [...] The commercial position was that they did not take the steps necessary to show exactly what the product they were intending to sell was."* (emphasis added) Source: Westlaw.uk 2001 WL 1346930. Lagap's efforts to clear the way have to be analysed against this background.

Lundbeck argued in its reply to the Statement of Objections that *"The Paroxetine ruling created powerful incentives for both Lundbeck and generic companies to settle instead of litigating. With respect to the UK, Lundbeck hesitated to rely entirely on one important, but isolated, first instance judgment, even though it was favourable to its position. At the same time, generic companies took this judgment as a negative signal that UK courts would be inclined to grant preliminary injunctions to originators absent sufficient action taken by the defendant to resolve the dispute before launch"* (ID 5394, page 58). However, Lundbeck itself stated that before the Paroxetine ruling, *"a preliminary injunction had not been granted in a patent case in the pharmaceutical sector for a long time"* (ID 5394, page 57). It is therefore difficult to see how the Paroxetine ruling, which according to Lundbeck *"was favourable to its position"* in that *"UK courts would be inclined to grant preliminary injunctions to originators absent sufficient action taken by the defendant to resolve the dispute before launch"* could have made Lundbeck less inclined to litigate compared to the situation that existed before the Paroxetine ruling. For Merck KGaA's and GUK's arguments in respect to this ruling see footnote 498.

³¹³ On November 8 and 18, 2002, the judge issued a consent order granting Lundbeck permission to conduct an inspection at Matrix, but at the same time ordering that any information arising out of these inspections would be confidential and could not be used for any other purpose than for the proceedings in England before the High Court of Justice, except with the written consent of Matrix. Subsequently, by letter dated 3 December 2002, Matrix agreed that the information gathered in the inspection could also be used by Lundbeck for judicial patent proceedings abroad, again on condition that confidentiality was guaranteed. See ID 239, pages 246-251, ID 2785, pages 1-3, ID 8, pages 464-465 and ID 240, page 19. See also ID 234, page 37.

³¹⁴ ID 222, page 13.

³¹⁵ ID 823, pages 8 and 16 to 20. See also ID 222, pages 12 to 14, ID 234, page 38, ID 239, pages 497-523 and 1687, ID 5394, page 163. In a witness statement to the United Kingdom court, Matrix stated about its old process (the so-called Matrix I process): "[...]" See ID 240, page 996. With respect to the Matrix II process, which included the washing step, Lundbeck stated in its reply to the Statement of Objections that *"It was only in April 2002 that Lundbeck learned for the first time that Matrix might claim a modification in its production process..."*; *"United Nordic Pharma's launch in the Danish*

(154) Following the inspection, Lundbeck withdrew its application for an interim injunction, a hearing for which had been scheduled in December 2002. [...] ³¹⁶ [...] ³¹⁷ However, Lundbeck continued to argue in the Lagap trial that the inspected process was not economically viable and that Matrix's product sold in the United Kingdom was actually produced with a (less cumbersome) infringing process using crystallisation. ³¹⁸ Lundbeck also accused Matrix of having forged batch data. ³¹⁹

(155) In an interim ruling on 14 February 2003, the United Kingdom judge stated:

"[an independent expert on whose views Lundbeck had relied]'s views have not only been used in this country. They were also relied upon by Lundbeck in support of a successful application for an interlocutory injunction in equivalent proceedings in Denmark. No doubt the court there was impressed with the [Lundbeck's expert]'s confidence that the Lagap product could not be made by any other process than that covered by the patent."

...

"Lundbeck and [Lundbeck's expert] now had to admit, having examined the process in operation in India, that their firm and unshakeable confidence that it was impossible for Lagap and its suppliers to be operating a non-infringing process was unfounded. The process that they had seen was indeed a non-infringing process and did produce a product which appeared to be Lagap's product."

The judge also stated that *"I must say now that I am not persuaded on the material shown to me that there is any credible case of forgery at all..."*. ³²⁰

market on June 14, 2002, was the first time when Lundbeck learned that Matrix-based citalopram had been launched on the market"; and "Generic companies started switching from Cipla's to Matrix's API from the end of September or the beginning of October 2002." See ID 5394, pages 163-164.

On 7 May 2002, Tiefenbacher filed in the Netherlands, the reference Member State, for a Type I variation to its marketing authorisation to cover Matrix's *"patent free extraction method for purification of Citalopram"*. This application was completed positively on 16 July 2002, see ID 1718, page 1. A filing for Cipla's *"patent free purification method"* was ready for filing on 24 September 2002. According to Tiefenbacher, this application was also approved after around two months after filing, see ID 1713, page 1. See also ID 1359, page 1, an e-mail from Tiefenbacher to Arrow, which explains that the Dutch authorities considered a type I variation was sufficient.

³¹⁶ *Inter alia*, patents no GB2375763 and EP1478635. In reply to the Letter of Facts, Lundbeck pointed out that there were probably more than two Matrix processes. See ID 6814, pages 30-41. In the Commission's view, this would only confirm the ability and freedom of API producers to amend their processes, if needed.

³¹⁷ In December 2002, a Finnish judge lifted an interim injunction that had earlier been granted against a generic company that had sold Matrix citalopram in Finland. In coming to this decision, the court had examined documents of the Matrix inspection from the Lagap litigation. Lundbeck's then CEO claimed to the press, however, that Lundbeck possessed *"decisive data"* that it had not presented in the Finnish proceedings but would present in the United Kingdom proceedings. See ID 1789, pages 25 and 36.

³¹⁸ See for instance ID 239, page 389 and ID 241, page 740. Lundbeck relied, in this respect, on an analysis it had made of chloro/bromo impurity ratios of Matrix products sold in the United Kingdom [...]*. See ID 823, pages 16 to 20. However, in the course of the Lagap proceedings, Lundbeck withdrew this analysis. See recitals (156) and (158) below.

³¹⁹ ID 823, pages 8 and 16 to 20. See also ID 222, pages 12 to 14, ID 234, pages 38 and 182, and ID 1789, pages 25 and 36. [...]* See ID 247, page 4. [...]* See ID 247, page 6.

³²⁰ H. Lundbeck A/S v Lagap Pharmaceuticals Claim No HC 02 CO 2978, 14 February 2003, 2003 Westlaw 1822925, page 2. A forensic expert appointed by the Court concluded that [...]*. See ID 244, pages 649 and 655-656; and ID234, pages 39 and 188.

- (156) In a report of 12 August 2003, Lagap's expert stated that *"Some of [Lundbeck's allegations], in particular those concerning so called "fingerprints" for purification methods, are highly flawed..."*.³²¹
- (157) In an internal assessment of 29 September 2003, Lundbeck estimated the chance that the United Kingdom judge would hold the crystallisation patent invalid at 60%.³²² At this time, Lundbeck was still optimistic about its chances that if the patent were held valid, it would also be found infringed, estimating the chance of infringement at 80%.³²³
- (158) Lundbeck's optimistic assessment on infringement changed radically, however, once the main proceedings started on 3 October 2003. The judge requested marked-up versions of the three expert reports prepared by Lundbeck's expert witness, for the purpose of clarifying what arguments Lundbeck was still relying on and what arguments it had withdrawn. Having reviewed the mark-ups in these expert reports, the judge summed up his impression as follows:
- "The impression that I get is that most of the technical, that is the chemical reasons, for alleging that the Matrix November process was a sham when it was shown to your clients and was not used before or since – most of those have gone, subject to small qualifications, may be little bit and pieces left over. That is right, is it not?"*
- Lundbeck's counsel responded:
- "Yes it is. The chloro-bromo ratio has gone. The dimer has gone. The economic benefit has gone. Those are the major items that I think your Lordship is referring to."*
- Lundbeck's counsel also declared about the Matrix II process:
- "I do accept that it can be run economically. It does depend on how you do the cyanation. They [Matrix] do the cyanation more efficiently than we have believed that they could do it."*³²⁴
- Lundbeck also admitted:
- "That is why the capacity has been deleted from the pleading. We are not saying that they did not have the absolute capacity."*³²⁵
- (159) Before any judgment on substance (validity of the patent, infringement of the patent) was reached, the parties settled on 13 October 2003. In the settlement, Lagap's parent company Sandoz agreed to drop all challenges against Lundbeck's crystallisation patent (including before the EPO) in exchange for Lundbeck a) withdrawing its claims of infringement, damages, forgery and perjury and b) granting Sandoz an irrevocable, non-exclusive royalty-free licence to Lundbeck's crystallisation patent

³²¹ ID 240, page 293 and ID 234, page 40. See also ID 240, page 294, where the same expert reiterated: *"I have seen no evidence that Matrix are infringing the Patents. Matrix have developed their own process for purifying Citalopram which is chemically viable and capable of producing [...] on an industrial scale. [...] [...]"*

³²² ID 846, page 3. One month earlier, on 19 August 2003, Lundbeck had still estimated that there was a 50% chance that the patent would be held invalid. See ID 9, page 450.

³²³ ID 846, page 3.

³²⁴ ID 244, pages 876 and 913 and ID 234, page 42. analysis ss

³²⁵ ID 234, page 106. See also ID 244, page 921.

covering the entire EEA.³²⁶ This licence allowed Sandoz to sell Matrix products in the United Kingdom also via other generic suppliers. In other EEA Contracting Parties than the United Kingdom, Sandoz could, however, only sell the product itself, not via other generic suppliers.³²⁷ Also in other EEA Contracting Parties, a definitive legal ruling finding the crystallisation patent valid and infringing was never made.³²⁸

- (160) An internal Lundbeck document probably dated shortly after the settlement analysed the Lagap litigation. It found that the United Kingdom judge *"did not accept our arguments:*

- *Chloro-bromo relationship*
- *Dimer*
- *Lack of capacity*
- *Economical incentive (no motive).*"³²⁹

This Lundbeck document depicted *"The alternative"* to a settlement with Lagap as:

"[The UK judge] would have ruled:

- *Non-infringement*
- *Patent invalid*
- *Vindicated Matrix and completely dismissed any doubt of fabrication*
- *Lundbeck to pay all costs*
- *Condemned Lundbeck*"³³⁰

Under the heading *"What's in it for us? Damage limitation"*, the same document stated as a benefit of a settlement with Lagap:

*"Avoiding a humiliating defeat which would be used against us in other jurisdictions".*³³¹

- (161) In another, subsequent analysis of Lundbeck's reasons for settling with Lagap, Lundbeck stated: *"Lundbeck realized that it was only a matter of time before Lundbeck would not be able to show that the processes were infringing."*³³²
- (162) Lundbeck later explained to the Commission: *"The judge indicated that Lundbeck would win the case if it could be proven that Matrix had forged the documents, but that entailed that the burden of proof of Lundbeck became much more severe as*

³²⁶ ID 237, pages 1205 to 1221.

³²⁷ See clause 2.6 of the licence agreement, ID 237, page 1218.

³²⁸ ID 1713, page 2. See also recital (185) below.

³²⁹ ID 903, page 14.

³³⁰ ID 903, page 17.

³³¹ ID 903, page 20.

³³² ID 823, page 19. Contrary to what Lundbeck argues in its reply to the Statement of Objections, ID 5394, page 74, the sentence is not taken out of context as the full quote shows: *"By this stage in the Lagap trial (late 2003) Lundbeck had spent the previous two years defending the Crystallization of Free Base Patent against Lagap and others in courts across the EEA. Lundbeck realized that it was only a matter of time before Lundbeck would not be able to show that the processes used were infringing. Under these circumstances, the benefits of continuing the case against Lagap (and others) seemed increasingly doubtful as time progressed (and attempts by generic companies to invent around Lundbeck's patents continued)."*

Lundbeck then had to prove in accordance with criminal law standards that Matrix had committed forgery to obtain a judgment for patent infringement...As a result hereof Lundbeck was cornered into a situation where it would have to prove that all entries in all batch documentation for all the final stage records of the batches made by Matrix were forged in order for the judge to find infringement. Based on that opinion, Lundbeck agreed to settle the case, which was effectuated by a settlement agreement dated 13 October 2003."³³³

- (163) In a separate "clearing the way" proceeding, launched on 11 April 2003³³⁴, the United Kingdom High Court of Justice, Chancery Division, Patents Court granted on 28 July 2003 a declaration of non-infringement to the company Niche Generics for generic citalopram supplied by the Indian API producer Sekhsaria, following an inspection at the latter's premises in India in May 2003. Lundbeck was ordered to pay Niche's legal costs. Niche entered the United Kingdom market in late September 2003.³³⁵
- (164) On 22 December 2003, another generic company, Neolab Ltd, also settled its litigation with Lundbeck.³³⁶ In October 2002, Neolab had launched generic citalopram from the Indian producer Cipla on the United Kingdom market.³³⁷ In November 2002 Lundbeck started infringement proceedings. Neolab lodged a counterclaim that Lundbeck's crystallisation patent was invalid.³³⁸ In December 2002 and February 2003, Neolab accepted voluntary injunctions until judgment was given in first instance in the Lagap litigation on the counterclaim of invalidity of Lundbeck's crystallisation patent or until 30 November 2003, whichever was the earlier.³³⁹ Lundbeck agreed in the Orders that it would have to pay damages if the invalidity ruling were to go against it. Following Lundbeck's settlement with Lagap of 13 October 2003, Lundbeck released Neolab from its injunction on 15 October 2003. Neolab re-started selling in the United Kingdom on 30 October 2003.³⁴⁰ However, Neolab still had an interest in obtaining damages from Lundbeck for the past through a finding of invalidity of Lundbeck's crystallisation patent. Based on Lundbeck's internal consideration that *"They will try to invalidate the crystal patent and claim damages ..."*³⁴¹, and because Lundbeck considered it had a *"90% likelihood of losing"* the litigation at that time³⁴², Lundbeck preferred to settle with Neolab. In the settlement of 22 December 2003, which terminated the proceedings, Lundbeck agreed to pay Neolab its incurred damages (for the year that Neolab was prevented from selling in the United Kingdom through the voluntary injunctions) in exchange for Neolab releasing Lundbeck from any claim for damages under the cross-undertakings in the Court Orders. Lundbeck in turn released Neolab from any

³³³ ID 222, pages 13-14.

³³⁴ ID 222, page 15.

³³⁵ ID 903, page 169.

³³⁶ ID 396, pages 459 to 491.

³³⁷ ID 845, page 99. Neolab had received a United Kingdom marketing authorisation for citalopram tablets of 10, 20 and 40 mg on 17 September 2002. See ID 682, page 6.

³³⁸ ID 396, page 481.

³³⁹ ID 396, pages 473 and 481.

³⁴⁰ ID 903, page 117.

³⁴¹ ID 903, page 23.

³⁴² ID 394, page 175. See also ID 845, page 99. This latter document shows that Neolab claimed that the second Cipla process did not infringe and that Lundbeck's crystallisation would not hold up in court.

claims under its patents for past sales and future sales until 31 March 2004, reserving its patent rights for the period thereafter.

- (165) Because of Lundbeck's settlements with Sandoz and Neolab and the agreements which are the subject of this Decision, the validity of Lundbeck's crystallisation patent was never decided by a United Kingdom court.³⁴³ After the Lagap settlement, Lundbeck continued to invoke the crystallisation patent in courts in other Member States, for instance in Belgium in 2003.³⁴⁴
- (166) At the EPO level, the crystallisation patent was first revoked in 2006 after opposition by a number of generic companies but was then reinstated in 2009 in amended form after an appeal by Lundbeck. The amendment in particular resulted in the deletion of claims 1, 2 and 5 as granted and in the limitation in the scope of claims 3 and 8 as granted. Claim 3, as finally upheld by the EPO Board of Appeals in 2011, states: "*A process for the manufacture of a salt of citalopram characterised in that one or more impurities of the formula [follows the chemical formula] wherein Z is halogen, are removed from a crude mixture of citalopram or from a crude salt of citalopram, by precipitating citalopram base in crystalline form, optionally re-crystallising said base one or more times and/or transferring said base into a salt thereof.*"³⁴⁵ This patent, as amended, expires in 2021.

6.4. Intervening in marketing authorisation procedures for generic citalopram

- (167) In August 2000, reacting to generic applications based on the Tiefenbacher file in Austria and in the Netherlands, Lundbeck headquarters sent out general instructions regarding action to be taken by Lundbeck national subsidiaries towards the marketing authorisation authorities in all EEA Contracting Parties. These actions included writing letters expressing "*serious public health concerns*" about the quality of the generic citalopram used for the application in the Netherlands, which would act as reference Member State for the mutual recognition process. According to Lundbeck: "*Due to the patent situation, generic applicants have to use methods of synthesis that differ from the method used for the reference product. The samples of the generic products tested by Lundbeck show unknown impurities exceeding the legal limit of 0.1%. These differences raise serious doubts whether the generic versions of citalopram are "essentially similar" to the reference product.*"³⁴⁶

³⁴³ Lundbeck estimated in September 2003 that if the crystallisation patent were invalidated, it would have to pay damages in the United Kingdom of between EUR [0-10]* and [10-20]* and in Scandinavia of between between EUR [0-10]* and [10-20]*, see ID 903, page 32.

³⁴⁴ ID 234, page 2.

³⁴⁵ See Board of Appeal of the European Patent Office, Decision of 2 July 2009 in Case T/1618/06, page 7. The companies that filed opposition were: Biochemie GmbH; Neuraxpharm Arzeinmittel GmbH & Co. KG; Stada Arzeinmittel AG; Ratiopharm; Hexal Pharmaforschung GmbH; Alfred E. Tiefenbacher GmbH; Biomo Pharma GmbH; Egis Gyógyszergyár RT; Merck dura GmbH; and Niche Generics Limited. Merck N.V. intervened later. See ID 2773, page 7. None of the generic undertakings that concluded the agreements with Lundbeck subject to this Decision opposed the patent at the EPO, with the exception of Merck. Lundbeck explained to the Commission that the amendment of the patent at the EPO restricted the list of impurities removed to halogen impurities for the manufacture of a salt – not a base – of citalopram. According to Lundbeck, the claims most relevant for the infringement litigation in the United Kingdom and elsewhere in the EEA were upheld. Halogen elements are: fluorine, chlorine, bromine and iodine. See ID 2773, pages 12 to 14.

³⁴⁶ ID 9, pages 751 to 753.

- (168) In October 2001, Lundbeck appealed to the Objections Committee of the Dutch Medicines Evaluation Board against the latter's decision in September 2001 to grant marketing authorisations to Tiefenbacher for generic citalopram sourced from the Indian companies Cipla or Matrix. Lundbeck complained that Tiefenbacher's application file was *"partially based on information with respect to the manufacturer of an active substance of which no valid information is available in the file, namely the Italian company VIS."* Lundbeck claimed in particular that the stability data and the bioequivalence studies in the registration file were based on citalopram produced by VIS.³⁴⁷ This objection was rejected on 25 January 2002.³⁴⁸ Simultaneously in October 2001 Lundbeck had lodged with the court of Amsterdam a request for an injunction against the Dutch marketing authorisations being used, including their further treatment under the mutual recognition procedure. This request was denied on 21 December 2001.³⁴⁹ Merck (GUK) internally commented: *"me thinks that Lundbeck are starting a general war here"*.³⁵⁰ In January 2002 Lundbeck lodged an appeal against the decision of the Objections Committee of the Dutch Medicines Evaluation Board confirming Tiefenbacher's marketing authorisation in the Netherlands but lost these proceedings on 11 July 2002.³⁵¹ It then appealed to the highest Dutch court, the Hoge Raad, but also lost this appeal.³⁵² Nevertheless, Lundbeck's intervention in the Netherlands delayed by more than half a year, until after Lundbeck had lost its appeal for an injunction in the Netherlands in July 2002, the issuing of marketing authorisations by the United Kingdom Medicines Control Agency to generic companies whose application in the United Kingdom was based on Tiefenbacher's registration file, including Arrow, Alpharma and Lagap.³⁵³ A contemporaneous Lundbeck document of 4 September 2002 stated: *"Following the decision [by the appeal court of Amsterdam rejecting Lundbeck's appeal on 12 July 2002] the MCA, UK...issued the national licences. But normally MCA issues within 14 days – this licence took more than 7 months!"*³⁵⁴
- (169) In December 2001, Lundbeck intervened with the United Kingdom Medicines Control Agency (MCA) submitting information regarding certain tests Lundbeck had done allegedly showing impurities in the API of the Indian company Natco, on the basis of which Merck (GUK) had filed an application for a United Kingdom

³⁴⁷ ID 621, page 8. Lundbeck had withdrawn VIS' registration file after it had acquired the company, see recitals (175) to (177) below.

³⁴⁸ ID 844, page 9, ID 846, page 168.

³⁴⁹ See recital (257) below.

³⁵⁰ ID 673, page 182.

³⁵¹ ID 904, page 280. See also ID 6082, page 34.

³⁵² ID 291, page 4, ID 844, page 9. Lundbeck stressed amongst others in its reply to the Statement of Objections (ID 5394, page 93-94) its strong interest in surveilling the quality of generic citalopram and argued that it had *"an ethical obligation to inform the authorities of potentially defective material to safeguard patient health"*.

³⁵³ In reply to the Statement of Objections (ID 5394, pages 94-95), Lundbeck contested the delay in the United Kingdom without, however, having been able to put into question the evidence cited in recitals (170), (171) and (384).

Tiefenbacher informed the Commission that a leading Tiefenbacher representative was invited to Lundbeck's headquarters *"on a Sunday (!) morning"* and was offered a *"significant amount of money in case Tiefenbacher stops the regulatory activities, especially in the UK. Due to the valid contracts with our customers Tiefenbacher saw no option to follow that approach."* See ID 280, page 7. However, Tiefenbacher neither indicated the date on which this would have happened nor provided any contemporaneous documents to corroborate this allegation.

³⁵⁴ See ID 904, page 281.

marketing authorisation. Lundbeck argued that the quality of Natco's product was not compliant with relevant guidelines.³⁵⁵ The MCA nevertheless granted the marketing authorisation on 9 January 2002.³⁵⁶

(170) An internal Lundbeck "generic citalopram update" of 28 June 2002 explained that on "26 June [2002] we [Lundbeck] submitted data re Natco impurities to MCA [the United Kingdom Medicines Control Agency ...]. Our aim is to try to delay the MRP [mutual recognition process] and to question the UK license."³⁵⁷

(171) A Lundbeck Business Development document titled "Generic citalopram update 04 09 2002" summarised:

"Conclusion

*We have delayed the issuing of the national licenses in all European countries from few to many months."*³⁵⁸

6.5. Eliminating the competitive threat of upcoming citalopram API producers

(172) A document prepared for a Lundbeck Board meeting of 24 April 1998 stated:

*"Contact with the potential producers of Citalopram is still sought for, for the possibility of stopping them in their attempts to reach the market through independent generic marketing firms. The strategy for these contacts is either to stop the further development of Citalopram with help from Lundbeck's production patents or to enter into partnerships with them, where under they become producers for Lundbeck."*³⁵⁹

(173) A Lundbeck report to the Board of Directors of 8 February 1999 stated:

"Lundbeck has been contacted by a number of firms who say they have been offered a citalopram registration file but who would instead prefer to cooperate with Lundbeck. Lundbeck is working to localise the generic producers who offer generic citalopram.

VIS, a fairly small Italian chemical manufacturer, have already said that they supply generic citalopram. Lundbeck have therefore begun negotiations on various forms of cooperation with them with a view to preventing VIS from supplying generic citalopram on the world market."

*After rumours that Merck Generics are synthesising citalopram, a meeting was held with their top management. At the meeting Merck Generics confirmed the fact, but were not able to confirm whether they were using a Lundbeck patented production method or whether they had developed a new method. A fresh meeting has been agreed."*³⁶⁰

(174) The first company to which Lundbeck applied this policy of making deals with API producers to prevent them from supplying generic citalopram was the Italian

³⁵⁵ ID 8, pages 357 to 360.

³⁵⁶ ID 682, page 120. For France, see ID 1021, page 61.

³⁵⁷ ID 848, page 40. Lundbeck undertook a similar approach to the Italian medicines evaluation body in September 2002. See ID 681, pages 119 to 123 and 141 to 143 and ID 356, pages 69 to 72. See recital (337) below.

³⁵⁸ ID 904, page 288.

³⁵⁹ ID 9, page 100.

³⁶⁰ ID 813, page 8. See also ID 9, page 316.

company Norpharma. In October 1998, Norpharma filed a patent application for its process for manufacturing citalopram which was different from Lundbeck's processes and two subsequent patent applications for improvements to that process in May and August 1999. One year later, in October 1999, Lundbeck purchased all three of these patent applications.³⁶¹ This purchase entailed that Norpharma's independent process for manufacturing citalopram, the first to become available, could not be used by generic companies to enter European markets with generic citalopram. Following the purchase, after having tested Norpharma's process, *"Lundbeck concluded that Norpharma's process patents did not offer an improved alternative to Lundbeck's existing process, and Lundbeck chose not to use the processes covered by Norpharma's patents commercially."*³⁶²

- (175) The second API producer to which Lundbeck applied its "deal making" strategy was the small Italian company VIS Farmaceutici S.p.A. ("VIS").³⁶³ Since the late 1990s, VIS had collaborated closely with Tiefenbacher to prepare generic citalopram for intended sale in Europe. Based on VIS' Drug Master File, Tiefenbacher submitted by the end of 1999 an application for a marketing authorisation for generic citalopram in the Netherlands. Tiefenbacher had expected to receive marketing authorisation for citalopram in the Netherlands by the end of 2000. Once this marketing authorisation had been recognised by other Member States³⁶⁴, this would have put VIS and Tiefenbacher in a position to immediately start supplying citalopram to generic

³⁶¹ ID 8, pages 45 to 48.

³⁶² ID 5394, page 98. As reported to the Commission by Norpharma: *"The initial contact with Lundbeck A/S in 1999 was by Norpharma. Norpharma s.p.a. was starting-up as a fine chemical company (the company had been established in 1997) and was interested to discuss the possibility of supply agreements on the medium-long term: the active principle Citalopram was one of many products to which Norpharma s.p.a. was thinking, as it had acquired and was further developing certain technologies to produce Citalopram. Actually, Norpharma s.p.a. had manufactured research & development samples, but had not yet scaled-up the method. Some time during the first quarter 1999 Norpharma s.p.a. sent a facsimile to Lundbeck A/S, the originator, in which it set-out that it would be amenable to qualify as a supplier of Citalopram. Lundbeck A/S responded promptly, but showed more interest in Norpharma's technology than on a possible supply agreement"* (see ID 995, pages 3-4). Lundbeck stated to the Commission: *"A supply agreement with Norpharma would not have been a viable option as Norpharma did not have proper production plant standards or capacity and it would have taken Norpharma at least three years to obtain the necessary government approvals for such production. An acquisition of Norpharma's technology and know-how was therefore considered preferable"* (see ID 5394, page 97). While Lundbeck in its reply to the Statement of Objections on the one hand argued that Norpharma's technology *"could prove useful"* (see ID 5394, page 96), the project group evaluating *"whether parts of the process could be used ... concluded [at the time] that no single part of the Norphama process was applicable in the current Lundbeck process."* (see ID 5427, page 9)

³⁶³ Despite the contemporaneous quote in recital (173) above that Lundbeck started negotiations with VIS *"with a view to preventing VIS from supplying generic citalopram on the world market"*, Lundbeck has argued to the Commission in its reply to the Statement of Objections that *"Lundbeck acquired VIS to obtain additional capacity."* (see ID 5394, page 98). It is true that following the acquisition, Lundbeck invested in VIS' production capacity and used VIS as a supplier of intermediates to Lundbeck. A contemporaneous report of a Lundbeck visit to VIS' production site of 9 July 1999 stated: *"VIS has Citalopram HBr on its 'menu', which obviously makes Lundbeck prick up its ears. Therefore, there have repeatedly been contacts between VIS and Lundbeck over the last couple of years. VIS tries to push Lundbeck into an agreement and we are trying to enter into the cheapest possible agreement. Our visit to VIS was therefore an attempt to find out how far ahead they are in the development of the process."* The same report stated: *"If one for a second disregards the purpose of the visit and the ongoing 'matter' between VIS and Lundbeck, VIS is an excellent contract manufacturer of intermediates/material for Lundbeck."* (translation from Danish, see ID 5394, page 100; see also ID 673, pages 22-23 and 34).

³⁶⁴ See recital (85) above.

suppliers in those European countries where Lundbeck did not enjoy any patent protection (Greece, Italy, Luxemburg, and Portugal), in those European countries where only Lundbeck's original process was protected (Austria, Denmark, Finland, the Netherlands, Norway and Sweden) as well as in those European countries where Lundbeck's compound patent protection had already expired (Germany, Spain).³⁶⁵

- (176) However, after Lundbeck had first in September 1999 concluded an agreement with VIS under which VIS agreed to supply citalopram to Lundbeck, containing restrictions on VIS' possibilities to supply third parties³⁶⁶, Lundbeck actually purchased VIS in October 2000.³⁶⁷ Immediately following the purchase, VIS/Lundbeck withdrew the VIS Drug Master File from Tiefenbacher's marketing authorisation application in the Netherlands, claiming impurities in the VIS product.³⁶⁸ With the same argument, Lundbeck also cancelled all of VIS' supply contracts (including, but not only, to Tiefenbacher) and offers of supply VIS had made. Tiefenbacher then switched to the Indian companies Cipla and Matrix as alternative API suppliers and used these companies as alternative suppliers in its applications for marketing authorisation in the Netherlands. According to Tiefenbacher, the withdrawal of the VIS Master Drug File by Lundbeck caused a delay in the granting of the Dutch marketing authorisation of at least nine months, the marketing authorisation being finally granted in September 2001.³⁶⁹
- (177) Another company which had wanted to market VIS' citalopram was Merck (GUK). Based on the VIS Drug Master File it had expected to receive a marketing authorisation in the United Kingdom in February 2001 and in other European countries, using the mutual recognition procedure, by December 2001.³⁷⁰ Lundbeck's withdrawal of VIS' Drug Master File forced Merck (GUK) to search for another supplier, which it found in the Indian producer Natco. According to GUK, Lundbeck's withdrawal of VIS' Drug Master File caused a delay of around nine months to Merck (GUK)'s preparation of entry.³⁷¹ An internal Merck (GUK) e-mail of 3 January 2001 stated: *"The dossiers were originally submitted to the MCA (the UK Medicines Control Agency) on 15/8/2000 (our resubmission with Natco batches was 14/6/01)."*³⁷²
- (178) CF Pharma, a small Hungarian API producer that was also preparing to produce generic citalopram, became the third target of Lundbeck's API deal-making strategy. [...]*.³⁷³ [...]*.³⁷⁴, [...]*.³⁷⁵ [...]*.³⁷⁶ In October 2002, Lundbeck' increased its

³⁶⁵ See recitals (109) to (111) above.

³⁶⁶ ID 10, pages 186 to 204.

³⁶⁷ ID 8, page 532. Taking into account the fair value of VIS' assets and liabilities, Lundbeck estimated that it had paid DKK 199 million (around EUR 26 million) for VIS' "goodwill", see Lundbeck's Annual Report for the year 2001, ID 1498, p. 60 and its annual report for the year 2000, ID 1503, page 60.

³⁶⁸ ID 295, page 1.

³⁶⁹ ID 280, page 6. Tiefenbacher explained to the Commission that the forced switch to Matrix and Cipla as API suppliers meant that new real time stability data had to be submitted to the Dutch authorities, which took at least 6 months. Tiefenbacher also claimed that it was approached by Lundbeck with an offer of money in case Tiefenbacher stopped its regulatory activities, in particular with respect to the United Kingdom. See footnote 353 and ID 280, page 7.

³⁷⁰ ID 673, page 23.

³⁷¹ ID 673, page 85; see also recital (221) below and footnote 446.

³⁷² ID 675, page 17.

³⁷³ [...]*. See ID 5, pages 12-13.

³⁷⁴ ID 5, pages 14-15.

investment and shareholding in CF Pharma. [...]*, CF Pharma became a supplier to Lundbeck of intermediates.³⁷⁷ The result of these actions was that CF Pharma was prevented from selling generic citalopram to the EEA markets.

- (179) It is important to realise the timing of Lundbeck's actions in respect of Norpharma, VIS and CF Pharma. It was only in March 2000 that Lundbeck filed a priority application for the crystallisation process of purification. API suppliers that had already been using crystallisation in combination with one of the original Lundbeck manufacturing processes could, based on prior use, claim that they did not infringe either the crystallisation patent or the original compound process once this latter patent had expired.³⁷⁸ An e-mail of Arrow's [employee function]* dated 5 August 2003 summarised the European citalopram situation over the last couple of years as follows: *"Towards expiry of the basic compound patent in Europe there was essentially only [one] source of raw material, VIS. The route that they employed was essentially that shown in the basic patent and this formed the basis for the generic registrations around Europe. In an attempt to restrict generic entry Lundbeck bought VIS and refused to supply material to generic companies. Lundbeck also started to file numerous patent applications aimed at blocking the "old" route of synthesis from being used. Of these by far the most troublesome was WO 01/68627 which covered a method of purifying citalopram base by recrystallization before conversion to the marketed hydrobromide salt."*³⁷⁹
- (180) Lundbeck was also closely monitoring API producers in India, which were now also gearing up to produce citalopram. As mentioned in recital (148) above, in January 2001 Lundbeck wrote to a number of API producers in India warning them of potential patent infringement. With respect to those Indian companies that were not deterred by these threats, that continued to search for non-infringing ways of producing citalopram and that were preparing to sell generic citalopram to EEA markets, Lundbeck pursued its deal-making strategy. For this dual purpose of deterrence and, if unsuccessful, deal-making, a visit to several Indian producers took place later that year.
- (181) A first Indian API producer that Lundbeck tried to eliminate in this manner as a competitive threat was the company Natco. This company had developed an allegedly non-infringing method to produce generic citalopram. Lundbeck visited the company in February 2001. According to Natco, Lundbeck was *"interested in initiating a commercial relationship with Natco"*. However, Natco rejected this proposal.³⁸⁰ Lundbeck subsequently entered into negotiations with Merck (GUK), which on behalf of the Merck Generics Group had a 'preferred' right to purchase Natco citalopram API for distribution in Europe.³⁸¹ Through two agreements with Merck (GUK), one for the United Kingdom covering the period between 24 January 2002 and 1 November 2003 and one for the rest of the EEA, covering the period

³⁷⁵ ID 5, pages 34 to 37.

³⁷⁶ ID 3167, page 1 and ID 178, pages 102 to 104.

³⁷⁷ ID 5394, page 103.

³⁷⁸ In its reply to the Commission's Letter of Facts, Lundbeck stated: *"In theory, it may be true that generics that had already been using free base crystallization before could have claimed prior user rights. The reality is, however, that none of them did."* See ID 6814, page 46.

³⁷⁹ ID 649, page 2.

³⁸⁰ ID 579, page 2. For further details on this meeting, see recitals (230) to (233) below.

³⁸¹ See recitals (234) and (330) - (331) below.

between 22 October 2002 and 22 October 2003, Lundbeck indirectly also aimed at preventing Natco from selling citalopram API to the EEA in that period. As these events are assessed in legal terms in this Decision, they are described in detail in section 7.2 below.

- (182) In June 2002, Lundbeck made an agreement with a second Indian API producer, Ranbaxy, which was at the same time also a major supplier of generic medicines in its own right in Europe. This agreement entailed that Ranbaxy would not sell citalopram API or citalopram medicines to the EEA. The agreement covered the period between 16 June 2002 and 31 December 2003. As these events are assessed in legal terms in this Decision, they are described in detail in section 7.7 further below.
- (183) Finally, in February 2003, Lundbeck was reported in the press to have made an offer to the Indian API producer Matrix to acquire Matrix's process rights for the manufacture of citalopram. According to Tiefenbacher, this offer was made in October 2002.³⁸² Contemporaneous Lundbeck documents confirm that a meeting with Matrix took place in October 2002.³⁸³ At the time, in a communication to the Bombay Stock Exchange, Matrix stated:

*"We would like to confirm that Lundbeck did approach us with a proposal to acquire process rights related to the process developed by us and also to stop production of citalopram. We rejected the offer in the larger interests of the company and to honour the supply commitments made to generic pharma companies in Europe, and thereby continue to service their requirements."*³⁸⁴

Matrix also told the press that the offer had amounted to "300 million Danish Crowns [... ~EUR 40 million]."³⁸⁵

6.6. Persuading generic suppliers to stop their efforts to enter the citalopram market

- (184) As described in section 6.5 above, Lundbeck had been quite successful in eliminating the competitive threat from the earliest producers of generic citalopram API, that is to say Norpharma, VIS and CF Pharma, in 1999 and 2000. Lundbeck's efforts in 2001 to persuade Indian API producers not to produce generic citalopram (or at least not to sell it to EEA markets) were, however, markedly less successful, as both Natco and Matrix refused. The Indian companies Cipla and Sekhsaria also continued their preparations to produce generic citalopram. Therefore, following expiry of Lundbeck's compound patent in January 2002 in most remaining EEA Contracting Parties, persuading generic suppliers to refrain from entering citalopram markets in the EEA became Lundbeck's last line of defence against imminent generic entry of citalopram.
- (185) Lundbeck tried to achieve this, firstly, by threatening or actually starting infringement litigation (using the process patents it had obtained since 1997 and in particular the crystallisation patent).³⁸⁶ In total, in response to a request for information of the Commission, Lundbeck listed 85 legal procedures concerning citalopram in 9 different EEA Contracting Parties (Belgium, Denmark, Finland,

³⁸² ID 291, page 4.

³⁸³ ID 2673, pages 30-31.

³⁸⁴ ID 290, page 1. See also ID 291, pages 24 to 26 and ID 904, page 69.

³⁸⁵ ID 291, page 29. See also ID 291, pages 15 to 28.

³⁸⁶ See recitals (144) to (152) above.

Germany, Netherlands, Norway, Spain, Sweden, United Kingdom) in which Lundbeck was involved in the period between January 2002 (United Kingdom) and June 2006 (Denmark). Most of these were infringement cases initiated by Lundbeck, launched against generic citalopram originating from Cipla or Matrix.³⁸⁷ In several of these countries, Lundbeck did manage, at least in an initial stage, to obtain interim injunctions and seizures, in particular against citalopram produced by Cipla. In a number of these cases, after the generic companies in question had switched to citalopram produced with the Matrix II process³⁸⁸, the injunctions and seizures were subsequently lifted in appeal (and further injunctions and seizures against other suppliers denied) or the case was settled.³⁸⁹ In Germany, all claims of infringement by Cipla and Matrix citalopram were rejected by the courts from the beginning.³⁹⁰ In the United Kingdom, all legal proceedings were settled by Lundbeck before a final ruling could be issued, with the exception of Niche's request for a declaration of non-infringement, which was granted.³⁹¹ In no Contracting Party to the EEA Agreement was a final ruling that the crystallisation patent was valid and infringed ever made by a court.³⁹²

- (186) In a number of other cases, which are the subject of this Decision, where generic suppliers appeared undeterred by Lundbeck's process patents, Lundbeck offered - and the generic supplier concerned accepted - a transfer of value to the generic

³⁸⁷ ID 234, pages 2 to 18. See also ID 2774. Lundbeck was also involved in an invalidation/infringement proceeding in Italy in 2005 regarding certain formulations of citalopram which Lundbeck had patented in Italy only.

³⁸⁸ See recital (154) above.

³⁸⁹ ID 234, pages 2 to 18. Examples are:

- an interim injunction of 17 June 2003 against Copyfarm in Denmark was lifted after appeal on 26 January 2004 (ID 234, page 5);
- an interim injunction of 21 March 2003 against United Nordic Pharma in Denmark was lifted after appeal on 26 January 2004 (ID 234, page 6);
- a request for an interim injunction against Ratiopharm in Denmark was denied on 25 April 2003; the denial was confirmed in appeal on 26 January 2004 (ID 234, page 7);
- an interim injunction of 5 July 2002 against Novartis in Finland was declared null and void on 23 December 2002 (ID 234, page 9).
- a request for an interim injunction against Ratiopharm in Finland was denied on 27 December 2002 (ID 234, page 10);
- a seizure granted against Hexal and Multipharma in the Netherlands in a summary procedure initiated on 6 December 2002 was subsequently lifted in the same procedure (ID 234, page 11);
- an interim injunction of 12 March 2003 against Desitin Pharma in Sweden was revoked in appeal on 4 June 2003 (ID 234, page 16).

³⁹⁰ See also ID 234, pages 119-122 and ID 5394, pages 67-68. See also recital (442) below.

ID 234, page 8. With respect to the patent situation for citalopram in Germany, an internal Alpharma document of 12 February 2002 stated: *"According to our latest information, the patent situation of Citalopram in Germany seems to be rather different from Holland and UK and Denmark. Obviously there is no patent issued and there will be no patent issued in Germany. Instead of that, Lundbeck got a so called "Gebrauchsmusterschutz" ("legal protection of utility models"). The infringement of the "legal protection of utility models" can not be taken as a basis for a Preliminary Injunction."* See ID 4817, pages 38-39. Lundbeck also explained to the Commission that in Germany courts will not grant interim injunctions unless the validity of the legal right in question is beyond any doubt. As utility models are unexamined rights, this is unlikely to be the case. See ID 5394, pages 56 and 180 and ID 5410, page 11. Tiefenbacher reported to the Commission that Lundbeck's utility model 200 07 303 was revoked by the German Patent Office on 5 November 2003. See ID 291, pages 5 and 31 to 35.

³⁹¹ ID 234, page 18. See also recital (163) above.

³⁹² ID 1713, page 2.

supplier as part of an agreement in which the generic supplier gave up, at least for a certain period of time, its efforts to enter the citalopram market.

- (187) As already mentioned, Lundbeck itself summarised this policy of deal-making most strikingly in the following words:

"It is like a poker game

- *We have been dealt a mediocre hand – no aces, a couple of queens and some small uneven cards*
- *But we have a large pile of \$\$\$ at our side*
- *We call it – "the art of playing a losing hand **slowly**."*³⁹³

- (188) Lundbeck realised - or should have realised - that this policy carried risks under Union competition rules. An internal Lundbeck e-mail reporting on discussions with Ranbaxy regarding a possible deal covering the EEA asks:

*"Do we want a deal? I guess a deal will be \$10M-\$20M or even more. My opinion is that it will be difficult – antitrust wise, costs and value for money..."*³⁹⁴

- (189) Some months after Ranbaxy and Lundbeck had concluded an agreement in which Ranbaxy agreed in exchange for a considerable sum of money not to sell citalopram in the EEA during the term of the agreement, Ranbaxy confirmed to Lundbeck that it had not sold any citalopram in the EEA after the agreement had been concluded. The Lundbeck email which distributed this news to key players within the undertaking Lundbeck warned: *"Strictly confidential – please do not forward this e-mail!"*³⁹⁵

- (190) In a Lundbeck Business Development document with the title "Generic citalopram update 04 09 2002", one can read the following:

"Sweden – NM Pharma

- *NM Pharma does not want to talk to us*
- *Email from ...Pharmacia (owners of NM Pharma):*

*"Thanks for inviting us to a meeting but no thanks, we have nothing to discuss. Under our Global Standards of Business Conduct and our Antitrust Policy, we cannot engage in further discussion on this topic..."*³⁹⁶

- (191) Also, a Lundbeck Business Development document with the title *"Generic citalopram update 22 11 2002"* stated:

"Deal making

³⁹³ See recital (131) above. In its reply to the Statement of Objections, Lundbeck explained that *"The 'mediocre hand' refers to Lundbeck's process patents, which, despite their validity and inherent value, are difficult to enforce, and would ultimately be worked around by generic competitors."* See ID 5394, page 81.

³⁹⁴ ID 681, page 88.

³⁹⁵ ID 681, page 151. In reply to the Statement of Objections (ID 5394, page 107), Lundbeck claimed that this e-mail did not intend to conceal a potential antitrust infringement, but rather to protect sensitive business information.

³⁹⁶ ID 904, page 303. One month later, in October 2002, Lundbeck made an agreement with NM Pharma's supplier of generic citalopram Merck (GUK) that Merck (GUK) would stop supplying NM Pharma. See section 7.3 below.

- *We have made a number of deals; although it is tricky*
 - *They fantasize of the value of the generics*
 - *It is illegal to block competition*
 - *Worthless taking out one of two or three players*
 - *However some of our deals have been very valuable.*³⁹⁷
- (192) This Decision concerns six agreements which Lundbeck concluded and operated in the period from January 2002 to December 2003 with the following four undertakings:
- **Merck** (first for the United Kingdom, covering the period between 24 January 2002 and 1 November 2003, followed by a second agreement for the rest of the EEA, covering the period between 22 October 2002 and 22 October 2003)³⁹⁸;
 - **Arrow** (first for the United Kingdom, covering the period between 24 January 2002 and 20 October 2003, followed by a second agreement for Denmark, covering the period between 3 June 2002 and 1 April 2003);
 - **Alpharma** (for the EEA, covering the period between 22 February 2002 and 30 June 2003);
 - **Ranbaxy** (for the EEA, covering the period between 16 June 2002 and 31 December 2003).
- (193) In total, for all of these agreements together, Lundbeck transferred a value of around **EUR 66.8 million**, consisting of the following transfers to individual generic undertakings:
- **Merck: +/- EUR 31.4 million** (EUR 19.4 million for the United Kingdom agreement and EUR 12 million for the agreement regarding the EEA excluding the United Kingdom)³⁹⁹;
 - **Arrow: +/- EUR 11 million** (EUR 10.4 million for the agreement regarding the United Kingdom and EUR 684.000 for the agreement regarding Denmark)⁴⁰⁰;
 - **Alpharma: +/- EUR 11.7 million** for the agreement regarding the EEA⁴⁰¹;
 - **Ranbaxy: +/- EUR 12.7 million** for the agreement regarding the EEA⁴⁰².

³⁹⁷ ID 847, page 57. Likewise, a Lundbeck strategy document probably dated early 2003 stated:
"Settling is a tricky business"

- *It is illegal to block competition*
- *Generics fantasize about the value of their products.*" ID 844, page 27.

In reply to the Statement of Objections (ID 5394, page 107), Lundbeck pointed out that the document also lists lawyers specialised in antitrust legislation as parties involved in the settling arrangements.

³⁹⁸ The agreement with Merck (GUK) for the rest of the EEA indirectly also aimed at stopping exports of the Indian API producer Natco. See recital (181) above.

³⁹⁹ See recitals (307) and (370) below.

⁴⁰⁰ See recitals (447) and (472) below.

⁴⁰¹ See recital (547) below.

⁴⁰² See recital (587) below.

- (194) Although these agreements were concluded against the background of patent disputes, none of the agreements finally resolved a patent dispute; the agreements rather postponed generic entry for a certain period of time, leaving open what would happen afterwards. As Lundbeck wrote to the Commission: *"Lundbeck's settlements did not remove uncertainty over whether a generic's challenge would eventually succeed, because they did not finally resolve the dispute"* and *"Lundbeck's agreements did not...ultimately decide when any generic company could enter the market."*⁴⁰³
- (195) From these agreements, four of which concern the United Kingdom market, it is clear that Lundbeck focused its efforts to delay generic entry through agreements to a large extent on the United Kingdom market. As Lundbeck stated in its reply to the Statement of Objections, *"The UK was both the most important EEA market at the time of the Agreements, and the focus of the dispute between Lundbeck and each of Alpharma, Arrow, GUK and Ranbaxy."*⁴⁰⁴ Moreover, with its specialised and critical patent court, the United Kingdom is an important Member State for testing patent infringement and invalidation cases. Generic companies tend to select the United Kingdom as one of the first countries in which they try to enter the market with a new generic product. A United Kingdom judgment finding that the manufacturing processes of an API producer did not infringe Lundbeck's process patents or, worse from Lundbeck's perspective, that Lundbeck's crystallisation patent was invalid, would have set a very negative example for Lundbeck which courts in other EEA Member States might well have taken into account in their own judgments. Lundbeck apparently believed that it would be difficult to obtain an interim injunction in the United Kingdom and that United Kingdom courts were *"not in general pro-patentee"*.⁴⁰⁵
- (196) The United Kingdom market was also one of the markets most sensitive to generic penetration. On 11 December 2001, Lundbeck wrote in its "Goal, Activity and Budget Plan 2002" with respect to the United Kingdom market:
- "The UK is the market that Lundbeck expects to be hit most severely by generic competition. Immediately following patent expiry in January 2002, generic sales are expected to take 60% of the citalopram business.*
- Cipralex (escitalopram) is planned to be launched in April 2002. The aim will be to convert the remaining part of the citalopram franchise to escitalopram as fast as possible, with strong focus on the first three months after launch. This implies a cannibalisation of the citalopram business, the effect of which is a reduction of citalopram sales of 65% in total on E [expected] 2001."*⁴⁰⁶

⁴⁰³ ID 1683, pages 3 and 2.

⁴⁰⁴ ID 5394, page 56. See also ID 681, pages 18-19 and ID 904, page 94.

⁴⁰⁵ ID 5481, page 3. In its reply to the Commission's Letter of Facts of 12 April 2013, Lundbeck stated: *"...the UK courts had not granted preliminary injunctions in the pharmaceutical sector for decades, and ...only a High Court judgment of October 23, 2001 had granted such an injunction in the Paroxetine matter. This High Court judgment was confirmed by the Court of Appeal only in 2003."* See ID 6814, page 46. With respect to Denmark, for which Lundbeck concluded an agreement with Arrow, Lundbeck believed that *"Interim injunctions are granted within about 6 months"* (ID 5481, page 3) and that it might therefore not be able to prevent Arrow's market entry through an application for an interim injunction. See ID 5394, page 212.

⁴⁰⁶ ID 163, page 409.

- (197) A management report of the same date of 11 December 2001 stated:
- "[Lundbeck's] generic strategy in the United Kingdom is complex, but is very important because of the significant impact that generic products have been shown to have on sales of branded products (sales of Prozac [branded fluoxetine] fell by 70% within a few months)."*⁴⁰⁷
- (198) On 7 January 2002, just two days after Lundbeck lost exclusivity for citalopram in the United Kingdom, an internal Lundbeck document shows that despite still holding or having applied for certain process patents, including in particular the crystallisation patent, Lundbeck expected for the year 2002 in the United Kingdom a reduction in sales *"at the hands of generics"* of GBP [25-50]* million (EUR [40-80]* million⁴⁰⁸) for citalopram and escitalopram together, from GBP [50-100]* million (EUR [80-160]*million) of expected sales without generic entry) to GBP [25-50]* million (EUR [40-80]* million).⁴⁰⁹ In other words, at this time Lundbeck expected to lose 56 percent of its sales of citalopram and escitalopram together in the case of widespread generic entry in the United Kingdom in 2002 alone. That Lundbeck fully expected this scenario to happen is confirmed by the fact that it is reflected in Lundbeck's official budget for the United Kingdom for the year 2002, which shows expected sales of EUR [25-50]* million for citalopram and EUR [0-30]* million for escitalopram (together EUR [25-80]* million).⁴¹⁰ In reality, after having concluded agreements with Merck (GUK), Arrow, Alpharma and Ranbaxy to keep generic citalopram out of the United Kingdom market, Lundbeck achieved sales of citalopram in the United Kingdom in 2002 of EUR [40-150]* million and of escitalopram of EUR [0-20]* million⁴¹¹, EUR [0-90]* million more than it had expected to sell if widespread generic entry had taken place.⁴¹²
- (199) Those agreements operated in the United Kingdom not only in 2002 but also in the first 10 months of 2003. In the first 10 months of 2003, Lundbeck sold EUR [50-100]* million worth of citalopram and escitalopram in the United Kingdom⁴¹³, EUR [0-30]* million more than it had budgeted for the same period expecting widespread generic entry as of December 2002.⁴¹⁴ For the year 2002 and the first 10 months of 2003 together, therefore, the four agreements concluded by Lundbeck covering the United Kingdom at a total cost of EUR 54.2 million generated additional budgeted Lundbeck sales of citalopram and escitalopram in the United Kingdom in the period concerned of EUR [40-110]* million (EUR [40-80]* million plus EUR [0-30]*

⁴⁰⁷ ID 815, page 85.

⁴⁰⁸ Using a GBP/EUR exchange rate of 0.61659 in January 2002, source European Central Bank.

⁴⁰⁹ ID 853.

⁴¹⁰ ID 2061.

⁴¹¹ ID 983, page 18.

⁴¹² Taking citalopram and escitalopram together, Lundbeck actually sold in the United Kingdom in 2002 EUR [40-170]* million (of which EUR [0-20]* million for escitalopram), compared to expected sales of EUR [40-80]* million in the case of widespread generic entry, a difference EUR [0-90]* million.

⁴¹³ ID 984.

⁴¹⁴ ID 2061. See also recital (206) below. There are no contemporaneous documents in the file showing Lundbeck's budgeted sales in 2003 in the United Kingdom in the absence of widespread generic entry, so the Commission could for the first ten months of 2003 only compare budgeted sales (which assumed widespread generic entry) with actually achieved sales. Those actually achieved sales may, however, have been higher or lower than would have been budgeted by Lundbeck for the United Kingdom market absent widespread generic entry.

million). Additional actual sales were EUR [0-120]* million higher (EUR [0-90]* million plus EUR [0-30]* million).⁴¹⁵

- (200) In any case, once Lundbeck had paid Merck and Arrow to keep them out of the United Kingdom market, these costs would have been sunk and would therefore not have prevented Lundbeck from making additional payments in the subsequent agreements with Alpharma and Ranbaxy to keep them out of the United Kingdom market as well.
- (201) Moreover, two of the four agreements in question, those with Alpharma and Ranbaxy, also covered all other EEA Contracting Parties.
- (202) Finally, as appears clearly from Lundbeck's strategy documents⁴¹⁶, what was at least as important for Lundbeck as a short term cost/benefit calculation, was the fact that Lundbeck managed successfully to introduce its successor product escitalopram in the United Kingdom in June 2002, six months after generic entry had become possible, four months before the first small-scale generic entry by Lagap actually occurred and 16 months before widespread generic entry in the United Kingdom occurred. Lundbeck itself called this a "*top result*".⁴¹⁷
- (203) A Lundbeck Business Development document titled "Generic citalopram update 21 05 2002" stated with respect to the United Kingdom:

"UK Strategy

<i>6 Jan</i>	<i>Product patent expired</i>
<i>24 Jan</i>	<i>Merck Generic UK deal for 12 months</i>
<i>24 Jan</i>	<i>Arrow Generics deal till 1 Jan 2003</i>
<i>8 Feb</i>	<i>Injunction against Arrow Generics [voluntary, as stipulated in the agreement]</i>
<i>22 Feb</i>	<i>Alpharma deal till 1 July 2003</i>
<i>15 Mar</i>	<i>Warning letters to Lagab (Novartis) & Ratiopharm</i>
<i>Mar</i>	<i>Injunction against Alpharma [voluntary, as stipulated in the agreement]</i>
<i>May</i>	<i>Cipralex [escitalopram] launch</i>
<i>May?</i>	<i>MA's [market authorisations] for Lagab (Novartis) and Ratiopharm</i>
	<i>Lu [Lundbeck] requests injunction or settles</i>
<i>??</i>	<i>MA's for Norton (Ivax), Sterwin (Sanofi) & Neolab</i>
<i>Oct??The patent infringement case against Arrows to be heard in court.</i> " ⁴¹⁸	

- (204) After Lundbeck had launched Cipralex (escitalopram) in the United Kingdom on 10 June 2002, a Lundbeck Business Development document with the title "Generic citalopram update 28 06 2002" stated in its conclusions:

⁴¹⁵ In the year 2002, Lundbeck gross profit (net sales minus cost of goods sold) for all products in the United Kingdom was [80-100]*% of net sales and its net profit (earnings) [40-60]*% of net sales. See ID 983.

⁴¹⁶ See sections 6.1 and 6.2 above.

⁴¹⁷ See recital (204) below.

⁴¹⁸ ID 847, page 4.

*"Launching CipraleX before generic competition in the UK – top result."*⁴¹⁹

- (205) A Lundbeck Business Development document titled "Generic citalopram update 04 09 2002" stated with respect to the United Kingdom:

*"The UK switch window is open and going into the 4th month!"*⁴²⁰

- (206) On December 2, 2002, Lundbeck wrote in its Goal, Activity and Budget Plan for 2003 regarding the United Kingdom market:

*"The expected entry of generic citalopram in Q1 2002 was very effectively postponed until October 2002, when the first generic citalopram was made available. Generic sales have been limited so far, but are expected to increase dramatically in December 2002 and to take some 60% of the Cipramil [citalopram] business in 2003 due to substitution by pharmacies. It remains obvious that the absence of generics for 10 months longer than expected in 2002 will continue to have a positive effect on the sales development of CipraleX [escitalopram] in 2003."*⁴²¹

- (207) On 13 October 2003, one and three quarters of a year after generic entry had become possible in principle in the United Kingdom and following its earlier agreements covering the United Kingdom with Merck, Arrow, Alpharma and Ranbaxy, Lundbeck also settled its only on-going infringement litigation in the United Kingdom with the generic company Lagap.⁴²² The settlement entailed that Lagap dropped all challenges against Lundbeck's crystallisation patent (including before the EPO) in exchange for an irrevocable, non-exclusive royalty-free licence to Lundbeck's crystallisation patent covering the entire EEA.⁴²³

- (208) This settlement with Lagap basically put an end to Lundbeck's efforts to prevent generic citalopram from being distributed in the United Kingdom.⁴²⁴ The agreement with Alpharma (EEA-wide, including the United Kingdom) had already ended by 30 June 2003. The agreements with Merck and Arrow for the United Kingdom were terminated on 1 November 2003 and 20 October 2003 respectively following Lundbeck's settlement with Lagap. The agreement with Ranbaxy (EEA-wide, including the United Kingdom) ended on 31 December 2003. Lundbeck's last legal action in the United Kingdom took place in January 2004, as it settled its infringement litigation with the generic supplier Neolab. This settlement included damages to Neolab for the period December 2002 to October 2003 in which Neolab had not sold on the United Kingdom market because of the infringement proceedings Lundbeck had initiated against it.⁴²⁵

- (209) Following Lundbeck's settlement with Lagap in October 2003 and the termination of Lundbeck's agreements with Merck and Arrow by the end of that same month, prices

⁴¹⁹ ID 848, page 47.

⁴²⁰ ID 904, page 259.

⁴²¹ ID 163, page 253.

⁴²² See recitals (113) to (159) above.

⁴²³ ID 237, pages 1205 to 1221. As part of the settlement, Lundbeck also explicitly withdrew its allegations of forgery and perjury against Matrix, see ID 237, page 1211.

⁴²⁴ Lundbeck claimed in its reply to the Statement of Objections that "Thus, to clarify, Lundbeck was and is still confident that the processes that were at issue in the Lagap litigation were infringing". See ID 5394, page 74.

⁴²⁵ ID 234, page 18, ID 891, page 258. See also recital (164) above.

of generic citalopram finally took on a strong downward trend.⁴²⁶ By December 2003, intense generic competition had brought the average price level of generic citalopram to 69% of the average price level of generic citalopram in September 2003, amounting to an average drop of 10 percentage points per month.⁴²⁷ As Lundbeck explained in a report to the Board of Management of November 2003: *"in November [2003] both Neolab and Niche Generics began giving considerable discounts on generic citalopram and the generic erosion is occurring very fast."*⁴²⁸

- (210) In January 2004, a Lundbeck management report signalled that *"the impact of generic competition in the UK has been significant. Sales are presently at the level of around 10% of the original Cipramil franchise."*⁴²⁹ The same document reported that *"this is equivalent to previous expectations and to the impact experienced by other compounds, e.g. fluoxetine."*⁴³⁰
- (211) By April 2004, the average price level of generic citalopram in the United Kingdom had dropped to roughly 31% of the September 2003 level, losing on average 9 percentage points every month between September 2003 and April 2004. By November 2004, prices of generic citalopram had dropped to a low of 10%⁴³¹ of the September 2003 price level, still dropping on average 3 percentage points per month between April 2004 and November 2004. After November 2004, generic prices remained stable until well into 2005.⁴³²
- (212) The graph below shows the evolution of the prices of Cipramil and generic citalopram.

Graph: Evolution of the weighted average generic citalopram prices per DDD in the United Kingdom, in GBP, 2002-2005.

Note: The numbers next to the generic citalopram figures represent the monthly percentage change in the weighted average generic citalopram price (base = September 2003).

⁴²⁶ Contemporaneous sales data show that in the periods when Lagap was alone on the market, Lagap's market price was stable and comparable to the prices of Lundbeck's suppliers. In periods when one or more other generic companies were present on the market – October 2002 to December 2002 for Neolab, from April 2003 for Sanofi, August 2003 for Merck (GUK) and from September 2003 for Niche and Ratiopharm –, the price of generic citalopram began a downward trend. When these companies stopped selling, the generic citalopram price would increase again to previous levels (Neolab's last stocks on the market apparently ran out in March 2003 (ID 394 page 27), while Sanofi sold little or no citalopram in June, August and September 2003 (ID 2457)). See ID 1937 for Lundbeck, ID 1691 for GUK, ID 1721 for Ranbaxy, IDs 1239 and 2614 for Lagap, ID 2629 for Neolab, ID 2457 for Sanofi, ID 678 for GUK, ID 2416 for Niche and ID 2497 for Ratiopharm.

⁴²⁷ The average price level of generic citalopram has been calculated as the weighted average of the prices of generic citalopram and Lundbeck's unbranded citalopram in the United Kingdom. See ID 1937, ID 1721, ID 1691, ID 2416, ID 1188, ID 1352, ID 1239, ID 2457, ID 2497, ID 2532, ID 2499, ID 2629, ID 2614, ID 2616.

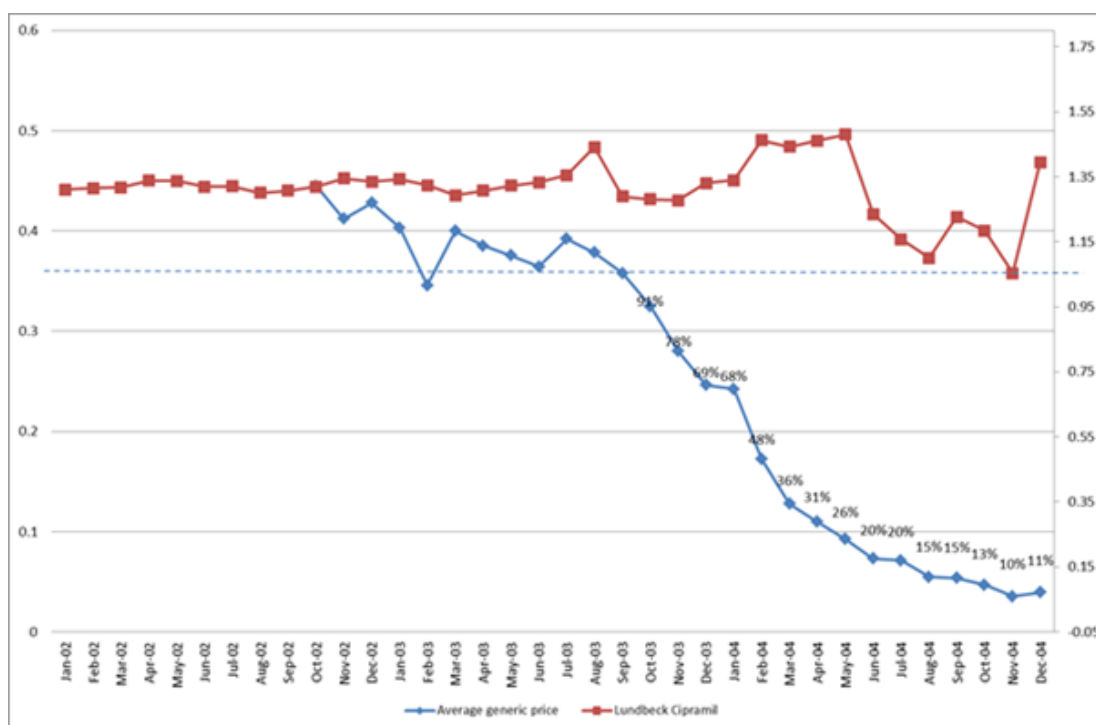
⁴²⁸ ID 891, page 258.

⁴²⁹ ID 892, page 2. The document does not specify whether sales or volumes are meant or what *"the original Cipramil franchise"* entails.

⁴³⁰ ID 892, page 12.

⁴³¹ The prices of GUK, Ranbaxy and Lagap dropped to 6% of Lundbeck's September 2003 price, while the price of Arrow dropped to 10% of the same. See IDs 1691, 1721, 1352, 1239, 1937.

⁴³² As shown by ID 1937, ID 1721, ID 1691, ID 2416, ID 1188, ID 1352, ID 1239, ID 2457, ID 2497, ID 2532, ID 2499, ID 2629, ID 2614, ID 2616.



Sources: ID 1937, ID 1721, ID 1691, ID 2416, ID 1188, ID 1352, ID 1239, ID 2457, ID 2497, ID 2532, ID 2499, ID 2629, ID 2614, ID 2616, ID 2971⁴³³

- (213) As of April 2004, Lundbeck began changing its citalopram strategy in the United Kingdom, by implementing two strategic commercial decisions for the United Kingdom market: Firstly, it started selling, on average, 60%⁴³⁴ of its citalopram volumes as unbranded citalopram at very low prices to several generic suppliers in the United Kingdom.⁴³⁵ Secondly, it started selling over 79%⁴³⁶ of the Lundbeck-branded citalopram (Cipramil) to a single supplier at a considerably lower price than before.⁴³⁷ These measures, taken in response to the generic competition, helped to

⁴³³ For Sanofi (ID 2457), the prices of June 2003 were replaced with an average of the respective previous and next values. Merck (GUK)'s (ID 1691) price of March 2004 was estimated as an average of the previous and next values. For Neolab (ID 2532), November 2003 sales used for the calculation of the average price comprise sales made until 23 November 2003. Also for Neolab, December 2003 contains estimated sales for the rest of November 2003, and estimated December 2003 sales contain estimated sales for the rest of November 2003 plus estimated December 2003 sales. Lundbeck's (ID 1937) sales of unbranded citalopram to Teva, Colorama, IVAX and Pliva, starting in April 2004, are included in the price calculation for generic citalopram. Lundbeck's calculation does not include sales [...]*, and neither sales and prices for the oral formulation, nor sales labelled 'parallel trade'. For Ranbaxy (ID 1721) prices, the monthly European Central Bank GBP/EUR exchange rate was applied for conversion into EUR. Also for Ranbaxy, sales of Niche and Ethigen citalopram made between January and April 2004 (ID 2971) were not taken into account, in order to avoid double counting. For Ratiopharm (ID 2497), no data was available after October 2004.

⁴³⁴ Monthly average until the end of 2004, see ID 1937.

⁴³⁵ In April 2004, Lundbeck started selling its citalopram to Colorama, Pliva and Ivax, and in May 2004 to Teva at prices below GBP [0-10]* per pack of 28 tablets of 28mg (ID 1937). The percentage of these sales in Lundbeck's total sales from May 2004 to December 2004 ranges between [...]*% and [...]*%, by volume, as shown in ID 1937.

⁴³⁶ Monthly average until the end of 2004, see ID 1937.

⁴³⁷ As of June 2004, Lundbeck started selling [50-80]*% to [70-100]*% of the Lundbeck-branded citalopram in the United Kingdom to the company [...]* at a price of GBP [0-15]* per pack of 28

stabilize Lundbeck's declining market share in citalopram, but they meant that Lundbeck's profit margin on citalopram sales decreased considerably.

- (214) With respect to the other EEA Contracting Parties, the end of the EEA-wide agreement with Alpharma on 30 June 2003, the EEA-wide Lagap settlement in October 2003, the termination of the EEA-wide agreements with Arrow and Merck in October 2003 and the end of the EEA-wide agreement with Ranbaxy on 31 December 2003 allowed these companies to start selling generic citalopram across the EEA. The table below shows Lundbeck's market shares in EEA countries in the years 2002 and 2003. This table shows that through the agreements with the undertakings subject to this Decision, covering the entire EEA for three of the four generic undertakings, Lundbeck protected significant market positions throughout the EEA.

- (215) Lundbeck market shares of anti-depressants in the EEA

Member State	2002	2003
AUSTRIA	[25-35]*	[30-40]*
BELGIUM	[20-30]*	[20-30]*
DENMARK	[20-30]*	[20-30]*
FINLAND	[35-45]*	[25-35]*
FRANCE	[10-20]*	[10-20]*
GERMANY	[0-10]*	[0-10]*
GREECE	[15-25]*	[15-25]*
IRELAND	[15-25]*	[20-30]*
ITALY	[15-25]*	[20-30]*
LUXEMBOURG	[15-25]*	[15-25]*
NETHERLANDS	[0-10]*	[0-10]*
NORWAY	[25-35]*	[20-30]*
PORTUGAL	[0-10]*	[0-10]*
SPAIN	[10-20]*	[10-20]*
SWEDEN	[20-30]*	[5-15]*
UNITED KINGDOM	[10-20]*	[10-20]*

Source: ID2596, ID678, ID1721. In ID2596, neither the hospital channel sales were taken into account nor the citalopram parallel sales. In ID678, Merck's aggregated citalopram sales in the United Kingdom for 2002 and January – October 2003 were provided in GBP, and were converted into EUR using average annual exchange rates

tablets of 20 mg as opposed to Lundbeck's price of GBP [0-20]*. Compare footnote 556. The NHS reimbursement price of GBP 16.03 was reduced only in January 2005 (ID 1201 page 2).

for 2002 of 1 EUR = 0.62883 GBP and for 2003 of 1 EUR = 0.69199 GBP. Source European Central Bank

Note 1: Lundbeck's market shares have been calculated based on Lundbeck's sales of citalopram and escitalopram in the periods concerned, compared with total sales of all anti-depressants within the ATC3 level group N6A. Sales by Lundbeck of other anti-depressants within this group have not been included in Lundbeck's market share calculation.

Note 2: Lundbeck's sales in the United Kingdom include sales to Merck (GUK) and to Ranbaxy. To avoid double-counting, the sales of Merck (GUK) and Ranbaxy in the United Kingdom market have not been included. Sales by Merck (GUK) and Ranbaxy in the EEA of other anti-depressants within N6A have not been included.

- (216) With respect to those generic companies with which Lundbeck had not settled earlier, in particular in other European countries than the United Kingdom, on 5 January 2004, an executive of Lundbeck circulated the following e-mail within the top of the organisation:

"We believe that citalopram has entered its last phase and that it is a matter of time before we in all EU countries will be faced with generic products likely to be non-infringing. We are therefore convinced that we are at a crossroad and we propose that we try to close all ongoing cases re Cipla and Matrix and the infringement of the crystallisation patent in EU.

...

We propose the following settlement terms

- *a non-exclusive royalty free licence to the crystal patent*
- *down payment of 1 million Euro for all European markets. Alternatively down payments of 200K Euro per market for France, Italy and Spain and 100K Euro for each remaining European market*
- *both parties refrain from claiming costs and damages re products based on Matrix*
- *Lundbeck will claim damage of period where products were based on Cipla.*⁴³⁸

- (217) As a result, Lundbeck settled in the first half of 2004 with Ratiopharm for the Union and Norway, Desitin for Norway, Sweden and Germany, Eurogenerics for Belgium, Merck Generics for Belgium, Tiefenbacher for the Netherlands, Neurax for the Netherlands and Ratiopharm for Belgium, allowing these generic undertakings market entry.⁴³⁹

7. LUNDBECK'S AGREEMENTS

7.1. Introduction

- (218) This Decision analyses in detail six agreements which Lundbeck concluded with four different generic undertakings in the course of two years (2002 and 2003). Of these

⁴³⁸ ID 681, page 138.

⁴³⁹ ID 845, page 93.

four generic undertakings, three were medicines suppliers (Merck – two agreements, Arrow – two agreements and Alpharma) and one was API producer and medicines supplier (Ranbaxy). The negotiation, the provisions, the implementation and relevant subsequent events of each agreement are described in detail in the following sections. The order chosen is to start with the earliest agreements (Merck and Arrow for the United Kingdom, concluded on the same day) and end with the most recent agreement, with the proviso that where one generic undertaking concluded two agreements with Lundbeck, the two agreements will be described directly after each other. This chapter will therefore first describe Lundbeck's two agreements with Merck, then its two agreements with Arrow, followed by Lundbeck's agreements with Alpharma and Ranbaxy respectively.

7.2. Lundbeck's agreement with Merck regarding the United Kingdom

7.2.1. The negotiation of the agreement

- (219) The description of events leading to Lundbeck's agreement with Merck (GUK) regarding the United Kingdom of 24 January 2002 starts with a meeting between Lundbeck and Merck Generics sometime at the beginning of 1999. In a report to its Board of 8 February 1999, Lundbeck wrote:

*"After rumours that Merck Generics are synthesising citalopram, a meeting was held with their top management. At the meeting Merck Generics confirmed the fact, but were not able to confirm whether they were using a Lundbeck patented production method or whether they had developed a new method. A fresh meeting has been agreed."*⁴⁴⁰

- (220) As described in recitals (175) to (177) above, by the year 2000 Merck (GUK) had come to rely for its intention of selling generic citalopram in Europe on the Italian chemical producer VIS Farmaceutici S.p.A. Based on the VIS Master Drug File, Merck (GUK) expected to receive a marketing authorisation in the United Kingdom in February 2001 and in other European countries, using the mutual recognition procedure, by December 2001.⁴⁴¹ However, in October 2000 Lundbeck acquired VIS and withdrew immediately thereafter VIS' Drug Master File for generic citalopram.
- (221) In a meeting with Merck (GUK) on 1 November 2000, Lundbeck representatives, in their capacity as [company function]* of VIS, justified this withdrawal by pointing to an impurity in the VIS material that exceeded the 0.1% regulatory threshold. Lundbeck also talked about its authorised distribution agreement with Nycomed in Denmark. One of the issues on which Merck (GUK) asked for an answer from Lundbeck was *"A possible consequential collaboration on the whole product"*.⁴⁴² Following the meeting, Merck (GUK) considered internally that the alleged impurity problem had in fact already been solved by VIS in September 2000⁴⁴³, shortly before the take-over, or in any case could be relatively easily overcome⁴⁴⁴, and that Lundbeck merely used the impurity as an excuse to withdraw VIS' Drug Master File with a view to preventing approval of the generic marketing authorisations based

⁴⁴⁰ ID 813, page 8. See also ID 9, page 316.

⁴⁴¹ ID 673, pages 7-8 and 23. See also ID 673, pages 17-18.

⁴⁴² ID 673, page 56, and also pages 54-55.

⁴⁴³ ID 673, page 75.

⁴⁴⁴ "...frankly this was an issue we could have overcome but Lundbeck forced them [VIS] to withdraw the DMF in UK." See ID 673, page 66 and ID 1130, page 1.

thereon.⁴⁴⁵ Merck (GUK) estimated that replacing the VIS Drug Master File in Merck (GUK)'s application for a marketing authorisation by the Drug Master File of a new supplier would lead to a delay in obtaining marketing authorisation of around nine months.⁴⁴⁶

- (222) Because of the withdrawal of VIS' Drug Master File, Merck (GUK) had to explore possibilities of buying citalopram API from other suppliers than VIS if it still wanted to enter the citalopram market.⁴⁴⁷ The material of the Indian company Natco, which was in the process of starting up pilot production, seemed promising. This material was exclusively sold via the Swiss company Schweizerhall.⁴⁴⁸ On 18 October 2000, Schweizerhall had sent a first written explanation of Natco's citalopram and the process to make it to Merck's German subsidiary Merck dura.⁴⁴⁹ At the same time, Merck (GUK) had hopes that some sort of a deal might still be possible with Lundbeck. In an internal Merck (GUK) e-mail of 6 November 2000, Merck (GUK) wrote:

"We have asked Lundbeck

- when they intend to validate the process they have and provide us with material*
- if we can order material from their process as they are now a general supplier of the active to the industry*

*they are frankly on the spot and cannot wriggle out of it...we may well get quite a nice deal. We of course asked if they would supply us with their product."*⁴⁵⁰

- (223) In an internal e-mail of 13 December 2000, Merck (GUK) considered that *"the quickest way forward on Citalopram is to persuade Lundbeck to give us their product and help them to protect their backs."*⁴⁵¹
- (224) On 11 January 2001 Merck (GUK), acting as raw material support group for the Merck Generics Group, sent a letter to VIS making a last attempt to persuade VIS to supply citalopram API to the Merck Generics Group.⁴⁵²

⁴⁴⁵ "Clearly a blatant attempt to stop them [VIS] from providing Citalopram for development purposes. [...] Anti trust if one saw it. " See ID 673, page 34. "It is obvious that Lundbeck bought VIS to stop generics." See ID 673, page 53. At the time, Merck (GUK) further observed: "there is a marvellous antitrust case in here somewhere." (E-mail of 20 October 2000, see ID 673, page 32) Finally, it considered taking legal action; this idea was abandoned by senior management, because "we would get no direct benefit". See ID 1130, page 1.

⁴⁴⁶ ID 673, page 85 without reference to any specific country. See recital (175) above, which explains that sales of VIS' citalopram would have been possible already in 2001 in a number of Contracting Parties of the EEA Agreement where Lundbeck did not – or no longer – enjoy(ed) patent protection for the citalopram product.

⁴⁴⁷ See for instance ID 1024, page 7.

⁴⁴⁸ See for instance ID 673, page 63.

⁴⁴⁹ ID 670, pages 3 to 14.

⁴⁵⁰ ID 673, page 53.

⁴⁵¹ ID 673, page 83. The reference to "protect their backs" could refer to a situation where Lundbeck would authorise Merck (GUK), several months before generic entry by other companies, to distribute Lundbeck-produced citalopram as a generic product under Merck (GUK)'s brand name at lower prices than Lundbeck's own brand-name citalopram, thereby already gaining a substantial market share in the generic market and protecting Lundbeck against the full impact of subsequent independent generic entry.

⁴⁵² ID 673, page 95.

- (225) On the same day, 11 January 2001, Lundbeck sent Merck Generics/Merck (GUK) a letter warning it of possible patent infringement on citalopram, annexing a list of 22 process patents or patent applications Lundbeck owned on the production of citalopram.⁴⁵³ This list included the crystallisation patent, as already granted on 6 November 2000 in the Netherlands as a utility model. It did not, however, mention that a patent application for the crystallisation process had been made in the United Kingdom (this United Kingdom patent application was published on 4 July 2001).⁴⁵⁴
- (226) In a letter of 16 January 2011 to Lundbeck, Merck (GUK), again in its capacity as raw material support group for the Merck Generics Group, stated: *"It is also the policy of the company to make low cost Generic pharmaceuticals available at the earliest opportunity through the global network of Merck Generics Group companies."* Merck (GUK) added that it remained available to discuss *"any collaboration with Lundbeck"*.⁴⁵⁵
- (227) In an internal e-mail of 30 January 2001, Merck (GUK) wrote: *"...we are just about to get going on replacing VIS with Natco...the only game in town right now so we go with the flow..."* Regarding Lundbeck, the e-mail stated *"do you want to approach them about a possible deal [concerning supply with Lundbeck's product]"*.⁴⁵⁶
- (228) In an internal memorandum of 5 February 2001, Merck (GUK) recognised that market entry in the United Kingdom with generic citalopram would be possible only after expiry of Lundbeck's basic patent on the compound on 5 January 2002.⁴⁵⁷ The same memorandum stated that Natco's process would be using Lundbeck's originally patented bromphthalide process, patent protection on which would expire with the compound patent. The memorandum continued by stating that Natco's process *"does not infringe any of Lundbeck's later process patents that we are aware of"*, including the ones stated in Lundbeck's letter of 11 January 2001, but also pointed out that *"there still exists the possibility that Lundbeck may file patents on 2 prior steps where there remain differences between the Natco process and the basic patent. We are not aware of any such patents. However, we will monitor the situation..."*⁴⁵⁸ In

⁴⁵³ ID 673, pages 96 to 99. In reply to the Statement of Objections, Lundbeck stated that it had sent on 11 January 2001 a warning letter also to Natco (see ID 5394, page 131 and ID 5447, page 1). The content would likely have been similar or identical to the letter sent to Merck (GUK).

⁴⁵⁴ ID 673, pages 96 to 99. See also recitals (248) to (249) below. In reply to the Statement of Objections, Merck KGaA argued that *"it is not clear whether GUK realised the potential impact of that [crystallisation] patent at this early stage, or was even aware of it."* (ID 5960, page 63) However, on 16 January 2001 GUK replied to Lundbeck's warning letter: *"thank you for the clarification of your Intellectual Property Rights, we will obviously spend time reviewing our continued work in light of these patents and patent applications."* (ID 5960, page 63) At least since 15 March 2001 GUK was fully aware that Lundbeck had *"applied for patents for crystalline forms, cleaning methods and formulae."* (See recital (230) below) Moreover, in an e-mail dated 19 November 2001, GUK explained: *"We are obviously aware of those patents disclosed in the Lundbeck letter..."* (See ID 673, page 171) Main utility models or patents of Lundbeck's crystallisation patent group were published or granted between November 2000 and September 2002 (see recital (113) above).

⁴⁵⁵ ID 673, page 106.

⁴⁵⁶ ID 673, page 122. In this context, in its reply to the Statement of Objections, GUK stressed that Merck (GUK) struggled *"with Lundbeck's obstacles in engaging an API supplier"*, see ID 6026, pages 59-61.

⁴⁵⁷ ID 673, page 124.

⁴⁵⁸ ID 673, page 124. See also ID 673, pages 128 and 161, ID 682, page 93 and ID 581, page 6. According to Lundbeck, Natco used the original alkylation 2002-2 process, see ID 5394, page 125 and recital (109) above. Lundbeck submitted in its reply to the Statement of Objections that the following quote would show that in Merck (GUK)'s view only the main part, not the entire process used by Natco,

other words, entering the United Kingdom market with Natco's generic citalopram would in principle be legally possible as of 5 January 2002, but not sooner. It was perhaps this time table that led Merck (GUK) to consider on 14 February 2001: *"We do have an alternative active supplier, but the quickest way to get a licence would be through Lundbeck."*⁴⁵⁹

- (229) On 20 February 2001, Merck (GUK) observed: *"we may well have to give Schiezerhalle / Natco some kind of guarantees of future purchases if we are ... to stop Lundbeck from doing what they are currently trying which is to buy up the world's supply... they are currently trooping round India trying to buy out all the processes and so on."*⁴⁶⁰
- (230) On 22 February 2001, Lundbeck visited Natco and its exclusive sales agent for citalopram, the Swiss company Schweizerhall, at Natco headquarters in India. According to a contemporaneous meeting report prepared by Schweizerhall and circulated inside Merck (GUK), Lundbeck emphasised, firstly, that escitalopram was soon to be launched in Europe. This was interpreted as meaning: *"The message Lundbeck wants to get across is that the racemic product [citalopram] will shortly disappear from the market or play only a minor role."*⁴⁶¹ Lundbeck then displayed all the ways known to Lundbeck to synthesise Citalopram and all the patents it had on manufacturing processes of citalopram, including the fact that it had *"applied for patents for crystalline forms, cleaning methods and formulae."* This was interpreted as: *"Lundbeck wishes to create the impression that it is not possible to produce Citalopram on a large scale of sufficient quality for licensing by a non-patent infringing method. The question arises then why Lundbeck bought VIS Farmaceutici."*⁴⁶² Then Lundbeck explained that it was already using the authorised generic suppliers Bioglan and Nycomed in Denmark. This was interpreted to mean: *"Lundbeck wants to show here that the market share for generic product companies independent of Lundbeck will not develop in the way that the generic industry had hoped."*⁴⁶³
- (231) Finally, Lundbeck *"said that because of the great demand for Citalopram they would buy material from Natco if the quality were acceptable. In view of the immediately previous descriptions of the expansions of Lundbeck's production capacities and the announcement that the racemic product would shortly be taken off the market, not a very realistic remark."*⁴⁶⁴ Natco rejected the offer to supply citalopram to Lundbeck, saying it was committed to distribute citalopram through Schweizerhall. Schweizerhall said it did not wish to supply citalopram to Lundbeck. Lundbeck then made an offer to Natco to buy two intermediates for the production of citalopram.

corresponded to this process: *"The main part of the process of Natco is given in the basic compound patent as an example of synthesis of citalopram. All the prior intermediates are also named although they use slightly different reagents for each step. [Name of Merck (GUK) employee] explained that as soon as the compound patent is off we are free to sell the material."* ID 673, page 128; see ID 5394, page 127. The quote, however, also indicates that Merck (GUK) had analysed the compound patent, which was about to expire, and that it considered that *"as soon as the compound patent is off we are free to sell the material."*

⁴⁵⁹ ID 673, page 126.

⁴⁶⁰ ID 673, page 130.

⁴⁶¹ ID 673, page 138.

⁴⁶² ID 673, page 138.

⁴⁶³ ID 673, page 139.

⁴⁶⁴ ID 673, page 139.

This was interpreted to mean: *"The enquiry about the two intermediates was certainly an attempt to break the alliance between Natco and Schweizerhall. However, Natco recognised themselves that it was not an offer to be taken seriously."*⁴⁶⁵

- (232) On 26 February 2001 Merck (GUK) concluded that Natco had the *"appropriate synthetic process to allow us to enter these markets at the earliest time."*⁴⁶⁶
- (233) Within the Merck Generics Group, an email of 2 March 2001 observed, *"Lundbeck left [Natco] after 45 minutes not knowing anything about Natco where they are and the quality of their material, which is excellent and good enough to get us through registration. If Lundbeck really knew we could be facing a Lundbeck buy-out of Natco. After Lundbeck left they faxed back an 'artificial' order which said if Natco had the right quality the [sic] they would order 2 tonnes [of citalopram] for 2 years at 5000USD/kg. Obviously this is a fishing exercise but potential 20 Mio USD which is Natco annual turnover is a significant order as is our project 1000kg order."*⁴⁶⁷ There is no indication in the file that Natco reacted positively to this offer. Indeed, as Merck (GUK) commented in an internal e-mail on 1 March 2001, *"they [Natco] have been offered a fortune by Lundbeck for their output and have refused in our favour...loyalty will have to be repaid though."*⁴⁶⁸ That same e-mail further stated: *"we will be committed to Natco when we move forward with them on this one...we cannot go back on this.....if we show any signs of registering with them and then going off to another supplier we can kiss the DMF goodbye....."*⁴⁶⁹
- (234) In the same e-mail of 2 March 2001, Merck GUK) confirmed its belief that the Natco process would not infringe any Lundbeck patents: *"The citalopram active process is heavily patented but the Schweizerhall process is non-infringing when the compound patent expires (checked out by patents group at Potters Bar [Merck (GUK)'s address]."*⁴⁷⁰ Merck (GUK) also noted that *"Schweizerhall are essentially the furthest ahead of all the potential AIMs [active ingredient manufacturers] (subject to Tiefenbacher –separate discussion). We have material from them at Alphapharm that will allow us to refile in many countries EU...in the next four months. This may well lead to a position where we are the only generic in the market place. It will certainly lead to a position of strength versus Lundbeck."*⁴⁷¹
- (235) On 15 May 2001, Merck (GUK), on behalf of the Merck Generics Group⁴⁷², concluded a Development and Supply Agreement regarding Racemic Citalopram HBr with Schweizerhall Pharma International GmbH.⁴⁷³ This agreement provided that for Germany, the United Kingdom, France, Finland, Norway, Sweden, Belgium, the Netherlands, Spain and Italy, Schweizerhall became for a period of eight years the preferred supplier of generic citalopram API to the Merck Generics Group, which

⁴⁶⁵ ID 673, page 139.

⁴⁶⁶ ID 670, page 24.

⁴⁶⁷ ID 1024, page 35. Regarding Lundbeck's limited understanding of Natco's process see recitals (260), (276) and (281).

⁴⁶⁸ ID 1024, page 37.

⁴⁶⁹ ID 1024, pages 34-35.

⁴⁷⁰ ID 1024, pages 34-35. See also Article 9.1 and ID 670, pages 57-58.

⁴⁷¹ ID 1024, page 34.

⁴⁷² ID 1509, page 1.

⁴⁷³ ID 670, pages 52 to 69. In the same month, Schweizerhall was acquired by Aceto Corporation.

would use the API to produce finished dosage forms of citalopram.⁴⁷⁴ The Merck Generics Group agreed to apply for marketing authorisations in these designated countries. "Preferred supplier" meant that the Merck Generics Group would, in principle, cover 100 per cent of its annual demand for these countries with Schweizerhall, for a period of at least eight years after launch.⁴⁷⁵ The API producer to be used was the Indian company Natco, which confirmed in an annex that they would honour the stipulated supply provisions. Schweizerhall and Natco were, in principle allowed to also sell their citalopram products to other clients in Europe, provided this would not lead to a temporary or complete cut off of supply of the API during the duration of the agreement.⁴⁷⁶ Merck (GUK) was a "preferred customer", meaning that its supply needs were to be given priority.⁴⁷⁷ Schweizerhall, from its side, indicated that it had only one other client in Europe for Natco's citalopram.⁴⁷⁸ Natco confirmed that they would sell only through Schweizerhall.⁴⁷⁹ Schweizerhall agreed to indemnify MG-Group in case of *"process patent infringement of the API in Germany as far as already published"*.⁴⁸⁰ The agreement also provided that *"To our best knowledge API manufactured by Natco will be non-infringing after these patents/SPCs expire which has been reviewed and confirmed by MG-Group."*⁴⁸¹ The patents and SPCs referred to were Lundbeck's original compound and processes patent and patents of the same patent family as listed in Annex 5 to the agreement and due to expire in most European countries in January 2002. Pursuant to the agreement, MG-Group had *"the right to perform a reasonable audit of Natco's manufacturing and quality control procedures, records, facilities as well as all supplements to ensure that Natco complies with the current Rules Governing Medicinal Products in the European Community and other areas"*.⁴⁸² In a Letter of Guarantee, Natco committed not to change its production/synthesis process of the API without prior written consent.⁴⁸³ There is no indication in the file that Natco would have changed its production process during the time of the events described in this Decision. The price agreed for the citalopram API was USD 3 900 per kilogram. The Merck Generics Group agreed to buy a minimum of 500 kilograms before the end of 2001 and a minimum of 1 000 kilograms before the end of 2002.

- (236) On 4 July 2001, the national United Kingdom patent application for Lundbeck's crystallisation process was published (GB 2 357 762) followed by a publication on 20 September 2001 of the PCT patent application (WO 01/68627).⁴⁸⁴

⁴⁷⁴ ID 670, page 55, Article 3.2.

⁴⁷⁵ See the preamble and Article 2.1 of the agreement.

⁴⁷⁶ See Article 2.3 and Annex 4 of the agreement.

⁴⁷⁷ See Article 1.4 of the agreement.

⁴⁷⁸ This second customer was the German company Hexal, see Article 1.4 of the agreement at ID 670, page 53. See also ID 670, pages 16 and 32. It appears, however, that Hexal subsequently switched to the Indian companies Matrix and Cipla as supplier of its API, see ID 844, page 29 and ID 903, page 4.

⁴⁷⁹ Natco had appointed Schweizerhall as its exclusive worldwide citalopram sales agent. The Merck Group used its Australian subsidiary Alphapharm to conduct designated product development work and to prepare the drug registration files. See ID 581, page 22 and ID 670, pages 52 and 67.

⁴⁸⁰ See Article 9.1 of the agreement. In Germany, patent protection for the citalopram compound and two original processes had already expired.

⁴⁸¹ See Article 9.1 of the agreement.

⁴⁸² See Article 5.1 of the agreement.

⁴⁸³ ID 670, page 67. In reply to the Letter of Facts, Merck KGaA explained: *"Indeed, the Natco process had to be monitored in detailed in order to avoid any infringement"*. See ID 6755, page 17.

⁴⁸⁴ See recitals (113) and (151).

- (237) An internal e-mail of Merck (GUK) of 5 September 2001 indicates that Merck (GUK) expected to be able to sell in the United Kingdom about GBP 9 million of Natco citalopram in the first year after launch, of which approximately GBP 7 million would be profit: *"Raw material Natco (Indian). This is non-infringing."*⁴⁸⁵
- (238) Another internal Merck (GUK) e-mail of 5 September 2001 stated that Lundbeck are offering *"a potential deal for the UK market...however we have to maintain a high threat posture."*⁴⁸⁶ Yet another e-mail of the same day showed that Merck (GUK) was getting ready for entry: *"The full 3 month launch stock may not be there on Jan 5th, but it should be there through Jan."*⁴⁸⁷
- (239) In an internal e-mail of 13 September 2001 Merck (GUK)'s [employee function]* estimated that in a best case scenario, Merck (GUK) expected to make GBP 9.7 million gross profit on its first year of sales of generic citalopram in the United Kingdom. The best case scenario assumed, *inter alia*, that there would be no other generic competition, that Merck (GUK) would achieve 40% market share from day one and that Merck (GUK) would sell at a price approximately 30% below the NHS list price. In a worst case scenario, Merck (GUK) was expected to make gross profits of GBP 2.2 million. This scenario assumed, *inter alia*, that there would be generic competitors, that Merck (GUK) would achieve only a 20% market share and that the price would be 50% below the NHS list price. According to the e-mail, the worst case scenario was considered *"very pessimistic"*, in particular because the citalopram market as a whole was still growing and because Merck (GUK) expected that it would be able to negotiate better citalopram API purchase prices from Natco with increased volumes.⁴⁸⁸
- (240) Another internal Merck (GUK) e-mail of 13 September 2001 stated:
"Lundbeck [sic] have not really dealt with us on a global basis as such they have tended to do the whole thing a little piecemeal with whoever they see a threat in a given market. They recently "summoned" [the [employee function] of Merck (GUK)] to one meeting and then followed up with another meeting with [Merck (GUK)'s [employee function]* and the [employee function]* of Merck (GUK)]. They commenced with threats..."you must be patent infringing, we will sue you to hell....They said their plan was to launch the Escitalopram and give it a whack with 450 reps and then withdraw the Citalopram.....good luck we said...this does not affect us launching as our file is in and running and so they cannot invalidate our application. So basically we ask for their product in advance of patent off and so on....From a technical point of view we hope to have approval in December in UK."*⁴⁸⁹
- (241) On 19 September 2001, Merck (GUK) internally rejected the idea of *"qualify[ing] a second source for Citalopram"* besides Natco, because on the one hand *"constant supply [by Natco with citalopram] should not be a problem"* and on the other hand *"we have potential still for litigation with Lundbeck"*. Although the document shows therefore that litigation with Lundbeck was a possibility, it also demonstrates that

⁴⁸⁵ ID 673, page 145.

⁴⁸⁶ ID 673, page 151.

⁴⁸⁷ ID 673, page 153.

⁴⁸⁸ ID 1024, pages 49-50. See also ID 1024, page 53.

⁴⁸⁹ ID 673, page 155.

Merck (GUK) was so confident in its legal position with Natco citalopram that it considered *"adding another source"* unnecessary.⁴⁹⁰

- (242) A Lundbeck internal e-mail of 28 September 2001 mentioned *"Talks with Merck Generics UK"* and *"Deal with Merck Generics UK?? Tbd."*⁴⁹¹
- (243) An internal Merck (GUK) e-mail of 28 September 2001 labelled *"RE Lundbeck"* transferred *"notes from yesterday"*. Those notes indicated two possible scenarios for Merck (GUK) to follow: The first scenario (*"current plans"*) calculated Merck (GUK)'s expected profits from its own sales of Natco citalopram in the United Kingdom. Merck (GUK) expected in this scenario to sell *"1m packs at profit of £9/pack. Worth £9m in year 1."* The second scenario, referred to in the notes as *"Plan 2...Supplied by Lundbeck"* raised the question: *"How to achieve the same profit figure?"* The second scenario was then split into two alternative proposals, one for a Merck (GUK) launch of Lundbeck citalopram prior to Lundbeck's compound patent expiry for citalopram in January 2002 and one for a Merck (GUK) launch of Lundbeck citalopram after the compound patent expiry. The second proposal stated: *"COG [cost of goods sold]'s of £5.44 (assume £11 selling price) will deliver £9m profit"*, and *"As selling price falls supply price falls."*⁴⁹²
- (244) An internal Merck (GUK) e-mail of 28 September 2001 sent by Merck (GUK)'s [employee function]* stated *"Met twice with Lundbeck in the UK to achieve a deal on Citalopram."*⁴⁹³
- (245) On 12 October 2001 Merck (GUK)'s [employee function]* wrote to Schweizerhall, Aceto and Natco:
- "...it is now time to move forward in readiness for the legal action from Lundbeck. This will vary in some markets from having documentation ready for when they try to injunct us, through the use of protective writs. There is the potential to prepare for UK, Sweden, France and Germany. In order to do this we need to provide certain documentation to our lawyers which they will ask us from time to time."*⁴⁹⁴
- (246) On 24 October 2001, Merck reported to Merck (GUK) that Lundbeck Germany had decided not to follow an early entry strategy for citalopram.⁴⁹⁵ Merck observed: *"Seems that they [Lundbeck] have reconfirmed their previous strategy to defend their product by all means"*. Merck (GUK) commented: *"and we intend to attack it by all possible means!!!"*⁴⁹⁶ and *"this says to me they will attack even if they are naked and have to throw tennis balls at us."*⁴⁹⁷ Shortly thereafter, on 12 November 2001 Merck (GUK) noted: *"despite the fact that the patent on the compound and the process we are using expires in Jan it is suspected that Lundbeck will try to injunct on the*

⁴⁹⁰ See ID 1021, page 33. See ID 5960, page 284.

⁴⁹¹ ID 903, page 40.

⁴⁹² ID 1995, pages 2 to 11.

⁴⁹³ ID 1996, page 2.

⁴⁹⁴ ID 1997, page 2.

⁴⁹⁵ ID 673, page 159. An early entry strategy generally refers to the conclusion of early entry agreements between the originator and a generic company for authorised generic entry. Such agreements are used by originator companies to anticipate generic competition by providing for a controlled market launch of a generic product generally before loss of market exclusivity. See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 325-339.

⁴⁹⁶ ID 673, page 159.

⁴⁹⁷ ID 1998, page 2.

*premise that they can confuse the issue in the injunction hearing and hence get a 'status quo' ruling" concluding that "actions to pre-empt any injunction were agreed to be worthwhile."*⁴⁹⁸

- (247) On 15 November 2001, German customs authorities seized, upon Lundbeck's request (based on a "customs watch notice"), containers of approximately 75 and 203 kg of Natco's citalopram. The seizure allowed Lundbeck to examine a sample of Natco's API.⁴⁹⁹ On the same day, Merck (GUK) internally observed: *"the patent litigation with Lundbeck has started today"*.⁵⁰⁰ In reply to the Statement of Objections, Lundbeck argued to the Commission that analysis of this sample showed that the observed low level of 5-Acetyl impurity *"necessarily required the use of the Crystallization Process"*.⁵⁰¹ However, at that time and until the conclusion of the agreement, Lundbeck neither knew which process Natco was precisely using nor had it certainty regarding any possible patent infringement.⁵⁰²
- (248) On the same day, 15 November 2001, Tiefenbacher sent Merck dura (which was a client of Tiefenbacher) an analysis it had made of the patents and patent applications Lundbeck had mentioned in its general warning letter to API producers and generic suppliers, including Merck (GUK), in January 2001.⁵⁰³ Merck dura passed the analysis on to Merck (GUK). For Lundbeck's crystallisation utility model in the Netherlands (NL 1016435), which had been granted on 6 November 2000, and the corresponding application in the United Kingdom (GB2357762), Tiefenbacher concluded: *"Describes the production of high purity Citalopram through the crystallisation of the base. In principle not applicable, as in our processes the base is not crystallised, but the product is cleaned through re-crystallisation of the hydrobromide. But: in some writings, protection for the production of high purity citalopram (>99.8%) is filed for. Will be monitored."*⁵⁰⁴ A Merck (GUK) patent expert commented: *"In relation to these patents, Tiefenbacher's conclusions are the same as mine in that none of the published patent applications disclosed in the letter constitute a problem."*⁵⁰⁵ This person did identify one new patent application of Lundbeck on 19 November 2001 that he believed Natco's process would *prima facie* infringe. However, he considered that this patent application (WO 01/68632A1) clearly lacked novelty and should therefore normally not be granted: *"The published search report in fact cites the basic compound patent [...] as a novelty destroying document."*⁵⁰⁶ A day later, on 20 November 2001, Merck (GUK) observed:

⁴⁹⁸ ID 673, pages 161 and 162.

⁴⁹⁹ ID 5394, page 132. According to a Lundbeck e-mail of 10 January 2002, Merck (GUK)'s lawyer confirmed *"that the Hamburg sample constitutes the Natco material of the quality which they have intended to bring on the UK market."* See ID 5394, page 124. In reply to the Statement of Objections, Lundbeck pointed out and provided evidence showing that it had internally analysed Natco's citalopram at different points in time throughout the years 2000-2003. See ID 5394, pages 122-127. This does not mean, however, that Lundbeck would have really understood at the time which process Natco was exactly using, see recital (233) and the references in footnote 467.

⁵⁰⁰ ID 1024, page 60, see also ID 673, page 182 and ID 1114, page 1.

⁵⁰¹ ID 5394, page 124.

⁵⁰² See recital (260) below.

⁵⁰³ See recitals (148) and (225) above.

⁵⁰⁴ ID 673, page 174, translation from German. The original German text uses the word *"Umkristallisation"*.

⁵⁰⁵ ID 673, page 171.

⁵⁰⁶ ID 673, page 171.

"However, the patent in question still applies to the NATCO route and will need to be monitored".⁵⁰⁷ In reply to the Statement of Objections, Lundbeck pointed out that although the EPO indicated the patentability in amended form, Lundbeck abandoned the corresponding European patent application EP 1274699 in the spring of 2005 for commercial reasons.⁵⁰⁸

- (249) On 16 November 2001, an internal Merck (GUK) e-mail commented: *"The fun & games has started already with citalopram as our suppliers [Schweizerhall/Natco] had a sample of raw material stopped at customs in Hamburg [on 15 November 2001] so that Lundbeck could take a sample! I'll call you later today to discuss if that's OK as we now know what patents they may come at us with initially. Therefore we should discuss how to best avoid an injunction in the UK. Lundbeck alleged potential infringement of two patents, an intermediate patent EP 0171943⁵⁰⁹ and a utility model DE 20007303⁵¹⁰. The utility model claims crystalline free base of citalopram and crystalline salts of citalopram prepared from the crystalline free base...The PCT application appears to be entering national phases in Europe rather than the regional phase at the moment. The NL patent is NL 1016435 C1 so it looks like this one has granted but the other national filings in Europe still appear to be applications."*⁵¹¹
- (250) On 19 November 2001, an internal Lundbeck e-mail reported that Merck (GUK) called Lundbeck on that day *"and asked if we were interested in a deal"*. Having answered *"maybe"*, Lundbeck considered internally: *"As soon as their UK approval is reality, we must be ready to make an agreement where they drop their registration in return for reduced compensation for the process patent infringement – which is quite legitimate – a nice solution on an otherwise complicated problem."*⁵¹²
- (251) On 27 November 2001, as a follow-up to Lundbeck's letter of 11 January 2001 warning of possible patent infringement⁵¹³, Merck (GUK)'s counsel requested from Lundbeck to *"let us know"* with respect to the large number of patents and patent applications referred to in the letter of 11 January 2001 *"which, if any, you consider our clients may infringe."*⁵¹⁴
- (252) On 29 November 2001, Aceto wrote to Merck (GUK): *"brilliant news from the Hamburg customs. They received instructions from the patent attorneys of the originator today that a.m. batch to be released for our disposal whereas the general procedure of stopping all Citalopram-consignments at the customs should go on (for a period of one year as disclosed by the customs earlier!!!). Of course we will claim*

⁵⁰⁷ ID 1999, page 2.

⁵⁰⁸ Regarding these e-mails see ID 5394, page 128, ID 5960, pages 13-14, 74-75, 138-139, 204; ID 6026, pages 38-39, ID 5446, page 1, and ID 171, pages 1687 and 1691. Merck KGaA indicated that *"the patent was in fact granted at a later stage in Spain under the reference ES 2159271 (B1) on 11 March 2002"*. (ID 6470, page 1) There is no indication in the file that the Spanish patent would have ever been legally challenged.

⁵⁰⁹ This patent covered Lundbeck's diol process. See recital (112) above.

⁵¹⁰ See footnote 226.

⁵¹¹ ID 1152, page 1. In the context of the Hamburg seizure, Merck (GUK)'s [employee function]* considered that there was a need to *"...check Natco and Alpha data for validation..."* Quoted by GUK in ID 6026, page 41. See further footnote 609.

⁵¹² ID 682, page 107. See also footnote 518.

⁵¹³ See recital (225) above.

⁵¹⁴ ID 8, page 363. See recitals (249), (256) and footnote 593.

for damages and claim that our consignments should be excluded from above stated procedure as simply no patent infringements are taking place." An e-mail exchange within Merck (GUK) evaluated the consequences of the customs watch notice and analysed the way forward.⁵¹⁵

- (253) On 3 December 2001, an internal Merck (GUK) e-mail reminded Merck (GUK) staff: *"Guys, let's keep in mind that stage one is to get a deal out of Lundbeck..."*⁵¹⁶
- (254) On 9 December 2001, Merck (GUK) internally stated: *"now pretty far advanced with discussions.... I think a deal is the most likely outcome now.....obviously we need to keep everyone apprised of the progress and where the chess game stands."*⁵¹⁷
- (255) On 11 December 2001 a meeting took place between Lundbeck and Merck (GUK).⁵¹⁸ The report of Merck (GUK)'s [employee function]* from this meeting stated:

"Met with [Lundbeck] today and they are keen to do a deal. The following points came out during our meeting:

- Currently they are taking legal action with the Dutch HA [health authority] re the Tiefenbacher [sic] active. If this is successful then we would have the only available product.*
- If they 'loose' then Tiefen[bacher] will be on the market in March/April 2003. They will be supplying Arrow.*
- Lundbeck have sampled our active and their only comment was that it is of poor quality and they may have to take this 'up with the MCA' [the United Kingdom Medicines Control Agency] when we launch.*
- They made no reference to our product infringing.*

They are very keen to do some sort of deal. I am keen to do this provided the numbers stack up as we will not have a product we could sell in real volumes until Q2... and that could be too late. I do not want to give Arrow a first to market.

- Lundbeck do not want a generic on the market.*
- However they could compensate us for the profit we would have made etc.*
- We could sell UK Lundbeck product to target the PI [parallel imports].*
- This will give us a good T/O [turnover] as well as the profit.*
- I would need some safeguards re generic supply if/when other generics enter the market.*⁵¹⁹

⁵¹⁵ See ID 673, page 190; ID 1124, pages 1-3.

⁵¹⁶ ID 2001, page 2.

⁵¹⁷ ID 1124, page 1.

⁵¹⁸ In reply to the Statement of Objections, Lundbeck argued: *"GUK – not Lundbeck – proposed the settlement."* See ID 5394, page 137. However, in its reply to the Statement of Objections, Merck KGaA claimed: *"Lundbeck appears to have called for a meeting"* and *"roll[ed] out the structure of a deal"*. See ID 5960, pages 79-80. Relevant in the present context is the fact that both parties participated in negotiating their deal.

⁵¹⁹ In reply to the Statement of Objections, Merck KGaA claimed that the latter words of this quote would show that *"from GUK's point of view the deal implied the likelihood of other generic entries."* (ID 5960, page 80, emphasis in the original) The Commission notes that the use in the present context of the

*I will go back to Lundbeck with some value/volume expectations (Any thoughts?) but to do a deal we will first need our MA [marketing authorisation]".*⁵²⁰

The input the author received back from Merck (GUK) on the "value/volume expectations" was:

*"Profit value should be as close to our "ideal" i.e., Our estimated net selling price less group cost X volume ..."*⁵²¹

- (256) On 13 December 2001, Merck (GUK)'s external lawyers replied to a letter of Lundbeck dated 10 December 2001⁵²² informing Lundbeck: *"Our clients intend to import citalopram into the UK shortly after 5 January 2002 which is the expiry date of the Supplementary Protection Certificate GB95024 extending protection of Lundbeck's UK patent GB 1 526 331 The citalopram is made using a process disclosed in the aforementioned GB patent."* The letter explained that the expiry of Lundbeck's product patent including the original process lead Merck (GUK) to assume that they did not infringe any Lundbeck patents: *"Our clients have been informed that Lundbeck recently obtained for testing a sample of the citalopram that it is intended Generics will import into the UK. Now that you have completed your tests and released the citalopram, we assume that you do not consider it infringes any patents. However, if this is not correct, please let us know which patents you say are relevant as we asked you on 27 November"*.⁵²³ In reply to the Statement of Objections, GUK explained: *"The aim of the letter is to preserve GUK's legal position by giving notice to Lundbeck that GUK intends to market its generic citalopram and request a statement from Lundbeck..."*⁵²⁴

- (257) On 21 December 2001, Merck (GUK) learned that Tiefenbacher (supplying generic citalopram to, inter alia, Merck (GUK)'s United Kingdom competitor Arrow) had completed the mutual recognition process for the marketing authorisations based on the product from Matrix and Cipla and that on that day a Dutch court had refused to issue a preliminary injunction against Tiefenbacher's marketing authorisation in the Netherlands. Merck (GUK)'s reaction to this news was:

*"...this just about puts them back in pole position.....can we discuss with Lundbeck what we can do to "assist" them.....will they try to get an injunction in UK ???????? [that is to say against Tiefenbacher citalopram as to be sold by Arrow]."*⁵²⁵

Shortly thereafter, on 26 December 2001, Merck (GUK) summed up:

"bottom line.....we are now neck and neck with Tiffenbacher.....they had their day 90 on 22nd Dec.....but they have to now wait for their licence.....as do

words "if/when" shows merely that Merck (GUK) wanted to include "safeguards" in the agreement, in case generic entry happened during the term of the agreement, which it considered a possibility. In fact, when a compound patent expires, generic companies will obviously try to enter the market as soon as possible (see recitals (69), (71), (72) and (79) above).

⁵²⁰ ID 673, page 195.

⁵²¹ ID 673, page 195.

⁵²² ID 904, page 111. See also footnote 546.

⁵²³ ID 682, page 93 (same as ID 8, page 362) and recital (251) above. It should be noted that it is possible that this letter could be considered to have expressed "a settled intention[...] to launch" in the sense of the Paroxetine case, see footnote 312 above.

⁵²⁴ ID 6026, page 40.

⁵²⁵ ID 673, page 200.

we.....the news on the legal action in Holland on Tiffenbachers licence is not good.....Lundbeck will not succeed apparently....."

The document also stated: *"we have to start to consider what we are going to do if the licence in the UK is not granted."*⁵²⁶

In reply to the Statement of Objections, Merck KGaA explained *"it was obvious that GUK perceived to be in a close competitive race against Tiefenbacher to obtain a license in the UK"* and stressed the *"significant competitive advantage"* to be the first generic to enter.⁵²⁷

Internally, Merck (GUK) reacted in the following way: *"[t]he sooner you can tie something up with Lundbeck, the better ..."*⁵²⁸

- (258) On 28 December 2001, Lundbeck replied to Merck (GUK)'s letter of 13 December 2001 claiming that the expired processes *"are not useful in commercial scale production"* and that *"the product tested by Lundbeck does not comply with the pharmaceutical guidelines"*. Lundbeck requested more information regarding the process used for the production of Natco's citalopram product.⁵²⁹
- (259) On 9 January 2002, four days after Lundbeck's basic patent expired, Merck (GUK) received a marketing authorisation in the United Kingdom for 10 and 20 mg citalopram tablets.⁵³⁰ This was the first approval for a generic company for citalopram in the United Kingdom.⁵³¹ Lundbeck had insisted on Merck (GUK) actually having a marketing authorisation before Lundbeck was willing to enter into an agreement with Merck (GUK).⁵³²
- (260) An internal Lundbeck e-mail of the same day, 9 January 2002, analysed Natco's process based on the DMF: *"The DMF does not indicate that the product has been purified by crystallisation of the free base. On the other hand the reaction conditions will lead to formation of the 5-acetyl Citalopram impurity (cf. the product marketed in Australia) which may be removed by crystallisation of the free base. However, we are not sure that they purify by crystallisation of the free base. We investigate this further."*⁵³³
- (261) Also on 9 January 2002, Lundbeck received the following information from an informed market player in the United Kingdom regarding Merck (GUK)'s planned launch there:
- "Generics UK have verbal approval of their licence and are awaiting final written approval which will be in the next week.*
- Currently their supply of citalopram is on a ship and delivery is therefore confirmed as 30.01.02. The general feeling is that this is very optimistic and that the more likely delivery timescale is middle to end of February.*

⁵²⁶ ID 673, page 198.

⁵²⁷ ID 5960, page 81 (emphasis in the original).

⁵²⁸ E-mail of 31 December 2001, see ID 1024, page 68.

⁵²⁹ ID 8, page 349; see also ID 8, page 359. For Merck (GUK)'s letter see recital (256) above.

⁵³⁰ ID 673, page 343, ID 660, page 8, ID 682, pages 5, 120-121.

⁵³¹ ID 673, page 343.

⁵³² See recital (250) above. See also Article 2.6 of the Settlement and Supply Agreement between Lundbeck and Merck (GUK), ID 8, page 210.

⁵³³ See ID 5494, page 1. See further recitals (276) and (281).

The prices of the GUK product are as follows:

10mg £6.96

20mg £11.55

40mg £19.57

Sterwin who were one of the VIS files (Sanofi) have had difficulty obtaining supply for their DMF and have tied up a deal with GUK."⁵³⁴

- (262) One day later, on 10 January 2002, Merck (GUK) and Lundbeck met in Copenhagen.⁵³⁵ At this point, intensive negotiations took place on an agreement between Lundbeck and Merck (GUK).
- (263) In an e-mail of 15 January 2002, Merck (GUK) indicated to Lundbeck the price it asked from Lundbeck for selling it 8 million tablets (partially already packed) of the Natco citalopram it already had in stock: *"Estimated cost per Kg £14,285 (i.e. £2m/140 kg).*"⁵³⁶ In an e-mail of 17 January 2002 to Merck (GUK), Lundbeck wrote: *"As I know you are aware the guys at Head office are very keen to receive the quantities of Products as promised in the initial discussions.*"⁵³⁷
- (264) Lundbeck and Merck (GUK) met at least on 15 January 2002⁵³⁸ and 18 January 2002.⁵³⁹ Several drafts of an agreement were exchanged in this period.
- (265) In an e-mail to Merck (GUK) of 18 January 2002 a Lundbeck representative made the following proposal regarding the envisaged purchasing by Merck (GUK) of Lundbeck citalopram:

⁵³⁴ ID 904, pages 151-152. These were prices for a 28 tablets pack at wholesale level. The same document explained that the prices to retailers would be around £1.50 higher and that the current average price for parallel imports at the retail level was £13.00 for 20 mg tablets. Merck (GUK)'s initial price of 20 mg tablets to retailers would therefore be at around the same level as that of parallel imports of Lundbeck's own citalopram.

⁵³⁵ ID 904, page 175.

⁵³⁶ ID 682, pages 123-124. From a comparison with Merck (GUK)'s purchase price of the citalopram API from Natco (USD 3 900/kg - see recital (235) above) - it is clear that the price Merck (GUK) asked of Lundbeck for the 8 million tablets reflected (at least) Merck (GUK)'s expected re-sale price in the United Kingdom, including a very significant profit (see recital (237) above), rather than the actual cost of goods sold. For Merck (GUK), the purchase price of 140 kilogram API of Natco citalopram had been $140 \times \text{USD } 3\,900 = \text{USD } 546\,000 = \text{GBP } 377\,855$ (at an exchange rate on 15 January 2002 of $1 \text{ USD} = 0.692024 \text{ GBP}$). The re-sale price of the tablets to Lundbeck asked for in this e-mail was therefore more than five times as high (GBP 2 million instead of GBP 377 855), even if one must take into account the cost of producing the tablets and (partially) of packing them. This purchase price of GBP 2 million for 8 million tablets was taken over in the agreement as concluded, see recital (267) below.

⁵³⁷ This refers to Merck (GUK)'s Natco material. ID 907, page 129. Compare with the product schedule to the agreement as concluded, ID 8, page 218.

⁵³⁸ ID 682, page 123.

⁵³⁹ ID 682, page 125, ID 907, page 129.

<i>Strength</i>	<i>Annual Volume</i>	<i>Selling Price</i>	<i>Purchase Price</i>	<i>Profit</i>
10 mg	375,000	£ 8.00	£ 5.60	£ 900,000.00
20 mg	1,500,000	£ 11.50	£9.10	£3,600,000.00
40 mg	210,000	£ 23.00	£20.62	£500,000
				£5,000,000.00

„540

The reaction from an executive within Lundbeck to this e-mail was *"I strongly disagree with the content of this email – we cannot and will not agree selling prices – this is illegal."*⁵⁴¹

- (266) In an e-mail of 23 January 2002 to Merck (GUK) explaining the changes Lundbeck had made to the draft agreement with Merck (GUK), Lundbeck wrote:

*"Inserted the option for Lundbeck to pay a monthly fee instead of delivery Finished Products in case the market price goes down (this is something I am sure we will discuss more if it happens, ideally it should not happen)."*⁵⁴²

7.2.2. The agreement

- (267) On 24 January 2002, Merck (GUK) and Lundbeck Limited, Lundbeck's United Kingdom subsidiary, concluded a *"Settlement and Supply Agreement."*⁵⁴³ The agreement was concluded for one year and covered the United Kingdom only.⁵⁴⁴ In its preamble, the agreement stated that Merck (GUK) *"had received notice"* from Lundbeck that Merck (GUK) might be infringing *"certain Intellectual Property"* of Lundbeck (Point B).⁵⁴⁵ The agreement itself did not specify any specific patent(s) Lundbeck believed Merck (GUK) would infringe.⁵⁴⁶ Nor had Lundbeck initiated any infringement litigation against Merck (GUK). The preamble continued by saying:

⁵⁴⁰ ID 682, page 132. In the agreement actually concluded between Lundbeck and Merck (GUK) the two parties agreed that Lundbeck would only sell 20 mg tablets to Merck (GUK), with a *"suggested selling price"* of £12.00. See recital (271) below.

⁵⁴¹ ID 682, page 132.

⁵⁴² ID 682, page 134.

⁵⁴³ ID 8, pages 207 to 222.

⁵⁴⁴ Lundbeck explained to the Commission that *"Lundbeck initially concluded an agreement with Generics UK covering only the UK because Generics UK initially had marketing authorization only in the UK."* See ID 823, page 51. Regarding the duration, Article 11.1 provided that *"this Agreement shall be for a period of twelve months commencing on the Effective Date"*. The *"Effective Date"* was defined in Article 1.1 as *"the date of delivery of the Products by GUK to the Company"*, which was determined in Article 2.2 as *"31/1-2002"* (note, however, that the Schedule talked about a *"January 25th delivery"*). Had it not been prolonged, the agreement would have expired on 31 January 2003.

⁵⁴⁵ This is presumably a reference to Lundbeck's warning letter of 11 January 2001, see recital (225) above and footnote 546.

⁵⁴⁶ The agreement merely said that Merck (GUK) might be infringing *"certain Intellectual Property"* of Lundbeck, *"Intellectual Property"* being defined as *"patents, trade marks, rights in design, copyright and database rights and all rights or forms of protection of a similar nature in any part of the world."* See preamble point B and Article 1.1.

"GUK does not accept that its product is infringing but recognises that there is an inevitable degree of risk in patent litigation plus delays and inconvenience and has agreed not to launch the Products⁵⁴⁷ subject to payment in accordance with the terms of this Agreement." (Point C)⁵⁴⁸

"The parties have further agreed that GUK shall purchase its requirements of the Finished Products from the Company and the Company is willing to supply GUK with the Finished Products for resale and GUK is willing to purchase the Finished Products on the terms and subject to the conditions of this Agreement." (Point D)⁵⁴⁹

Article 1.1 defined "Finished Products" as "products containing citalopram in finished pack form to be supplied by the Company to GUK pursuant to this Agreement;"

Article 2.1 of the agreement provided:

"The parties agree that there is a risk that certain actions of GUK in respect of the Product and the proposed marketing, distribution and sale of the Products by GUK could give rise to a claim on the part of the Company that GUK's actions may constitute an infringement of the Intellectual Property of the Company."

Article 2.2 provided that "As a result, in consideration of the payment of the sum of £2 million" by Lundbeck, Merck (GUK) agreed to "deliver up" its stock of close to 8 million tablets of Natco citalopram to Lundbeck.⁵⁵⁰

With respect to a possible link of the agreement with the crystallisation patent, Lundbeck argued in its reply to the Statement of Objections that it had at least previously sent GUK warning letters with a list of patents including the crystallisation patent (ID 5394, page 142). In its reply, Merck KGaA argued that the link to the crystallisation patent would have been clear from the context (ID 5960, page 121); similar arguments were made by GUK, which pointed in this context also to the seizure by the Hamburg customs (ID 6026, pages 33-35 and 40-41; see recital (247) above). Internally, Lundbeck did reflect whether Natco might infringe its crystallisation patent. See recitals (150), (247), (260), (281) and (283). Also, Merck (GUK) was aware that Lundbeck might invoke the crystallisation patent (if and when granted in the United Kingdom) against the Natco citalopram, see recitals (248) and (249) above. It is therefore possible that the parties had the crystallisation patent in mind when concluding the agreement. However, at the time when Merck (GUK)'s counsel requested in November 2001 an identification which patents had been infringed by GUK precisely, if any, Lundbeck gave no reply. (ID 904, page 111; see also recital (249) above) Evidence shows that Lundbeck, in fact, did not really know which process Natco was precisely using and could therefore not determine whether GUK was infringing any of its patents.

Article 1.1 defined "Products" as "*the citalopram products developed by GUK in raw material, bulk product and finished pack form as set out in the Schedule and manufactured in accordance with the specification for Products as supplied by GUK at the date of signature. Attached to Schedule 2*". In reply to the Statement of Objections, Lundbeck and GUK claimed "*Schedule 2 ... refers to products supplied by Natco*", although it did not explicitly mention the name Natco; Lundbeck explained this fact by stating that the Schedule "*is redacted to avoid disclosure of Natco's confidential information*". (See ID 5394, page 141; ID 6026, page 11) In its reply, Merck KGaA pointed out that the provisions of the agreement clearly referred to Natco based citalopram as "***all of GUK's Citalopram products were manufactured with Natco's API, both at the time and also later, due to the exclusive supply clause of GUK's agreement with Schweizerhall until 2008.***" (See ID 5960, page 134, emphasis in original)

ID 8, page 208.

ID 8, page 208.

It is noteworthy that earlier drafts of the agreement had stated that Merck (GUK) would "*deliver or destroy*" the products, at Lundbeck's discretion, see for instance ID 673, page 207. Article 2.2 foresees that "[t]his delivery shall take place on 31/1-2002..." However, the Schedule talked about the "*January 25th delivery*".

In Article 2.3 of the agreement Merck (GUK) agreed, *"in consideration of the payment...of £1 million"* by Lundbeck to deliver 173 kg of bulk citalopram material still to be received from Natco.

The purpose of these sales of tablets and bulk citalopram, as understood by Merck (GUK) at the time of the conclusion of the agreement, was to take this Natco citalopram *"out of circulation."*⁵⁵¹ The products were delivered to Lundbeck and later destroyed by Lundbeck.⁵⁵²

Article 2.4 provided that the *"payments made"* and the *"delivery up of the Products by GUK"* pursuant to Articles 2.2 and 2.3 *"shall constitute full and final settlement of any [infringement] claim [...] up until this date."*

In Article 2.6 Merck (GUK) gave warranty *"that it has a marketing authorisation for the sale of the Products"*, referring to the citalopram from Natco.

Article 2.7 stated that *"GUK will not grant duplicates in favour of any third party of its marketing authorisation during the Term for marketing use in the Territory."*

Article 3.2 of the agreement provided that *"The Company agrees to sell the Finished Products and GUK agrees to exclusively purchase the Finished Products from the Company for resale by GUK and its Affiliates in the Territory during the Term on the terms and subject to the conditions of this Agreement."* *"The Company"* was defined as Lundbeck Limited.⁵⁵³ *"Affiliate"* meant any other company in the Merck Generics Group.⁵⁵⁴

Article 4.1 of the agreement provided that Lundbeck would accept all orders placed by Merck (GUK) for Lundbeck citalopram tablets of 20 mg during the term of the agreement for 100% of the quantity forecasted for sale by Merck (GUK). As opposed to what had been envisaged in earlier negotiations between Lundbeck and Merck (GUK), the agreement only provided for Lundbeck sales to Merck (GUK) of tablets of 20 mg, not of tablets of 10 or 40 mg.⁵⁵⁵

(268) Article 6.2 of the agreement provided:

"The Company [Lundbeck] agrees that provided that GUK orders the Volume of Finished Products during the Term, then GUK shall be guaranteed Net Profits of £5 million (or such pro rata figure if GUK orders less than the Volume). If the market price for the Finished Products decreases during the Term, then the Company agrees to reduce the Cost Price accordingly to ensure that GUK is guaranteed to realise Net Profits of £5 million on sales of the Volume (or pro rata if GUK orders less than the Volume).....For any month in which the Company fails for any reason to deliver Finished Products ordered by GUK it shall ensure that GUK is paid such amount as is equal to the Net Profit GUK could reasonably have been expected to make...had the Finished Products been delivered."

(269) Article 12 of the agreement provided:

⁵⁵¹ ID 682, page 133.

⁵⁵² In reply to a request for information of 12 March 2010, Lundbeck stated that it initially stored the products and following the expiration date, destroyed the stock. See ID 823, page 49.

⁵⁵³ See the preamble, point 2.

⁵⁵⁴ See the definitions in Article 1.1, ID 8 page 208.

⁵⁵⁵ See recital (265) above and recital (271) below.

"...The parties agree that if, following termination [of the agreement], GUK decreases the prices at which it sells the Finished Products such that it makes sales at below the prevailing market price, the guaranteed Net Profits (per clause 6.2) shall not apply in respect of such sales."

- (270) The definition of Volume in Article 1.1 of the agreement was:

"the volume of Finished Products notionally to be ordered by GUK from the Company pursuant to this Agreement as set out in the Schedule, it being recognised that GUK shall have no obligation to purchase such volume and that such volume is set out in this Agreement by way of a mechanism to ensure (if and to the extent that such volume is achieved) that GUK receives Net Profits as set out in clause 6.2."

- (271) The Schedule to the agreement indicated as "Volume per month" "125,000 packs" at a "[...] price for the Finished Product – Cipramil 20 mg 28 blisterpack" of "£8.65" and a "Suggested selling price" of "£12.00".⁵⁵⁶
- (272) Lundbeck later explained to the Commission that *"Under the agreement, Generics UK undertook to deliver its products to Lundbeck in consideration of compensation of GBP 3 million for 7.9 million tablets and 173 kilograms of active ingredients. The agreement also included a supply arrangement whereby Generics UK agreed to exclusively purchase its requirements of citalopram from Lundbeck for resale in the UK."*⁵⁵⁷
- (273) Lundbeck started delivering these packs as 31 January 2002 and continued to do so for the full duration of the agreement and its two prolongations until 1 November 2003.⁵⁵⁸ It is apparent from a comparison of the timing and quantity of products delivered by Lundbeck to Merck (GUK) and those sold by Merck (GUK) that Merck (GUK) did not sell any Natco material in the United Kingdom prior to the agreement with Lundbeck. Merck (GUK)'s first sales in the United Kingdom consist of 125 000 packs of 28 tablets of 20 mg supplied by Lundbeck to Merck (GUK) on 25 January 2002 and sold by Merck (GUK) still in the same month.⁵⁵⁹ It is also apparent from sales information provided to the Commission by Lundbeck that when Merck (GUK) ordered more than the 125 000 packs per month agreed, the purchase price was

⁵⁵⁶ ID 8, page 218. The quantity of 125 000 packs per month served as the volume basis for calculating Merck (GUK)'s guaranteed profit. In fact, as mentioned in Article 4.1 of the agreement, Merck (GUK) was allowed to order more, in line with expected demand, but in that case Merck (GUK)'s purchase price of Lundbeck's citalopram would increase to ensure that on the whole Merck (GUK) would still make the same amount of profit over the term of the agreement and not more. See for instance ID 850, page 89. See also recital (273) below. As for Merck (GUK)'s re-sale price, this was a suggested selling price to wholesalers. Lundbeck's own official sales price to wholesalers in the United Kingdom at this time was GBP 14.03 for the same pack of 28 tablets of 20 mg, although in practice considerable discounts were given on that price. See ID 1937. The NHS retail price to patients at this time, which served as the basis for reimbursement, was GBP 16.03. See ID 1024, page 51 and ID 1072, page 2. If Merck (GUK) sold for £12.00 to wholesalers, this would mean that the retail price would be around £13.50, which is slightly above the retail price of parallel imports into the United Kingdom of Lundbeck's own citalopram. See ID 904, page 151, which explains that the margin from wholesaler to retailer was around £1.50. See also recital (265) above.

⁵⁵⁷ ID 823, page 23.

⁵⁵⁸ ID 841, page 925, ID 823, page 50. For the two prolongations, see recitals (289) and (301) further below.

⁵⁵⁹ Compare ID 841, page 925 with ID 677, page 3. See also ID 673, page 229, ID 823, page 49, ID 660, page 8 and ID 846, page 168.

adjusted upwards so as to give Merck (GUK) the same amount of total profit per month as if it had purchased 125 000 packs per month.⁵⁶⁰

- (274) It may be observed that the financial result for Merck (GUK) of the agreement with Lundbeck came very close to the result Merck (GUK) had expected from one year of selling Natco's product in the United Kingdom. Merck (GUK) had expected to be able to sell in the United Kingdom about GBP 9 million of Natco citalopram in the first year after launch, of which approximately GBP 7 million would have been profit.⁵⁶¹ In another scenario Merck (GUK) expected GBP 9 million of profits in the first year.⁵⁶² The best case scenario Merck (GUK) had imagined would have given it a profit of GBP 9.7 million in the first year.⁵⁶³ Through the agreement with Lundbeck, Merck (GUK) gained GBP 8 million (that is to say GBP 3 million for the sale of citalopram to Lundbeck and GBP 5 million through the distribution agreement) in a year, of which probably around GBP 7 million were net profit.⁵⁶⁴

7.2.3. Events during the implementation and extension of the agreement

- (275) On 30 January 2002, Lundbeck's crystallisation patent GB 2357762 was granted in the United Kingdom. As mentioned in recital (151) above, this patent, as granted in the United Kingdom, also contained claims relating to the crystalline base of citalopram itself and to pharmaceutical compositions.⁵⁶⁵
- (276) On 2 February 2002, Lundbeck internally discussed the fact that Natco had applied for a patent for 'An Improved Process for High Purity Citalopram and its Hydrobromide Salt': "What does that mean? That they're probably infringing our crystal patent?" The internal reply to this question was: "We won't be able to see the content of the patent application for another 6 months. [...] It's quite possible that they [Natco] crystallise the base, but we've no way of proving that at the moment."⁵⁶⁶

⁵⁶⁰ ID 841, page 925. See also recitals (280) and (295) below.

⁵⁶¹ See recital (237) above.

⁵⁶² See recital (243) above.

⁵⁶³ See recital (239) above.

⁵⁶⁴ The cost to Merck (GUK) of the Natco citalopram it sold to Lundbeck for GBP 3 million is unlikely to have significantly exceeded GBP 1 million: The quantity of citalopram Merck (GUK) sold to Lundbeck (in the form of tablets) under Article 2.2 of the agreement amounted to 140 kg, see ID 673, page 229. The amount sold under Article 2.3 (in the form of bulk material) was 173 kg, making for a total of 313 kg of API. Merck (GUK) bought the citalopram API from Natco for a price of USD 3 900/kg. The total purchase cost of Merck (GUK) for the quantity of 313 kg API was therefore USD 1 220 700 = approximately GBP 850 000 (at the exchange rate of 1 USD = 0.698241 GBP in January 2002). To this should be added the cost to the Merck Generics group of converting the API into tablets and, partially, of packing them, see ID 673, page 229. An internal e-mail of Merck (GUK) of 11 March 2003 confirms that Merck (GUK) assessed the profit on the sale of stock to Lundbeck at GBP 2 million. See ID 673, page 474. See recital (363) below.

⁵⁶⁵ This meant that the United Kingdom patent was on the one hand more likely to be infringed than without these claims, but on the other hand also more likely to be found at least partially invalid.

⁵⁶⁶ ID 681, page 113 and 114 (translation from Danish); see also page 91.

Merck KGaA indicated that the patent in question (EP1368330, which corresponds to WO 02/066453) was never granted (ID 5960, page 143).

With respect to yet another Natco patent application, WO 2004/016602 A1 of 14 August 2002, published on 26 February 2004, hence not the one discussed in Lundbeck's e-mails dating from February 2002, Lundbeck pointed out in its reply to the Statement of Objections that "according to the WIPO International Preliminary Examination Report of October 20, 2003, 'the invention as defined in at least some of the claims does not appear to meet the criteria mentioned in Article 33(1) PCT, that is to say does not appear to be novel/or to involve an inventive step [...]'". Lundbeck claimed that this

(277) On 6 February 2002, Merck (GUK) stated in an internal e-mail: *"run a check as to what now is our 'exposure' on the API... [...] – ordered for the UK – where launch is now delayed until we have resolved patent issues/product formulation... and that is likely to take a year or so..."*.⁵⁶⁷

(278) On 18 February 2002, Merck (GUK) wrote in an e-mail to Lundbeck:

"Is there any possibility of increasing the volume you supply us (as well as increasing th[e] cost to us to £9.99). We have over 200,000 packs on back order as of today (all at or over £12)." ⁵⁶⁸

In the same e-mail exchange, Merck (GUK) asked: *"Can we discuss the remainder of the UK active for the next 12 months. Are you interested in purchasing this? This will be in the order of 1000 (ish)." Lundbeck informed Merck (GUK) about its decision "not to purchase any further substance" from Merck (GUK) beyond the quantities agreed.*⁵⁶⁹

(279) On 21 February 2002, Merck inquired based on a press release, whether GUK had signed an agreement with Lundbeck. In the press release, GUK was reported as having stated to the press that *"it had entered a deal [...] instead of producing its own, cheaper version of Lundbeck's Cipramil. 'We have taken a more sensible and commercial view to working with the brand originator rather than face possible legal action'"*, while Lundbeck was reported claiming that *"this agreement means that we now reach certain areas of Britain where we were not present before"*.⁵⁷⁰

(280) On 25 February 2002, an e-mail from Merck dura to Merck (GUK) stated:

"Merck dura plans to launch citadura/citalopram in April 2002. ...

As you probably know Lundbeck (Originator) fights very hard against generic competition all over Europe. In Germany the patent situation is different from other European countries and the patent is considered to be weak. Thus some generic companies try to invalidate the patent and work together with Tiefenbacher from whom be bought our registration.

For Merck dura the situation now becomes very difficult. On one side we are together with Tiefenbacher, we get the goods and the registration from them, and we have the same interest in the invalidation of the existing patents, on the other side Generics UK has a contract with Lundbeck and is probably interested in keeping the patent situation as it is. Tiefenbacher knows about the contract with Generics UK and doesn't trust us anymore. In the meantime they would like to keep us out of the business.

patent application would show that Natco used the crystallisation process as purification method and that Natco therefore infringed Lundbeck's crystallisation patent. (See ID 5394, page 126) However, the Commission notes that at the time Lundbeck was not sure about this (see recitals (281) and (283)). Nor did Merck (GUK) consider to be infringing, see the summary of evidence in footnote 1317.

⁵⁶⁷ ID 673, page 318.

⁵⁶⁸ ID 850, page 103.

⁵⁶⁹ ID 850, page 103.

⁵⁷⁰ ID 1024, page 72. In reply to the Statement of Objections, Merck KGaA claimed that the agreement itself was not circulated to the parent Merck KGaA. See ID 5960, page 82.

..., are there any items in the contract Generics UK/Lundbeck which have relevance to Germany? Do you have any concerns from the view of the Merck generics group if we fight against Lundbeck's patent?

...my idea is to continue all necessary activities to launch the product."⁵⁷¹

- (281) On 2 March 2002, concerning Natco's patent application mentioned in recital (276) above, Lundbeck wondered: *"It's most probably a patent on purification, possibly crystallisation of the free base, like ours. Another possibility is an optimum ratio of solvent to base at the alkylation stage."*⁵⁷² Lundbeck's [employee function]* was still not sure how Natco was manufacturing and stated that *"SPE has shown that it is possible to make an active pharmaceutical ingredient (API) that very probably does **not** require crystallisation of the free base "*.⁵⁷³
- (282) A Merck (GUK) e-mail of 7 March 2002 mentioned that Alphapharm, Merck's Australian subsidiary which produced the citalopram finished dosage forms based on Natco's API⁵⁷⁴, had noticed *"a potential major problem with the impurity profile"* of the Natco product. The e-mail concluded by saying: *"At this stage, we have to determine the full cause of the discrepancy in the results and until that is done, we have to assume that potentially we have a big problem with regards to impurity profiles, since this impurity is not present in the Lundbeck product. If the level of the impurity is verified, then the necessary steps will have to be undertaken by Natco to reduce the level of the impurity below 0.1%, possibly by an additional recrystallization."*⁵⁷⁵
- (283) On 8 March 2002, an internal Lundbeck e-mail stated regarding sample "003/L/00" which Lundbeck had taken of Natco citalopram: *"This indicates a final crystallisation as stated in the 2005 method."*⁵⁷⁶ The reference to the year "2005" would mean an alleged infringement of the 2005 patent, not of the crystallisation patent⁵⁷⁷ based on which Lundbeck litigated against generic companies.
- (284) On 13 March 2002, Merck (GUK)'s patent law counsel sent a letter to Lundbeck to resolve patent law questions,⁵⁷⁸ and a reminder on 12 April 2002.⁵⁷⁹ A further letter

⁵⁷¹ ID 675, page 25.

⁵⁷² ID 681, page 113 (translation from Danish). See already recital (150) above.

⁵⁷³ ID 681, page 113 (translation from Danish, emphasis in original). See further footnote 299, recitals (150) above and (283) below.

⁵⁷⁴ GUK explained to the Commission that *"GUK and its affiliates, except Merck dura with respect to citadura..., sourced the finished dosage form for citalopram in-house through Alphapharm, a Merck entity based in Australia", "In the period 2001 to 2004, Alphapharm produced the following quantities of citalopram tablets destined for the European market..."* (ID 1267, page 15) and *"Alphapharm produced the final dosage product based on raw material supplied by Natco"* (ID 660, page 17).

⁵⁷⁵ ID 673, pages 339-340. Lundbeck interpreted this document as admitting that Natco infringed Lundbeck's crystallisation patent. See ID 5394, page 129. However, in its analysis of 15 November 2001, Tiefenbacher had already considered that Lundbeck's crystallisation patent was *"In principle not applicable, as in our processes the base is not crystallised, but the product is cleaned through re-crystallisation of the hydrobromide. But: in some writings, protection for the production of high purity citalopram (>99.8%) is filed for. Will be monitored."* See recital (248) above.

⁵⁷⁶ ID 8, page 344. See recital (151) above.

⁵⁷⁷ See recital (151) above.

⁵⁷⁸ ID 904, page 115. ID 904, page 114 contains a letter dated 6 March 2002 with identical wording as the letter of 13 March 2002, but without signature. Lundbeck apparently considered in its reply to the Statement of Objections that the first letter of 6 March 2002 was sent (ID 5394, page 136), whereas Merck KGaA did not claim that (ID 5960, page 85). It should be noted that the letter of 13 March 2002

was sent on 15 November 2002 related to the EEA Agreement.⁵⁸⁰ Apparently, Lundbeck never responded to any of these letters.

(285) On 5 July 2002, Merck (GUK) received six new United Kingdom marketing authorisations for the distribution of citalopram tablets of 20 mg (five marketing authorisations) and 10 mg (one marketing authorisation).⁵⁸¹ Merck (GUK) had applied for these additional marketing authorisations in the hope that it could license these to other generic companies wanting to sell in the United Kingdom. The supplier for the purpose of these marketing authorisations was Natco.⁵⁸² However, as Article 2(7) of Merck (GUK)'s agreement with Lundbeck explicitly prohibited the granting of duplicates of Merck (GUK)'s marketing authorisation to third parties, nothing came of this during the term of the agreement.

(286) A Lundbeck Business Development document with the title "*Generic citalopram update 04 09 2002*" stated:

"What have we spent out of the pocket?"

<i>Company</i>	<i>Market</i>	<i>Time</i>	<i>Cost</i>	<i>M DKK</i>
<i>Merck Generics</i>	<i>UK</i>	<i>24.1.03</i>	<i>£3M</i>	<i>40</i>
<i>Arrow</i>	<i>UK</i>	<i>31.12.02</i>	<i>£5M</i>	<i>65</i>
<i>Alpharma</i>	<i>EU</i>	<i>30.6.03</i>	<i>\$12M</i>	<i>100</i>
<i>Arrow</i>	<i>DK</i>	<i>15.5.03</i>	<i>\$0.7M</i>	<i>5</i>
<i>Ranbaxy</i>	<i>EU</i>	<i>10.6.03</i>	<i>\$5M</i>	<i>40</i>
<i>Out of the pocket</i>				<i>250</i>

"What have we spent totally?"

<i>Company</i>	<i>Market</i>	<i>Margin</i>	<i>Cost</i>	<i>M DKK</i>
<i>Out of the pocket</i>				<i>250</i>
<i>Distribution</i>	<i>UK</i>	<i>£419K per mth</i>	<i>£5M</i>	<i>65</i>

did not refer to any letter sent on 6 March 2002. It is therefore likely that the letter dated 6 March 2002 remained a draft that was never sent. In any case, the letter of 13 March 2002 reiterated Merck (GUK)'s position that it was not infringing and pointed to the fact that 12 months were now available to resolve the issue: "*Our clients do not consider that their Citalopram product will infringe any valid and subsisting Lundbeck patents, but understand that Lundbeck may take a different view. Our clients would like to resolve this issue entirely and although the settlement effectively affords 12 months for the matter to be resolved, there seems no merit in waiting too long to assess the issues.*"

⁵⁷⁹

ID 904, page 113.

⁵⁸⁰

See recital (359) below.

⁵⁸¹

ID 682, pages 5-6.

⁵⁸²

ID 1509, page 3.

<i>Merck Generics</i>				
<i>Distribution Ranbaxy</i>	<i>UK</i>	<i>10% vol at 40%</i>	<i>£1.5M</i>	<i>20</i>
<i>Less UK discount anyway</i>			<i>?</i>	<i>(35)</i>
<i>Total spend</i>				<i>300</i>

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These tables show that Lundbeck considered that its purchase of Merck (GUK)'s citalopram tablets and citalopram bulk as well as its distribution agreement with Merck (GUK) amounted to a "Cost" for Lundbeck of GBP 3 million and GBP 5 million respectively, in exchange for which Lundbeck had bought "Time" until 24 January 2003.

(287) In an e-mail to Lundbeck of 28 November 2002 Merck (GUK) proposed to extend the agreement, which was due to expire by the end of January 2003, until the end of July 2003 in exchange for a guaranteed profit of GBP 500 000 per month.⁵⁸⁴

(288) On 20 December 2002, Merck (GUK) internally observed:

"I also spoke to [employee name] about the position in the UK and he said that he wants to continue the agreement to sell Lundbeck's product until after the trial judgement. I explained to him that we had an excellent case and that we shouldn't get injuncted if Lundbeck sued if we launched in Jan but he seemed happy to wait and not disturb what he sees as a steady market at the moment.*

[...] Does this mean that the validity of the patents will be contested fully? [...]

*It would be better for us if the patents are declared invalid as if only infringement is argued, with a cursory argument on validity which is not proved, we may have to prove our non-infringement at some stage as well if we were to launch our own product in the future."*⁵⁸⁵

(289) On 10 January 2003, the two parties agreed to extend their Settlement and Supply Agreement until 31 July 2003 and to slightly vary it.⁵⁸⁶ Merck (GUK) was guaranteed net profits of GBP 400 000 per month and a clause was added saying that either party had the right to terminate the agreement if another generic company launched competing generic citalopram in the United Kingdom and Lundbeck did not challenge it through the courts.

(290) On 17 January 2003, Merck (GUK)'s counsel wrote: "we have received no response at all from Lundbeck in response to our various letters to them. That is clearly useful."⁵⁸⁷

⁵⁸³ ID 904, pages 305-306.

⁵⁸⁴ ID 673, pages 407-408.

⁵⁸⁵ ID 1111, page 1.

⁵⁸⁶ ID 8, pages 223-224.

⁵⁸⁷ ID 1112, page 1.

- (291) On 27 January 2003 Merck (GUK) sent a draft of a supply agreement to the United Kingdom company Ivax Pharmaceuticals UK.⁵⁸⁸ According to this draft, the two parties were considering to enter into an agreement under which Merck (GUK) would supply citalopram to Ivax Pharmaceuticals UK for re-sale in the United Kingdom for a period of two years. The draft does not mention when the agreement would enter into force. A Merck (GUK) e-mail of 5 February 2003 explains that the "problem" with the draft agreement is that *"Ivax will be expecting imminent delivery whereas GUK do not want to supply before a key court case takes place (not involving GUK) which could take place in about September."*⁵⁸⁹
- (292) On 9 February 2003, Merck (GUK)'s [employee function]* received the following e-mail: *"The court case that was scheduled for Jan which would end our contract has been moved out. This is Know is a pain in the Arse but I have no control over this. Rather than build up a stock mountain I have asked the orders to be pushed out."*⁵⁹⁰
- On 10 February 2003, Merck (GUK)'s [employee function]* replied and explained in an internal e-mail to the Merck Generics Group:
- *"I was expecting a court case to resolve the patent issues in Jan. We intended to launch straight after this"*⁵⁹¹ *as we were confident that the patents would be overturned.*
 - *This case was delayed first until July and now October.*
 - *I intend to launch once the patents have been removed but this is a bit of a moveable feast.*
 - *The last thing I want to do is to mess you guys up but at present I do not think we will launch before Q3/4."*⁵⁹²
- (293) On 21 February 2003, Merck Generics sent a letter to Natco trying to explain why it had entered into agreements with Lundbeck for the United Kingdom and the remainder of the EEA promising not to sell citalopram. With respect to the United Kingdom market, Merck Generics wrote that according to recent United Kingdom jurisprudence, generic companies had to *"clear the undergrowth" by making a concerted effort to demonstrate that they do not infringe every patent... We therefore decided at the time to come to an arrangement in the UK for one year to allow us time to "clear the undergrowth". This timing has expired however we have continued to stay the watch what happens as Lundbeck are suing other parties. This trial is scheduled for June.*" It also disclosed its strategy to *"wait until June in the hope that Lundbeck succeed and we can enter the market with limited competition. Rest assured that should Lundbeck be unsuccessful we will be vigorously marketing the product"*.⁵⁹³

⁵⁸⁸ ID 673, pages 419 to 430.

⁵⁸⁹ ID 1113, page 1.

⁵⁹⁰ ID 673, page 434.

⁵⁹¹ In reply to the Statement of Objections, Merck KGaA claimed that *"GUK was able to build up stock because the Agreements contained a clause in which Lundbeck agreed not to assert its patent rights during the operation of the Agreements."* (ID 5960, page 105; a similar argument was made in GUK's reply, ID 6026, page 14) In relation to this comment, which is related to Merck KGaA's argument of "clearing the way", see footnote 593.

⁵⁹² ID 673, page 434.

⁵⁹³ ID 673, pages 437 to 445.

- (294) An internal e-mail of Merck (GUK) of 11 March 2003 summarised the profit Merck (GUK) realised from the two agreements with Lundbeck (regarding the United Kingdom and the EEA excluding the United Kingdom) as follows:

"

	<i>Lundbeck UK</i>	<i>Lundbeck Europe</i>
<i>First Deal</i>	<i>£,000</i>	<i>Eur 000</i>
<i>Profit on sale of stock</i>	<i>2,000</i>	
<i>Guaranteed Profit Feb 02-Jan 03</i>	<i>5,000</i>	
<i>Second Deal</i>		
<i>Guaranteed Profit Feb 03-Jul03</i>	<i>2,400</i>	
<i>Payments Oct 02-Sept 03</i>		<i>12,000</i>
<i>Total</i>	<i>9,400</i>	<i>12,000</i>

„594

- (295) On 7 April 2003, a Merck (GUK) employee made the following remarks in an internal e-mail to Merck (GUK)'s [employee function]*:

"Am analysing our Mar results which aren't looking great!

I think we are fooling ourselves with Cipramil. Whilst it is great for turnover we are really only generating extra business for Lundbeck – unless we can get something more tangible than their goodwill. It also ties up a great deal of cash which we don't have not to mention warehouse distribution customer service etc.

I know it's a bit negative but it is disguising some underlying issues. With good sales our shareholders will expect good profit – which as you can see below is not likely to happen.

	<i>Sales</i>	<i>Margin</i>	<i>%</i>
<i>Sales from Reports</i>	<i>11,941</i>	<i>2,975</i>	<i>25%</i>
<i>Cipramil</i>	<i>4,391</i>	<i>583</i>	<i>13%</i>
<i>[other product]</i>	<i>1,572</i>	<i>1,114</i>	<i>71%</i>
<i>Core Business</i>	<i>5,978</i>	<i>1,278</i>	<i>21%</i>

Given that we make some £400k in each of Cipramil and [other product] (once everyone had had a piece of it!) and our overheads are close to £2m per month we are struggling to make a profit pre R&D and NTR."⁵⁹⁵

The reaction of Merck (GUK)'s [employee function]* was:

*"This only supports my view that we should change tack re citalopram post July. We should also look at slowing the rate of sale to say 150k ish a month to improve the gross margin."*⁵⁹⁶

- (296) An internal Merck (GUK) e-mail of 2 July 2003 stated regarding "Citalopram 20 mg": *"I cannot stress how important this is. I must be able to sell this on the 1st Aug."*⁵⁹⁷
- (297) An internal Merck (GUK) e-mail of 20 July 2003 shows that Merck (GUK) was preparing itself to start selling Natco citalopram in the United Kingdom as soon as the United Kingdom agreement with Lundbeck expired at the end of July 2003.⁵⁹⁸
- (298) On 16 July 2003, Lundbeck sent a draft of a second extension agreement to Merck (GUK), proposing an ensured profit of GBP 250 000 per month to Merck (GUK), instead of the GBP 400 000 per month agreed in the first extension.⁵⁹⁹ The justification for this decrease in ensured profit was that there were now *"several members in the "club"."*⁶⁰⁰ Lundbeck had calculated internally that *"Given an expected monthly turnover of £3M we can go up to more than £1M per month since the other agreements "only" involve a cost of ~£400k together."*⁶⁰¹
- (299) A Merck (GUK) internal e-mail of 1 August 2003 said:
- "Launched – first orders out +/- £3mio – [final offer wasn't good enough!!]."*⁶⁰²
- (300) A Lundbeck document entitled "Generic update citalopram 13 08 2003" stated:
- "Deal with Merck Generics UK (MGUK) prolonged"*
- *Initially Lundbeck did not succeed in prolonging the deal with MGUK before its expiry on July 31*
 - *Between August 1st and 4th, MGUK sold generic citalopram corresponding to £3.3M sales into the market*
 - *On August 5th, Lundbeck managed to re-establish the deal with MGUK, effective to the end of the year*
 - *One month notice*
 - *£750K per month."*⁶⁰³

⁵⁹⁵ ID 673, page 479.

⁵⁹⁶ ID 673, page 479.

⁵⁹⁷ ID 673, page 482.

⁵⁹⁸ ID 673, pages 482 to 485.

⁵⁹⁹ ID 903, pages 47 to 51.

⁶⁰⁰ ID 682, page 47.

⁶⁰¹ ID 682, page 47.

⁶⁰² ID 2008, page 2.

⁶⁰³ ID 845, page 103. See also ID 682, page 68.

The citalopram sold by Merck (GUK) between 1 and 4 August 2003 was Natco generic material.

- (301) The second extension was agreed on 6 August 2003.⁶⁰⁴ Guaranteed net profits to Merck (GUK) were increased to GBP 750 000 per month. The extension was to run until 6 January 2004, but each party had the right to terminate it if Lundbeck failed to initiate legal proceedings against generic entry by another company or in the event that judgment was given against Lundbeck in the Lagap litigation.⁶⁰⁵
- (302) On 2 September 2003, Lundbeck wrote an e-mail to its external patent counsel in the United Kingdom: *"As discussed several times during the last two years, we believe that it is most likely that the generic citalopram marketed by UK-Generics infr[r]inges our process patents, in particular GP pat no 2357763 (desmethylcitalopram removal process) and EP Patent No 1169314 and the corresponding GB Patent No 2357762 (purification by crystallisation of citalopram free base)." The e-mail continued by explaining the evidence, on which Lundbeck based its belief: "Unfortunately, the process description in the DMF does not describe the purification process in details. As you know, following to the seizure of bulk material in Hamburg, UK-Generics asked us to tell which patents they infringe. However, since the product was out of specifications we just answered that we could not determine from a product which could clearly not be marketed in Europe and we asked UK-Generics to inform of their process. However, they have not accepted to reveal any details regarding the process [...]. Copies of certificates of analysis of Natco bulk samples and Merck samples are attached. [...] In at least one of the bulk samples we have identified the citalopram desmethyl amide [...] This impurity is indicative of the purification process covered by our GB pat no 2357763. [...] The 5-acetyl citalopram impurity is present in all samples. [...] Though this impurity may be reduced to the 5-(2-hydroxyethyl)-citalopram, crystallisation of free base is considered as the only likely industrial process. [...] In addition to efficient removal of the impurities formed during the alkylation process, the crystallisation of citalopram free base would also make purification of earlier intermediates, such as the 5-cyano-phthalane, superfluous, thus increasing the yield. The 5-cyanophthalane will comprise the corresponding 5-Cl and 5-Br impurities which will be converted to 5-Cl- and 5-Br-citalopram, respectively. These impurities may be removed efficiently by recrystallisation of the free base. I understand from our conversations over the years that it is your view that based on the above it is likely that the UK-Generics product will infringe our process patents if marketed in the UK. Please let me have your written comments."*⁶⁰⁶
- (303) On 29 September 2003, Merck (GUK) observed in an e-mail: *"We have not been sued by Lundbeck. We agreed between us (Lundbeck and Merck Generics) to a voluntary suspension of the selling of our product in UK and Europe for 1 year with the aim of clarifying the issues without resorting to litigation. We wrote several letters to Lundbeck without a response. Lundbeck have had a full opportunity to discuss things but have not responded. We launched in UK recently at expiry of the*

⁶⁰⁴ ID 8, pages 225-226. Apparently the agreement was backdated: An e-mail between Merck (GUK) and Lundbeck was still exchanging a draft of the agreement on 14 August 2003, see ID 673, pages 497 to 499.

⁶⁰⁵ See recital (152) above.

⁶⁰⁶ ID 8, pages 340-341. See also recital (284) above.

*UK agreement, we were not sued. (Others have been though). The European agreement expires end of October this year. As a result we believe we cannot be injuncted by Lundbeck in any jurisdiction because of their lack of any attempt to resolve litigation during our voluntary withdrawal from the market."*⁶⁰⁷

- (304) Between 29 September and 1 October 2003, an exchange of e-mails inside Merck (GUK) discussed a citalopram analysis made by Aceto, Natco's exclusive sales agent. The exchange showed some uncertainty inside Merck (GUK) about whether Natco citalopram might infringe Lundbeck's crystallisation patent.

On 29 September 2003, Aceto sent the following e-mail to Merck (GUK) with the subject line "*Claim 3 EP 1169314*" (the EP crystallisation patent) containing an analysis of the concentrated mother liquor in form of "*Chromatograms*":

*"The carboxylic acid derivative plays indeed no role as already assumed. [process description]"*⁶⁰⁸

[process description]*. *Shall we try to collect more data to support this?"*

Merck (GUK) internally commented:

"With claim 3 s[t]ating that the impurity is 'removed from a crude mixture of citalopram or from a crude salt of Citalopram by precipitating Citalopram base in crystalline form, optionally re-crystallising said base one or more times and /or transferring said base into a salt thereof.

[process description]*. *I would interpret that as infringement of the above claim – What is your opinion on this?*

To my understanding, the only way that non infringement would be proven is if the said impurity was either not possible due to the synthetic route (as per most of those cited in the claim) or not detectable (as in the case of the carbosylic acid)."

In reply, the point was made, however, that *"All the claims in this patent require the precipitation of crystalline citalopram free base. As the Natco process [process description]*, there can be no infringement of the claims regardless of what impurities are removed."* The response within Merck (GUK) to this was: *"I would just like to understand how do you know that Natco process [process description]*"*

The discussion was concluded by the following remarks: *"Natco tells us that the citalopram base is not isolated in a crystalline form but we have no evidence other than the batch records. We have left it at that point with the knowledge that the Natco process follows the prior art and if Lundbeck allege the process infringes then their claim must be invalid."* It was also observed that *"We have launched the product in the UK a few months ago and Lundbeck have not attacked us."*⁶⁰⁹

⁶⁰⁷ ID 1117, page 1; see also ID 846, page 168.

⁶⁰⁸ It should be recalled that claim 3 of Lundbeck's crystallisation patent, as finally upheld by the EPO Board of Appeals in 2011, restricted the list of impurities removed through the patented process to halogen elements. See recital (166) above.

⁶⁰⁹ ID 673, pages 503 to 509. The reference to "*the product*" concerns Natco's generic citalopram, which Merck (GUK) briefly sold in the United Kingdom market in the first days of August 2003 (see recital (300) above), not the Lundbeck-branded citalopram Merck (GUK) was distributing for Lundbeck. See also ID 1024, page 79 and ID 675, page 36.

In reply to the Statement of Objections, Merck KGaA claimed: *"It had to rely on what Natco said"*, which would have added to its uncertainty regarding potential patent infringement. ID 5960, page 212.

- (305) On 29 September 2003, Lundbeck internally considered the strategy it would follow in case of a "*Total victory*" in the Lagap litigation. A total victory would mean a "*Court case outcome: Patent validated; Matrix infringes*".

"Agreements

Merck Generics (Natco) – seeks to prolong agreement

Arrow (Cipla & Matrix) and [...] (Cipla) – agreements terminate automatically, do nothing

Alpharma (Cipla & Matrix) – agreement has terminated, do nothing

*Ranbaxy (Ranbaxy) – agreement terminates 31 Dec 2003 – do nothing or consider prolonging the agreement"*⁶¹⁰

- (306) On 10 October 2003, while Lundbeck was preparing its settlement with Lagap, Lundbeck told Merck (GUK) it wanted to terminate the agreement with Merck (GUK) as of 1 November 2003. Merck (GUK) therefore decided the time had now come to offer other companies active in the United Kingdom, including Ivax Pharmaceuticals UK, supply contracts for Natco citalopram for delivery as of 1 November 2003.⁶¹¹ Following Lundbeck's conclusion of the settlement with Lagap on 13 October 2003, Lundbeck formally terminated the agreement with Merck (GUK) on 22 October 2003 with effect from 1 November 2003. In its letter to Merck (GUK), the Lundbeck representative wrote: "*I know that both companies have benefited from working together...*"⁶¹²
- (307) In total, over the entire period of operation of the agreement from 24 January 2002 to 1 November 2003, Lundbeck transferred a value to Merck (GUK) of GBP 12.65 million (corresponding to approximately EUR 19.4 million)⁶¹³ under the agreement regarding the United Kingdom, consisting of:
- GBP 3 million for Merck (GUK)'s stock of Natco material;
 - GBP 5 million of guaranteed profit in the first year;
 - 6 times GBP 400 000 in the first extension between February 2003 and July 2003 = GBP 2.4 million;

In its reply, also GUK submitted that it faced uncertainty given that it had "*no evidence other than the batch records*" (claiming that it "*did not have the data to verify*") and "*there were many indications in the data provided by Aceto that Natco was potentially infringing*". ID 6026, pages 35, 41, 46-48. However, the e-mail exchange also shows that Merck (GUK) decided "*We have left it at that point*". This means that all in all Merck (GUK) did not consider it necessary to request any further data. Furthermore, it should be recalled that according to Article 5.1 of Merck's agreement with Schweizerhall, Merck had inspection rights, which it could have exercised had it considered that necessary: "*MG-Group shall have the right to visit Natco's plant where the API is manufactured on any business day upon reasonable prior written notice to Schweizerhall.*" During such visit, Merck was entitled to "*perform a reasonable audit of Natco's manufacturing and quality control procedures, records, facilities as well as all supplements to ensure that Natco complies with the current Rules Governing Medicinal Products*".

⁶¹⁰ ID 846, page 7.

⁶¹¹ ID 673, page 513.

⁶¹² ID 682, page 81.

⁶¹³ Using an average annual exchange rate for 2002 of 1 EUR = 0.62883 GBP and for 2003 of 1 EUR = 0.69199 GBP, source European Central Bank.

- 3 times GBP 750 000 in the second extension between August 2003 and end of October 2003 = GBP 2.25 million.

7.2.4. Subsequent events

- (308) An internal Merck (GUK) e-mail of 12 November 2003 shows that Merck (GUK) kept meticulous track of whether the amount of profit actually received from its sales of Lundbeck citalopram in the United Kingdom corresponded to the ensured profit amounts agreed in the main United Kingdom agreement and its two extensions. These calculations show that at that point in time Lundbeck still owed Merck (GUK) slightly over GBP 1 million for the three agreements together. The figures were sent to Lundbeck *"to finish off Cipramil."* Over the entire period, Merck (GUK) had sold close to GBP 50 million worth of Lundbeck product in the United Kingdom.⁶¹⁴
- (309) When Merck (GUK) re-started selling Natco citalopram in the United Kingdom as of 1 November 2003, Lundbeck did not start infringement proceedings against it.⁶¹⁵

7.3. Lundbeck's agreement with Merck regarding the EEA excluding the United Kingdom

7.3.1. The negotiation of the agreement

- (310) As Lundbeck explained to the Commission, *"Lundbeck initially concluded an agreement with Generics UK covering only the UK because Generics UK initially had marketing authorisation only in the UK."*⁶¹⁶
- (311) An internal Merck (GUK) document of 21 June 2000 indicated in the Commission's view that once GUK would have obtained a marketing authorisation for citalopram in the United Kingdom, which at that time it expected in February 2001 based on raw material supplies from VIS⁶¹⁷, it intended to use the mutual recognition procedure to submit applications in April 2001 for marketing authorisations in Germany, Spain, Austria, Sweden, Belgium, Finland, France, Denmark, the Netherlands, Ireland and Norway. In all these countries, Merck (GUK) expected to obtain marketing authorisation by December 2001. The same document mentioned that *"Iceland, Luxemburg, Italy and Greece are also interested."*⁶¹⁸
- (312) An internal Merck (GUK) e-mail of 19 March 2001 also shows that Merck (GUK) was planning for market entry into other EEA Contracting Parties than the United Kingdom, partly via the Swedish generic supplier NM Pharma: *"The registration strategy of UK, Sw and France allows each of these 7 months to get a licence, prior to patent off."*⁶¹⁹
- (313) On 15 May 2001, as already explained, Merck (GUK) concluded a Development and Supply Agreement regarding citalopram with Schweizerhall based on Natco's citalopram. Merck (GUK) contractually committed itself to file for marketing

⁶¹⁴ ID 673, pages 515 to 519.

⁶¹⁵ ID 660, page 8, ID 823, page 49.

⁶¹⁶ ID 823, page 51.

⁶¹⁷ As described in recital (177) above, Merck (GUK) suffered a loss of about ten months in obtaining United Kingdom marketing authorisation due to Lundbeck's withdrawal of VIS' Drug Master File. Merck (GUK) re-submitted the application, now with Natco as raw material supplier, to the United Kingdom Medicines Control Agency on 14 June 2001.

⁶¹⁸ ID 673, page 23.

⁶¹⁹ ID 675, page 2.

authorisations in Germany, France, Finland, Norway, Sweden, Belgium, Netherlands, Spain and Italy. For further details see recital (234) above.

- (314) An internal Merck (GUK) e-mail of 12 June 2001 shows that Merck (GUK) was co-operating with the Swedish company NM Pharma to sell the citalopram Merck (GUK) would buy from Natco in Sweden.⁶²⁰
- (315) On 14 June 2001, Merck's German subsidiary Merck dura concluded a supply agreement for citalopram with Tiefenbacher for sales in the German market.⁶²¹
- (316) A Merck (GUK) e-mail of 21 June 2001 stated the following:
- "With respect to the filing of the Citalopram dossier in Sweden in the name of NM Pharma at this time we perceive the following potential interaction with Lundbeck:*
- There is a very high risk that Lundbeck will issue a threatening letter (100%), if for no other reason than to gain more information about our product.*
- There is also a high risk (75%) that they will sue us on the grounds of process or quality or both.*
- Purchase of VIS allowed them to publicly question quality with the Health Authority.*
- If we are sued we perceive there will be a low risk (15%) of being injuncted based on the fact that we clearly follow the synthetic process as disclosed in the basic patent.*
- If we are injuncted we believe we have a high potential of winning (90%).*
- The whole process will involve lawyers, expert witnesses and Merck Generics extend their full support, co-operation, and experience in fighting any litigious action brought about by Lundbeck."*⁶²²
- (317) On 12 October Merck (GUK)'s [employee function]* wrote to Schweizerhall, Aceto and Natco:
- "...it is now time to move forward in readiness for the legal action from Lundbeck. This will vary in some markets from having documentation ready for when they try to injunct us, through the use of protective writs. There is the potential to prepare for UK, Sweden, France and Germany. In order to do this we need to provide certain documentation to our lawyers which they will ask us from time to time."*⁶²³
- (318) An internal Merck (GUK) e-mail of 3 January 2002 indicates that the national Swedish submission for marketing authorisation was made on 21 August 2001 and the French on 20 September 2001.⁶²⁴
- (319) An internal Lundbeck e-mail of 13 February 2002 indicates that Lundbeck had become aware that the Swedish company NM Pharma expected a marketing authorisation in Sweden, based on Natco material from Merck (GUK).⁶²⁵ Moreover, NM Pharma had a strong distribution network in Norway.⁶²⁶ Around this time,

⁶²⁰ ID 673, page 143.

⁶²¹ ID 1267, page 15. See also ID 1272.

⁶²² ID 675, page 6. With respect to Merck (GUK)'s awareness of a possible infringement risk posed by the crystallisation patent, see recital (113) and footnote 454 above.

⁶²³ ID 1997, page 2.

⁶²⁴ ID 675, page 17.

⁶²⁵ ID 723, page 66.

⁶²⁶ ID 681, page 130.

Merck (GUK) was in fact shipping Natco citalopram to the Merck subsidiary⁶²⁷ Gerard Laboratories in Ireland. Some of this material was destined for sale in Sweden, Norway, Denmark and Finland.⁶²⁸ An e-mail from Gerard to Merck (GUK) of 6 February 2002 states in this respect: *"Sweden to launch in March, Norway, Denmark and Finland 3 months later."*⁶²⁹

- (320) In reply to the Statement of Objections, Merck KGaA argued that the injunction proceedings against Tiefenbacher in the United Kingdom and elsewhere lead Merck (GUK) to believe *"the risk of injunction to be similarly high"*. In support, Merck KGaA quoted the following e-mail of 18 February 2002: *"the obvious outcome we would like is that all get injuncted and this then spreads into Europe in some way...Swedish license is on the way and MR is in process...the only problem being that we have the usual long lead time before day zero is set..."*⁶³⁰ However, if anything, this e-mail shows that Merck (GUK) saw a unique opportunity for launching its own generic with limited competition, if generic companies relying on the Tiefenbacher file were to be injuncted throughout Europe.⁶³¹ While Merck (GUK) observed that Lundbeck litigated against other generic companies across Europe, it also quoted an e-mail showing that Merck (GUK)'s case differed from those litigated by Lundbeck in Sweden: *"We also have to bear in mind that for our product Lundbeck is searching for a specific intermediate which we do not have because we changed to the other basic process. So they cannot use the same arguments as they used first time against Ratiopharm and Biochemie."*⁶³² Nevertheless, the litigation, in Merck KGaA's view, showed legal uncertainty in the market.⁶³³ Merck KGaA submitted that *"[g]iven Lundbeck's all-out-attack on several European fronts", "on the one hand, [Merck (GUK) ...] prepared for generic launch at risk and widespread litigation; on the other hand, it began discussions with Lundbeck. This dual strategy was also the result of increasing uncertainty."*⁶³⁴
- (321) For the e-mail of 25 February 2002 exchanged between Merck dura and Merck (GUK) see recital (280) above.

⁶²⁷ ID 1509, page 3.

⁶²⁸ ID 673, pages 275-276, 318, 322. Probably all of this material was to be distributed in these countries by the Swedish company NM Pharma. See recital (326) below.

⁶²⁹ ID 673, page 318.

⁶³⁰ ID 1021, page 2; ID 5960, page 87.

⁶³¹ See ID 1021, page 29 and ID 673, page 439 and recital (293) above.

⁶³² ID 5960, pages 83-111; ID 1021, page 31 (e-mail of 9 August 2002 related to Sweden). Pointing to certain proceedings in the Netherlands (ID 5960, page 88), Merck KGaA claimed that the Statement of Objections did not sufficiently acknowledge the risk that national court proceedings might have been suspended until completion of EPO opposition proceedings. A similar argument was made by GUK in reply to the Statement of Objections in particular with respect to Germany (ID 6026, pages 54-55). The Commission notes that it is clear that the suspension of proceedings in view of EPO opposition proceedings in a Member State is only one of many possible steps that may be considered by a court.

⁶³³ In relation to "uncertainty", Merck KGaA pointed to the patent law doctrine of equivalents. According to Merck KGaA, this doctrine requires that *"the meaning of the invention"*, that is to say not just the wording, is considered to determine any possible infringement. The doctrine therefore potentially extends the scope of the patent beyond its literal interpretation. See ID 5960, pages 25, 89-90, 206-211, 290, 300 and 303.

⁶³⁴ ID 5960, page 88.

- (322) An internal Merck (GUK) e-mail of 7 March 2002 mentioned Natco product destined for *"Europe, initially Sweden/France."*⁶³⁵
- (323) On 29 April 2002 Merck Generics' Swedish subsidiary reported to Merck (GUK) that Lundbeck had obtained approval of its crystallisation patent in Sweden and had sent a letter to Swedish pharmacies announcing actions against companies which Lundbeck considered involved in an infringement of this patent. Lundbeck's letter referred to Ratiopharm and Biochemie, which *"have been informed about the patent application but have chosen to market their copies of Cipramil"*.⁶³⁶
- (324) The first mention of a possible agreement between Lundbeck and Merck (GUK) regarding the EEA (excluding the United Kingdom for which an agreement already existed) was made in an internal Merck (GUK) e-mail of 1 May 2002: *"I understand...you are starting to talk of a pan-Euro deal with Lundbeck."* The e-mail also mentioned the need to think about *"compensating"* Aceto (Natco's exclusive sales agent).⁶³⁷
- (325) On 3 May 2002, NM Pharma received a national marketing authorisation in Sweden for Natco citalopram from Merck (GUK).⁶³⁸ Sales by NM Pharma in Sweden started on 21 May 2002 and were *"very encouraging"*.⁶³⁹
- (326) In a contact with Lundbeck, on or shortly prior to 28 May 2002⁶⁴⁰, Merck (GUK) informed Lundbeck that NM Pharma had launched the Natco product on the Swedish market⁶⁴¹ and that NM Pharma would use the mutual recognition procedure to obtain additional marketing authorisations in Finland, Norway, Denmark, the Netherlands, Belgium and Spain. Merck (GUK) further said that on 6 June 2002, Merck (GUK) would start a mutual recognition procedure based on its own United Kingdom marketing authorisation for *"the remaining countries"* Ireland, France, Germany, Austria, Italy, Portugal and Greece. Merck (GUK) also told Lundbeck [incorrectly] that it held *"exclusive rights for Natco"*.⁶⁴² According to Lundbeck's report, Merck (GUK) had said: *"The UK deal has been very beneficial for Lundbeck."* Lundbeck reported that Merck (GUK) was *"interested in a new deal."* Lundbeck replied in

⁶³⁵ ID 673, page 339.

⁶³⁶ The reaction from Merck (GUK) was: *"I'd just like to remind everybody we have already in our possession a signed expert report...about our process. The conclusion is that it is not infringing. Notwithstanding this we have also arguments against the Lundbeck 'position' if needed."* ID 673, pages 347-348. See also ID 1024, page 79, ID 675, page 36 and ID 1021, page 7 (where Merck (GUK) mentioned that it expected a warning letter from Lundbeck as a result of NM Pharma's citalopram approval in Sweden).

In relation to this expert report, in reply to the Statement of Objections, GUK clarified that GUK had commissioned the Expert Report at the end of 2001. *"[The expert ...] advised only on whether the Natco process fell within the scope of the original compound patent GB1526331 or the EP patent 0171943 which protects Lundbeck's cyanophthalide processes as set out above. His conclusion is that the Natco process follows the process as set out in the original compound patent. However, his Expert Report does not assess potential infringement of patents other than the two patents GB1526331 and EP 0171943 and its conclusions are therefore limited accordingly."* See ID 6026, pages 34-35.

⁶³⁷ ID 673, page 350; see also page 352. Aceto was mentioned here in the United Kingdom context, not the EEA context.

⁶³⁸ ID 847, page 31.

⁶³⁹ ID 1022, page 4.

⁶⁴⁰ ID 907, page 167.

⁶⁴¹ See also ID 848, page 38.

⁶⁴² See recital (235) above.

these negotiations that it believed Natco was infringing and that it would be forced to start legal action in Sweden very soon. Lundbeck then asked for a "*valuation of a deal*" for:

- "*Sweden 12 months*
- "*UK 6 months extension*
- "*Remaining EU 12 months.*"

(327) In an internal e-mail to other Merck Generics subsidiaries in Europe, Merck (GUK) wrote on 28 May 2002: "*We are currently in discussion with Lundbeck regarding the best strategy for Europe for Citalopram. In order to progress these discussions we URGENTLY need an annual forecast from you.*"⁶⁴³

(328) Internal Merck (GUK) sales forecasts of Natco citalopram in Europe, dated 5 June 2002, show that Merck (GUK), partly via NM Pharma and partly via other Merck Generics subsidiaries, intended to sell in:

- Austria (as of January 2003)⁶⁴⁴;
- Denmark (as of March 2003);
- Finland (as of May 2003);
- France (as of June 2002);
- Germany (as of December 2002);
- Ireland (as of February 2003);
- Italy (as of January 2004);
- Netherlands (as of December 2002);
- Spain (as of May 2003); and
- Sweden (as of May 2002).

The amount of sales estimated for one year of sales after market entry was EUR 21 million, of which almost EUR 14 million was profit.⁶⁴⁵

(329) On 6 June 2002, Lundbeck sent to Merck (GUK) a draft of an agreement for the EEA excluding the United Kingdom. The draft mentioned that Merck (GUK) was the exclusive supplier of Natco in this territory. The draft proposed that Lundbeck would pay EUR 7.5 million to Merck (GUK) "*in consideration of the settlement arrived at.*"⁶⁴⁶

(330) In an internal e-mail of 6 June 2002, a Merck (GUK) employee clarified:

"...it must be understood that we do not have an exclusive supply agreement with Natco. We have an exclusive agreement as far as purchase price is concerned but if we did not agree to purchase at the proposed Natco price they can go elsewhere so clause 3 page 2 [of the draft EEA agreement under negotiation with Lundbeck,

⁶⁴³ ID 675, page 34.

⁶⁴⁴ In fact, Lundbeck enjoyed patent protection in Austria until April 2003, see recital (111) above.

⁶⁴⁵ ID 675, pages 38 to 44.

⁶⁴⁶ ID 682, pages 181 to 186.

talking about Merck (GUK) being exclusive supplier for Natco; this is actually clause 4 on page 2 of the draft agreement – the word "exclusive" was deleted in the final agreement] *is not accurate...unless we get an agreement for Lundbeck to effectively purchase (or be compensated enough by Lundbeck to allow us to purchase) all the forecasted RM [raw material] from Natco for this 1 year.*

I also feel the value in the contract is far too low and should be probably 3 times higher (plus RM [raw material]). If Merck and Natco are Lundbeck's worst nightmare they can afford to pay more for the advantage they get. Our patent position is strong and Lundbeck have so far not responded in the UK to our letters etc. This must bode well and make it extremely difficult for any future attempts by Lundbeck to get an injunction in UK.

*I also presume that if we do sign any agreement at a fair price there will be no attempt at 'circumventing it' although that it seems to be possible with the contract as it stands."*⁶⁴⁷

- (331) The reaction of a second Merck (GUK) employee on the same day to this e-mail was:

On the lack of an exclusive supply agreement with Natco:

"NB point...and Lundbeck need to understand this and the implications..."

On compensation for Natco and the settlement amount:

*"...bear in mind that there are two ways to look at this....(a) we are settling because we are fearful that we may not prevail in the courts...in which case Natco would not sell any material anyway...and at least in any injunction period. I know you may feel strongly about winning this...but these things can go either way. (b) If we are going to make something out of this, [even tho we would not be on all Eu markets in any event...it is logical to 'look after' Natco...and clearly the preference would be to pass this cost on to Lundbeck as far as is possible. If we cannot do this fully (or at all)...we will need [for goodwill purposes as much as for anything else] to do it out of the settlement compensation."*⁶⁴⁸

- (332) In an e-mail to Lundbeck of 10 June 2002, Merck (GUK) wrote with respect to the draft agreement:

"We clearly will require further input from you in relation to our raw material commitments. We have just over 2,000 kgs in stock or in transit for launch requirements at US\$5,500 per kg. The future of this material needs to be agreed. Ideally, Lundbeck should purchase this from MGG [Merck Generics Group].

*NM Pharma in Sweden market our product but on their licence. Their profit projections are €3mio for the period under discussion."*⁶⁴⁹

- (333) On 18 June 2002, Merck (GUK) sent an e-mail to Lundbeck with the following content:

"Original 7.5 for MGG [Merck Generics Group] stands

Additional 2.5 for NM [NM Pharma]

⁶⁴⁷ ID 673, page 365. For a possible meaning of the "circumventing" aspect, see recital (351) below.

⁶⁴⁸ ID 673, page 374.

⁶⁴⁹ ID 682, page 190.

API +/- US\$5"⁶⁵⁰

- (334) An exchange of internal Merck (GUK) e-mails of 19 June 2002 related to "French citalopram" raised a problem in France:

"According with a patent problem on the active ingredient, citalopram dossier is blocked at the French authorities. The dossier was assessed, he received a favourable informal agreement, but the formal agreement is delayed according with the decision on the patent."

A Merck (GUK) manager replied:

"The basic compound and SPC in France has expired. Our product [...] so we do not have a patent problem at all."⁶⁵¹ Please can you explain the situation to [...] Merck employees] because they are defending this allegation from the brandleader.

Please can you explain what the issues are relating to the patents. We even have expert statements available about our process. We are selling in Sweden and the brand has not injuncted us yet."⁶⁵²

- (335) An internal Lundbeck document of 20 June 2002 stated:

"Deal with Merck Generics has been turned down because they doubled the price – we will now pursue NM Pharma in court and try to make a deal with NM Pharma at the same time."⁶⁵³

- (336) An e-mail of Pharmacia (NM Pharma's owner) to Merck (GUK) dated 26 June 2002 informed:

"No WC semifinal for none of us but we all have a mutual winner in Citalopram.

I have just received some additional sales figures for Citalopram Sweden, which is encouraging.

In May the AIP turnover was 86 tEUR, the figures for June until today is 312 tEUR.

Not only that, GEA the last competitor to Citalopram for the moment on the Swedish market has withdraw[n] theirs product. They have probable received a 40 pages greeting from Lundbeck."⁶⁵⁴

- (337) An internal Lundbeck "generic citalopram update" of 28 June 2002 mentioned that "NM Pharma received a national Swedish registration 3 May based on Natco and Merck Generics" and that Merck (GUK) "Has also filed a national French

⁶⁵⁰ ID 683, page 1.

⁶⁵¹ GUK claimed confidentiality for the text in square brackets. ID 673, page 124 compared "Natco's proposed synthetic process" against the processes claimed in Lundbeck's compound patent and concluded that it infringed those processes as long as the compound patent was not yet expired.

⁶⁵² ID 675, page 63. With respect to the "expert statements" to which this document refers, in its reply to the Letter of Facts (ID 6812, page 11), GUK claimed that the same reservations may apply as for ID 673, pages 347-348 (see footnote 636 above). However, ID 675, page 63 speaks about "statements", apparently several expert opinions. In any case, on 24 October 2002, Merck (GUK) internally concluded again: "we still don't infringe...including the crystalline base patent." See recital (357) below. For further details with respect to Merck (GUK)'s patent assessments, see recital (754) below.

⁶⁵³ ID 846, page 36. An internal Merck (GUK) e-mail of 19 June 2002 confirms that at this point in time negotiations broke down. See ID 673, page 384.

⁶⁵⁴ ID 1021, page 13.

application."⁶⁵⁵ This document expected launch dates for Natco material distributed via Merck (GUK) in June 2002 in France, August 2002 in Austria, October 2002 in Germany, the Netherlands, Spain and Ireland, November 2002 in Belgium, December 2002 in Denmark, March 2003 in Finland and October 2003 in Italy.⁶⁵⁶ On the envisaged agreement with Merck (GUK), the document explained:

"- Agreed price € 7.5M

- Suddenly, the price tag doubled to € 15M

€7.5M + €2.5M (NM) + €5M (Natco)

- No thank you."⁶⁵⁷

The same document explained that, following the break-down in negotiations with Merck (GUK), *"26 June [2002] we submitted data re Natco impurities to MCA [the United Kingdom Medicines Control Agency] and we allowed MCA (at their request) to disclose the data to Merck Generics. Our aim is to try to delay the MRP [mutual recognition process] and to question the UK license."*⁶⁵⁸

- (338) On 11 July 2002, an internal Merck (GUK) e-mail stated: *"... we are waiting and preparing for Lundbeck to attack us around the world"* and inquired about invalidity arguments.⁶⁵⁹ At the same time, Merck (GUK) internally considered: *"we need to discuss the status of some of the more material cases across the group to assess criteria for: (a) Initiating action [as opposed to responding] (b) Continuing or settling disputes. You will note that some of the legal fees are significant and we therefore need to look at the ROI of this and what actions are needed to manage and to reduce these amounts if they cannot be avoided altogether."*⁶⁶⁰
- (339) An internal Lundbeck document of 20 August 2002 indicates that Lundbeck intended to invoke its crystallisation patent against Natco citalopram sold by NM Pharma in Sweden as soon as the EPO would have granted it (which occurred on 4 September 2002).⁶⁶¹
- (340) An e-mail exchange of 26 August 2002 between Recordati, Lundbeck's co-marketing partner for Lundbeck-produced citalopram in Italy, indicates that Merck (GUK) had lodged an application for a marketing authorisation in Italy under the mutual recognition process, based on its United Kingdom marketing authorisation. Recordati inquired after Lundbeck's intentions and stated: *"There is no need to stress the business at risk."*⁶⁶²
- (341) In an internal Lundbeck e-mail of 29 August 2002, Lundbeck reported to its subsidiary in Ireland on a contact that had just taken place with Merck (GUK): *"They*

⁶⁵⁵ ID 848, page 37.

⁶⁵⁶ ID 848, page 38.

⁶⁵⁷ ID 848, page 39.

⁶⁵⁸ ID 848, page 40. Lundbeck undertook a similar approach to the Italian medicines evaluation body in September 2002. See ID 681, pages 119 to 123 and 141 to 143 and ID 356, pages 69 to 72.

⁶⁵⁹ ID 1021, page 27.

⁶⁶⁰ ID 675, page 66.

⁶⁶¹ ID 816, page 100.

⁶⁶² ID 903, page 142. See also Recordati's e-mail of 2 September 2002: *"We do not have too much time."* See ID 681, page 118.

[Merck (GUK)] say that the MRP [mutual recognition procedure] is finalised on 4 November 2002 and that they expect to launch [in Ireland] in March 2003."⁶⁶³

(342) On 4 September 2002, the EPO granted Lundbeck's crystallisation patent, which covered a purification manufacturing process.⁶⁶⁴

(343) An internal Lundbeck "generic citalopram update" of 4 September 2002 stated:

"Merck Generics and Natco

- *MRP [mutual recognition procedure] for IRL, GER, I, B, LUX, B & POR will have day 90 on 4 Nov 2002*
- *It is expected that NM Pharma has a similar MRP for FIN, N, DK, NL & ESP with day 90 in Oct or Nov 2002*
- *Generic Natco citalopram is expected to hit the market in Q1 2003.*"⁶⁶⁵

(344) A Lundbeck Business Development document with the title "Generic citalopram update 04 09 2002", stated the following:

"Natco

[...]

- *Merck Generics is based on Natco and is on the market in Sweden*
- *Potential problems with impurity levels*
- *Possibly crystallising and infringing*
- *We are building a case against them*

[...]

Sweden – NM Pharma

- *NM Pharma does not want to talk to us*
- *Email from ...Pharmacia (owners of NM Pharma):*

*"Thanks for inviting us to a meeting but no thanks, we have nothing to discuss. Under our Global Standards of Business Conduct and our Antitrust Policy, we cannot engage in further discussion on this topic."*⁶⁶⁶

(345) On 9 and 10 October 2002, an exchange of Merck (GUK) e-mails discussed the issue of existing stocks (API and tablets) and orders of API in relation to the proposed deal with Lundbeck.⁶⁶⁷

Regarding the proposed deal with Lundbeck, considering the internal evaluation of API on stock and on order, Merck (GUK) concluded:

⁶⁶³ ID 723, page 3.

⁶⁶⁴ See recital (113) above.

⁶⁶⁵ ID 904, page 278.

⁶⁶⁶ ID 904, pages 255 and 303. One month later, in October 2002, Lundbeck made an agreement with NM Pharma's supplier of generic citalopram Merck (GUK) that Merck (GUK) would stop supplying NM Pharma. See section 7.3 above.

⁶⁶⁷ ID 673, pages 386-389.

"We have an "agreed offer" on the table at the moment which substantially offers us a "bird-in-the-hand" situation which I feel gives us a strong result even taking the below into account.

I have already put Alpha on hold [...]

*The deal is for 12 months which means that, depending on a possible further lucrative extension, we could start manufacture again mid-2003 and use up most of the existin[g raw material]."*⁶⁶⁸ (Highlighting added)

Merck (GUK) did not expect any problems with extending the shelf life of the citalopram raw material, as the product was considered stable.⁶⁶⁹

With respect to existing stocks and orders, the e-mail exchange listed in total US\$ 9,234,000 worth of API, of which around 20 per cent was "on hand" and around 80 per cent "on order" (half of which related to Alpha). However, these numbers were apparently not finalised: *"As things stand now, we have this supplier gearing up for 3000 kilos for 2003... and looking at the above numbers, I am struggling to see where the 3000 comes from [although accept that no monthly figures are in for Europe...]"*.⁶⁷⁰

Regarding "manufactured tablets", the e-mail commented: *"...we either sell them – or find a place to sell – or its a cost..."*. Concerning orders, the e-mail concluded: *"Where orders are in for manufacture [...] your call as to whether these are put on hold now, or later ..."*.⁶⁷¹

The same e-mail asked whether USD 1 million was enough to compensate Natco, which was confirmed as probably being sufficient given that there were *"many options for the discussion with Natco."*⁶⁷² As part of the e-mail exchange, Merck (GUK) considered that *"The supplier will need some explaining [and probably something more tangible] if they are to understand any serious reductions to our forecast – which will be needed as the lower orders are made – or are delayed/cancelled."*⁶⁷³

- (346) In an e-mail of 11 October 2002, Lundbeck confirmed to Merck (GUK): *"OK to the 12 mill euro."*⁶⁷⁴ The settlement amount having thus been agreed, the two parties exchanged a number of drafts of a full-fledged agreement in the following days. At this time, as of 7 October 2002, in anticipation of the conclusion of an agreement

⁶⁶⁸ ID 673, page 387. A similar content has a different Merck (GUK) e-mail of 9 October 2002 commenting on the "deal": *"which means re-scheduling production mid-2003."* See ID 1021, page 35.

⁶⁶⁹ ID 673, page 386. With respect to tablets, the e-mail exchange considered: *"The shelf life of a finished product only starts from the time of manufacturing of the tablets."*

⁶⁷⁰ It should be noted that moreover, the numbers in that e-mail do not appear to add up, because under "1.", the e-mail listed "API on hand at Alpha": 397 Kgs and "API on order by Alpha": 575 Kgs, whereas the summary just counted these latter 575 kgs. Moreover, some figures had unresolved comments such as, for instance, API allocated to "Alpha": *"most of these are 'reject' status – which I understand Alpha has to resolve with the supplier [otherwise a very expensive write-off is coming up]"*. See ID 673, page 388.

⁶⁷¹ ID 673, page 388.

⁶⁷² ID 673, page 386.

⁶⁷³ ID 673, page 389.

⁶⁷⁴ ID 903, page 129.

with Lundbeck, Merck (GUK) stopped making deliveries of Natco material to NM Pharma.⁶⁷⁵

- (347) By the time Merck (GUK) and Lundbeck entered into an agreement for the EEA excluding the United Kingdom on 22 October 2002, Merck (GUK) had obtained one marketing authorisation for generic citalopram based on Natco's Drug Master File in the territory covered by the agreement, namely in Sweden (3 May 2002).⁶⁷⁶ After concluding the agreement with Lundbeck, and during its operation, Merck (GUK) obtained further marketing authorisations based on Natco's Drug Master File in Austria (10 December 2002), Belgium (16 December 2002), Norway (17 January 2003), Denmark (26 February 2003), Luxembourg (26 February 2003), Germany (29 April 2003), Finland (16 May 2003), Portugal (17 May 2003), Ireland (3 June 2003) and France (30 September 2003).⁶⁷⁷

7.3.2. *The agreement*

- (348) On 22 October 2002, H. Lundbeck A/S and Merck (GUK) concluded a "*Settlement Agreement*" for a year, covering the EEA excluding the United Kingdom.⁶⁷⁸

The preamble to the agreement stated that "*GUK is a supplier in the Territory of pharmaceutical products containing Citalopram manufactured by or on the basis of deliveries from Natco Ltd. ("Natco").*" (preamble, Point D). The preamble also stated that Lundbeck had performed laboratory analyses of Merck (GUK)'s citalopram and believed that Natco's production method to produce Merck (GUK)'s citalopram infringed Lundbeck's patents or patent applications in different European countries, as listed in appendix A to the agreement. (Point F) This appendix listed the different national equivalents of Lundbeck's crystallisation patent "*(the validity of which is not admitted by GUK)*". The preamble then continued by saying that "*GUK has disputed that the production method used by Natco Ltd. and/or GUK infringes Lundbeck's intellectual property rights*" but that "*Lundbeck and GUK have arrived at a settlement in order to avoid costly and time-consuming patent litigation, the outcome of which cannot be predicted with absolute certainty.*" (Points G and H) At the time of conclusion of the agreement, no litigation was taking place between Lundbeck and Merck (GUK) anywhere in the territory covered by the agreement.

In Article 1.1 of the agreement, Merck (GUK) agreed that, "*subject to payment of the Settlement Amount*", it "*shall cease the sale and supply of pharmaceutical products containing Citalopram in the Territory to its Affiliates and/or to any third party (including, without limitation, ceasing to sell and supply NM Pharma AB) during the term of this Agreement and shall use all reasonable efforts to ensure that Natco ceases to supply Citalopram and products containing Citalopram in the Territory for the term of this Agreement.*"

"*Affiliates*" should be understood to mean other companies in the Merck Generics Group.⁶⁷⁹ An appendix B listed all the citalopram sales Merck (GUK) had made

⁶⁷⁵ ID 683, pages 60 and 62. See also ID 675, pages 84 to 89 and 90 to 97.

⁶⁷⁶ On 18 April 2002, Merck dura obtained a marketing authorisation in Germany. However, this marketing authorisation was based on Tiefenbacher's Drug Master File (using Matrix and Cipla as API suppliers), not on Natco's Drug Master File. See ID 1273 and ID 1267, page 23.

⁶⁷⁷ ID 1273.

⁶⁷⁸ ID 8, pages 227 to 233.

⁶⁷⁹ See the definition of "Affiliate" in Article 1.1 of the agreement.

between 1 January 2002 and 17 October 2002 in the territory (the EEA excluding the United Kingdom). All sales listed had been to NM Pharma in Sweden. Article 1.1 further confirmed that:

"GUK and GUK's Affiliates have made no further sales of products containing Citalopram since 1 October 2002 in the Territory."

Article 1.2 of the agreement stated:

"In consideration of the settlement arrived at between the parties hereto Lundbeck shall pay to GUK EURO 12 million (the "Settlement Amount")...". Three million euro was to be paid immediately and the remainder in monthly instalments until the expiry of the agreement. The article ended with the following provision:

"Notwithstanding the foregoing, it is expressly understood and agreed that Lundbeck shall not be required to make any payment pursuant to this Article 1.2 which has not yet fallen due in the event that Natco supplies Citalopram or products containing Citalopram in the Territory during the term of this Agreement."

Article 1.5 of the agreement stated:

"The parties will during the term of this Agreement use all reasonable efforts to seek to resolve their disagreement of the issues set out in the Recitals."

Article 4 provided: *"...upon the effective date of termination of this Agreement for whatever reason, any party shall be entitled to exercise and prosecute any intellectual property rights owned by or licensed to such party as such party sees fit."*⁶⁸⁰

- (349) In the light of their wording, the provisions in Article 1.1 and 1.2 appear to have had a dual purpose for Lundbeck: Firstly, Merck (GUK) committed itself not to sell any citalopram in the EEA excluding the United Kingdom, including to group companies and third party suppliers, from whatever supplier the citalopram came. Secondly, Lundbeck would only continue paying the settlement amount as long as the API supplier Natco refrained from selling in the territory, to whatever buyer, whether within or outside of the Merck Generics Group of companies.⁶⁸¹ Lundbeck therefore

⁶⁸⁰ In reply to the Statement of Objections, Merck KGaA argued that Article 4 of the EEA agreement was only a standard formality. See ID 5960, page 155. Moreover, Merck KGaA went so far as to claim that *"the fact that Lundbeck allowed GUK to prepare the launch immediately after expiry of the EEA Agreement even indicates that Lundbeck had objectively and implicitly waived its right to assert its patent rights against GUK post expiry"*. (ID 5960, pages 301 and 310) GUK argued that Article 1.5 *"was intended to protect GUK against litigation from Lundbeck upon expiration of the Settlement Agreements"*. (ID 6026, page 25) The Commission notes that Article 1.5 coexists with Article 4. The latter determines that no party waives any of its intellectual property rights, in particular also not any right to request interim injunctions. In fact, to avoid any misunderstanding Article 4 explicitly reserves each parties' right to prosecute any patent right *"upon the effective date of termination of this Agreement"*. GUK's and Merck KGaA's argument is therefore in plain contradiction to the wording of Article 4 of the agreement. In this respect, Lundbeck clarified that the agreements *"did not finally resolve the disputes"* (see recital (80) above). Moreover, Merck (GUK) internally stated at the time for the (rest of the) EEA: *"[I]f and when the time comes to discontinue the agreement we will be ready to defend our rights."* (See recital (355) below; Merck (GUK) made a similar statement for the United Kingdom: see recital (288) above.) This shows that Article 4 in the EEA agreement was not just a formality, did not *"protect GUK against litigation"* and that Merck (GUK) knew very well that the agreements did not resolve its patent dispute with Lundbeck.

⁶⁸¹ Lundbeck later explained to the Commission that it believed *"that Generics UK had an exclusive agreement with Natco and therefore, to Lundbeck's knowledge, [Natco] could not deliver citalopram in*

aimed for the agreement to have effect both towards Merck (GUK) and (indirectly) towards Natco.

- (350) With respect to the settlement amount, one may observe that the amount of EUR 12 million agreed with Lundbeck comes very close to the profit projections Merck (GUK) had prepared on 6 May 2002 for one year of sales of Natco citalopram after market entry in the EEA.⁶⁸² Those projections had shown close to EUR 14 million of profit for Merck (GUK). However, from this amount should be deducted sales that would start only after the agreement with Lundbeck had ended, such as in Italy where sales would not start before January 2004. Italy accounts for almost EUR 2.5 million of profit. It would therefore seem that the settlement amount of EUR 12 million was based on the estimated profits Merck (GUK) could have made in the EEA in the year covered by the agreement if Merck (GUK) had entered the market.⁶⁸³
- (351) The 'circumventing' loophole in the agreement Merck (GUK) referred to internally earlier⁶⁸⁴ might be that Article 1.1 imposed the obligation to cease the sale and supply of pharmaceutical products containing citalopram only on Merck (GUK), including, in the final agreement, "to" affiliated companies within the Merck

API form to any other company." See ID 823, page 57. In Lundbeck's view this should influence the interpretation of Article 1.1 of the agreement, see ID 5394, pages 159-160. However, as indicated in recitals (330) and (331), based on a draft of the EEA agreement of 6 June 2002 which said that "*Natco Ltd. has appointed Merck as exclusive distributor in the Territory...*" (see ID 673, page 368), Merck (GUK) had taken the view that Lundbeck needed to understand that Merck(GUK) did not have an exclusive supply agreement with Natco and the implications thereof. The agreement actually concluded only mentions that "*GUK is a distributor in the Territory...*" of Natco (see ID 8, page 228). This implies that Merck (GUK) informed Lundbeck that it was not the exclusive distributor for Natco in the EEA before Lundbeck concluded the agreement with Merck (GUK) related to the EEA (excluding the United Kingdom). This also explains why the agreement as actually concluded contained the wording in Article 1.1 that Merck (GUK) "*shall use all reasonable efforts to ensure that Natco ceases to supply Citalopram and products containing Citalopram in the Territory for the term of this Agreement*" and the wording in Article 1.2 that "*Lundbeck shall not be required to make any payment pursuant to this Article 1.2 which has not yet fallen due in the event that Natco supplies Citalopram or products containing Citalopram in the Territory during the term of this Agreement*", neither of which was part of the draft agreement of 6 June 2002 and which would have been superfluous if Merck (GUK) had been the exclusive distributor of Natco in the EEA (see ID 673, pages 367 to 372). Finally, this observation is consistent with the purpose of Lundbeck's visit at Natco as described in recital (181) above. See also recitals (229)-(232) above. Regarding the interpretation of Article 1.1 see also section 12.3.5.2 below.

⁶⁸² See recitals (327) and (328) above. In reply to the Statement of Objections, Merck KGaA criticised the Commission's calculations claiming that "[t]he SO errs when deducing [...] 2.5 million Euro for Italy as the profit for Italy is clearly not included in forecasted profit of 14 million Euro". See ID 5960, page 318. However, contrary to Merck KGaA, ID 675, page 40, shows that in the overall profit calculation of € 14 million an amount of € 2.5 million was included for Italy (i.e € 1,544,000 for 20 mg and € 926,400 for 40 mg strength). The calculations are therefore correct.

Possibly in view of this claimed mistake, Merck KGaA explained that "*GUK expected to make profits of € 14 million, had there not been the litigation and market exclusion risk*". "*Litigation and market exclusion risk*" would therefore explain the reduction of the payment by € 2 million compared to the profit forecast of € 14 million. See ID 5960, page 315. The Commission notes that based on this explanation, the value that Lundbeck transferred to Merck (GUK) reflected also the exclusion value that was represented by avoidance of competition by Merck (GUK).

⁶⁸³ A draft of 6 June 2002 of the agreement has a settlement amount of EUR 7.5 million. See ID 675, page 49. This amount is comparable to Merck (GUK)'s estimated profit before May 2003 of EUR 6.4 million and Merck (GUK)'s alternative estimated profit, at an assumed market share of 15%, before May 2003 of EUR 7.3 million. See ID 675, pages 40 and 44 and ID 675, page 54.

⁶⁸⁴ See recital (330) above.

Generics Group, but not strictly speaking on Merck (GUK)'s affiliates themselves. The other companies within the Merck Generics Group were therefore, strictly speaking, free to sell citalopram, at least from other suppliers than Natco, in the EEA. This formulation may have been based on the fact that Merck (GUK) acted as the raw materials supplier for the entire Merck Generics Group. However, Merck (GUK) later stated to the Commission that other companies within Merck Generics were free to license themselves citalopram in finished dosage form.⁶⁸⁵ Merck dura, in particular, continued selling Tiefenbacher citalopram in Germany from 15 April 2002 throughout the period of Lundbeck's EEA agreement with Merck (GUK). In an e-mail of 7 November 2002, Merck dura wrote to Merck (GUK) that *"Merck dura ...had in 2001 two meetings with Lundbeck in Hamburg discussing cooperation opportunities in Hamburg. At the end, Lundbeck denied further negotiations as they believed to get the Es-Citalopram registration to escape generic competition. In the meantime we had several legal proceedings against Lundbeck concerning patent issues. By clever changing the raw material sources we could successfully keep our product in the market."*⁶⁸⁶

- (352) Natco does not appear to have sold its citalopram to any other suppliers in Europe during the period of the EEA agreement. In a letter to Merck Generics of 14 February 2003, Natco wrote: *"Other than MG, there is no other active licence of formulation with Natco as a source"* and *"After the unexpected shortcut of needs end of last year (forecast figures being decreased in 2 steps from 3.300 kg to 2.200 kg after 1.875 kg being supplied in 2002), there is tremendous uncertainty about when exactly the originally projected quantities will be picked up. This makes us extremely nervous, as you are our only customer."*⁶⁸⁷ In reply, the [employee function]* of Merck Generics wrote Natco a soothing letter, mentioning in passing Merck (GUK)'s two agreements with Lundbeck but not offering any damage compensation to Natco.⁶⁸⁸ It is noteworthy that that letter also announced Merck (GUK)'s intended "vigorous launch" in all European markets following the expiry of the agreements without considering any possibility that Lundbeck's patents, which would still be in

⁶⁸⁵ ID 1509, page 1.

⁶⁸⁶ The reference to *"changing the raw material source"* appears to refer to a change from Cipla to Matrix. Merck dura stated in infringement proceedings with Lundbeck in Germany that at the latest since 4 September 2002, Merck dura had been selling citalopram from Matrix only, produced in accordance with the Matrix II process. See ID 235, page 884. In the e-mail of 7 November 2002, it appears that a possible withdrawal of Merck dura from the German market as a result of the Merck (GUK) agreement with Lundbeck was discussed between Merck (GUK) and Merck dura. In the e-mail of 7 November 2002 from Merck dura to Merck (GUK), Merck dura wrote: *"Even if Merck dura would withdraw citadura from the market there remain 9 generic competitors still offering a generic version of citalopram. So I can't see the advantage for Lundbeck if only Merck dura leaves the market."* See ID 675, page 117. In the end, although challenged by Lundbeck on 16 September 2002 (ID 6814, page 81), Merck dura continued selling on the German market. See ID 677. This, however, does not allow the conclusion, as Lundbeck and GUK apparently considered in reply to the Statement of Objections (ID 5394, page 159; ID 6026, pages 16-17), that GUK was free to sell citalopram not sourced from Natco in the market, as this was prohibited by Article 1.1 of the agreement. Moreover, Merck (GUK) internally concluded that *"I also presume that if we do sign any agreement at a fair price there will be no attempt at circumventing it"* (see recital (330) above).

⁶⁸⁷ ID 673, page 490.

⁶⁸⁸ ID 673, pages 437 to 445. Merck (GUK) argued in this letter towards Natco that *"we considered the strategic option of being able to launch without fear of injunction in any jurisdiction in October 2003"* (page 440). See, however, also recitals (288) and (355).

force, could hinder such launch (*"We maintain the position we are non-infringing..."*⁶⁸⁹).

- (353) Contrary to the agreement for the United Kingdom, the EEA agreement did not provide for Merck (GUK) to distribute Lundbeck citalopram.

7.3.3. Events during the implementation of the agreement

- (354) On 22 October 2002, Merck (GUK) immediately informed NM Pharma of its withdrawal from the market: *"we have decided to temporarily withdraw the product from the Scandinavian market. We have come to this view only after careful consideration and on the basis that we cannot realistically at this stage undertake any legal action to defend our position. We also strongly advise NM not to sell any further Citalopram product and to return existing stocks [...] In the event that you do not return existing stocks, this notice serves to inform NM that we cannot indemnify you..."*⁶⁹⁰

- (355) On 23 October 2002, an internal Merck (GUK) e-mail explained Merck (GUK)'s rationale for the agreement with Lundbeck as follows:

"They (Lundbeck) hold up to 20 process patents on this molecule and they have made it quite clear through their past actions that they intend, whether they have a case or not to defend their product for as long as possible.

Lundbeck know that when they bought Vis that we started working with Natco and they have somehow managed to get hold of material that they can test. It is there [sic] contention that this material shows evidence through the impurity profile that it infringes one of their process patents. This is not the case as we know, but they don't, that the material is in fact produced by a route contained in patent that has now expired. However as with all these things one faces a choice. Science can be used to both support or pervert the course of justice and in a case like this Lundbeck can adopt delaying tactics which are both expensive, time consuming and frustrating to all involved (including the courts). We are 100% confident that our evidence will show that we do not infringe any of their IP [intellectual property] on this product but in order to do this we undoubtedly will have to take part in some long complex court cases which could delay us for some time to come with regard to full commercial exploitation of the product we now have approved.

As always we are happy to defend our rights in this case but we felt on balance that the collaboration with Lundbeck was the better option for the TIME BEING. The agreement allows us to obtain a return on our investment in this product and does not in any way compromise our ability to launch at a later date and take on any legal actions Lundbeck might care to engage in. All round given the short term nature of the agreement (12 months) we feel this is the option we should choose at this time.

*I would stress that in no way is this decision an admission of the validity of the argument that Lundbeck might try to use against us and if and when the time comes to discontinue the agreement we will be ready to defend our rights."*⁶⁹¹

⁶⁸⁹ ID 673, page 439.

⁶⁹⁰ ID 675, page 108. Concerning Merck (GUK)'s obligation to stop supplying citalopram to NM Pharma, see recital (348) above.

⁶⁹¹ ID 675, page 403.

- (356) On 23 October 2002, NM Pharma answered to Merck (GUK)'s letter of 22 October. *"you advise us not to sell any further Citalopram and return existing stock [...]. The reason for this is, according to your letter, that you 'cannot realistically at this stage undertake any legal action to defend [your] position'. We find this reason very vague and are reluctant to stop the marketing of Citalopram without additional information. We assume that there have been developments in the patent situation, and that new research carried out by you that have prompted your letter.*

We ask that you as soon as possible, in accordance with our agreement, provide us with a copy of this recent patent research and any other relevant information that will help us understand the shift in your position. In the absence of an explanation based on disclosed facts, we do not accept your abovementioned letter as releasing you from your obligation to indemnify us according to Article 12 C. of our agreement. For the time being, NM Pharma will continue to sell Citalopram and Merck Generics are under the agreement obliged to continue to supply us with the product.

*Please be informed that Lundbeck has not claimed that NM Pharma is infringing any patent rights, nor do we have knowledge of any request for a preliminary injunction or other legal action against NM Pharma."*⁶⁹²

Subsequent draft letters and letters illustrate that Merck (GUK) tried to provide a plausible explanation to NM Pharma (other than mentioning the EUR 12 million payment from Lundbeck) of why Merck (GUK) had decided to stop supplying NM Pharma with Natco citalopram tablets.

- (357) First, a draft Merck (GUK) letter of 24 October 2002, destined for NM Pharma is advising *"that it is our intention to withdraw the product from the Swedish market and that we will not be able to supply you with further stocks."*⁶⁹³ No mention is made of any compensation payment from Merck (GUK) to NM Pharma. The draft letter justified Merck (GUK)'s withdrawal from the market by the difficulty and expense of showing that Merck (GUK) did not infringe Lundbeck's patents. An internal reaction from Merck (GUK)'s [employee function]* to this draft stated:

"NM know the patent position; we've shown them our evidence and argued before to them directly that there are a large number of patents and that we still don't infringe...including the crystalline base patent.

*I've tried a different tac, but I am not going to admit that we were wrong in our assessment of the patent situation."*⁶⁹⁴

Another draft (without signature) dated 25 October 2002, which appears to have been sent in that form to NM Pharma⁶⁹⁵, stated: *"Lundbeck [...] have indicated through*

⁶⁹² ID 675, page 109. Internally, Merck (GUK) wondered the following day: *"any idea why it is that Lundbeck have not tried to sue?"* See ID 675, page 102.

⁶⁹³ ID 675, page 99.

⁶⁹⁴ ID 675, page 104. It appears from the exchange of e-mails that Merck (GUK)'s [employee function]* resisted draft language suggesting patent infringement problems. He was *"not going to admit we were wrong in our assessment of the patent situation."* This meant that he still believed Merck (GUK) was right in its assessment that *"we still don't infringe...including the crystalline patent."* See in particular also recital (355) above. In the end management decided to *"modify the whole thing to make it clear that this is a commercial decision..."* See ID 675, page 104, and also page 102.

recent actions that they intend vigorously to "defend" their product and their intellectual property in every way. [...] It is clear to us that [Lundbeck ...] intend[s] to try to use [...] tests [of samples] to show that Natco infringe their Intellectual Property on routes of synthesis in some way. We naturally disagree with such assertion, as in our view the process used comes from a patent which has expired, and which therefore cannot be claimed as one on which infringement can be based. However, we are also aware that they have been granted a number of patents, which claim some elements of the same process contained in the not expired patent. This in our view is incorrect as it must now be prior art; however, the European Patent Office does not seem to apply sufficient rigour to the examination to exclude this possibility and therefore the patents are granted and are, prima facie, legally valid. Lundbeck have the ability, resources and desire to sue under these patents [...]

As we have previously explained in some detail to you, we could fight any claims Lundbeck may make in this respect in Sweden. However, they are threatening us not just in Sweden, but in a pan-European wide manner and we therefore had to consider all our markets. [...] The cost in the UK alone for this type of work [injunction, experimentation in front of expert witnesses, legal action] has been over £400,000 per case. This, if translated throughout all European jurisdictions, would be prohibitively expensive especially if injunctions are granted.

In recent contact with Lundbeck we have been given an undertaking from them that we will, in good faith and without compromising our future position, undertake to try and clear all the IP issues as soon as we can. We expect to sort this out without resorting to expensive litigation. [...] Even if we are temporarily off the market, establishing a modus vivendi for the future must be the right way to proceed, especially since we know the alternative brings with it the certainty of significant and unnecessary costs. Even if we still end up disagreeing we will at least be significantly strengthening our position to ensure injunction could be granted against us in any of the European jurisdictions. Thus at least we should be able to derive income during any litigation period..."⁶⁹⁶

- (358) Second, a letter of 15 November 2002 from Merck (GUK) to NM Pharma persuaded NM Pharma to accept Merck (GUK)'s decision: *"suffice it to say that we have looked at the matter at some detail and concluded, as previously stated, that the risk of costly and damaging infringement proceedings from Lundbeck is significant. [...] to be perfectly honest, I think there is a real risk of our correspondence proving counterproductive if we get bogged down by the minutiae of the Agreement [between Merck (GUK) and NM Pharma]."*⁶⁹⁷
- (359) On 15 November 2002, Merck (GUK)'s counsel sent a letter to Lundbeck in relation to *"...the settlement agreements entered into [...] and in particular the recent agreement dated 22 October 2002..."*:

⁶⁹⁵ See ID 675 page 107. Given that the internal Merck (GUK) e-mail to which this letter was attached circulated *"...a trilogy of correspondence relating to our recent communication with NM on our withdrawal of the product Citalopram from the Swedish market"*, it is likely that this version of the letter was actually sent.

⁶⁹⁶ ID 675, pages 110-112.

⁶⁹⁷ ID 675, page 120.

"As noted [...] Lundbeck has made laboratory analyses of Citalopram products made by our clients and believe the production method used infringes the patents set out in Appendix A to the Agreement. Our clients have disputed that the production method used infringes Lundbeck's intellectual property rights.

*Pursuant to Article 1.5 of the Agreement, our clients seek to resolve the issues between them and Lundbeck. There seems to be no merit in delaying attempts to assess and resolve the issues. Please let us know what evidence Lundbeck has that leads it to believe our clients' product or production methods infringe the patents set out in Appendix A so that our clients may consider this".*⁶⁹⁸

- (360) A Lundbeck management report of 2 December 2002 stated that Lundbeck expected the agreement with Merck (GUK) to have the greatest impact on the Swedish market.⁶⁹⁹
- (361) On 14 January 2003, Merck (GUK) informed the Austrian Merck Generics subsidiary that it could not use the marketing authorisation it had just been granted (based on Natco material) until October 2003. The Austrian subsidiary had been planning to enter the market in April 2003.⁷⁰⁰
- (362) A letter of 21 February 2003 from Merck Generics to Natco indicated that by this date Merck (GUK) had, directly or through NM Pharma, obtained marketing authorisations and had completed all internal issues such as pricing in Ireland, Sweden and the United Kingdom: *"Licences gained and marketable"*. Because of delays in obtaining marketing approvals, Merck expected to be in the same situation by the end of June 2003 in Austria, Belgium, Denmark, Finland, Germany, Italy, Luxemburg, Norway and Portugal and before the end of 2003 in France, the Netherlands and Spain. Tables attached to the letter *"show two things: only three markets have generic competition (Sweden, Netherlands and Germany) and only 2536 kilograms have been sold which includes Natco, Matrix, Max, Sumika, Ranbaxy and Fermion material as all those companies are presenting non-infringing material in the market place..."* The letter mentions the fact that Merck concluded agreements with Lundbeck for the United Kingdom and the EEA, but does not mention any compensation payment from Merck to Natco. With respect to the EEA agreement, Merck Generics wrote: *"At the end of October last a further agreement was made with Lundbeck to say that we could not launch for a year and that we would both use this time to resolve any patent issues between us. Strategically we looked at the timings of our licence approval, the cost of litigation in each country (up to £500,000 per jurisdiction) the downside being injuncted for an unspecified period (i.e. at the mercy of court time and the wranglings of lawyers) and the fact that the only market fully genericised was Germany."*⁷⁰¹
- (363) The internal e-mail of Merck (GUK) of 11 March 2003 quoted in recital (294) above summarised the profit Merck (GUK) realised from the agreement relating to the EEA (excluding the United Kingdom) *"Total": "Eur" "12,000"*.⁷⁰²

⁶⁹⁸ ID 2012, page 2.

⁶⁹⁹ ID 816, page 234.

⁷⁰⁰ ID 675, page 126.

⁷⁰¹ ID 673, pages 437 to 445. See also recital (293) above and recital (367) below.

⁷⁰² ID 673, page 474.

- (364) In a fax of 18 July 2003, Merck (GUK)'s [employee function]* wrote to the French Merck Generics subsidiary:

"Lundbeck took samples of our product as they impounded it in Germany more than 18 months ago and they received samples of the finished dosage in UK in January 2002.

As a result of a court case in the UK; GSK vs Generics UK for Paroxetine a legal precedent was set such that a generic manufacturer was required to prove they did not infringe the intellectual property rights of the originator. Applying this rule Merck Generics wrote to Lundbeck on a number of occasions seeking clarification of any infringement specifically for Citalopram.

*It was subsequently agreed between the parties [Lundbeck and Merck (GUK)] that they would work together in good faith and explore the possibility of infringement of Intellectual Property rights. From the samples received by Lundbeck and the data they have on our process, they have not questioned our ability to produce the product by a lapsed basic process and they have not questioned the quality of the product they have tested. Therefore we feel that summarising the details of the discussions should at least demonstrate that in good faith Merck Generics Group has respected the Intellectual Property Rights of Lundbeck in developing and producing a high quality generic pharmaceutical."*⁷⁰³

- (365) An internal Merck (GUK) e-mail of 10 August 2003 mentioned: *"Our European deal with Lundbeck ends on 23rd October – they are pressuring us to re-new."*⁷⁰⁴

- (366) An internal Lundbeck document entitled "Generic update citalopram & escitalopram" of 16 September 2003 stated with respect to Merck in France:

"- Our European deal terminates by 22 Oct

....

- We suggested that Merck stays out [of France] for up to six months against payment

*- They are not interested – the opportunity costs are too high – they will be the first generic entrant in F."*⁷⁰⁵

- (367) On 1 October 2003, Merck (GUK) informed the French Merck Generics subsidiary that it could not sell generic citalopram in France until after expiry of Merck (GUK)'s agreement with Lundbeck in October 2003: *"BUT Most importantly, we have an agreement with Lundbeck not to sell in Europe until sometime around the end of October this year... We agreed not to sell citalopram in our EU markets for 1 year (this was agreed October/November 2002) because of the potential for litigation and the uncertainty of outcome for both parties. As part of the agreement the parties agreed to look into the patent issues. This patent (or its equivalents) [the crystallisation patent] was known about by both parties at the beginning of this agreement. We have written several times to Lundbeck asking for their views and in order to resolve the issue as per the agreement. We have not received a response*

⁷⁰³ ID 2009, page 3.

⁷⁰⁴ ID 2010, page 2.

⁷⁰⁵ ID 903, pages 24-25.

from them".⁷⁰⁶ In this context, Merck (GUK) advised its French subsidiary against now starting an invalidity action against Lundbeck's crystallisation patent. Instead, Merck (GUK) said: "...there is no reason to expect an injunction to be granted against you in France, provided you launch after the expiry of the agreement. If Lundbeck do threaten you it would be best to discuss these facts with them....I think then that any Lundbeck action will then cease."⁷⁰⁷

- (368) An internal Lundbeck document of 20 October 2003 reported that Merck Generics had launched generic citalopram in Belgium on 10 October 2003.⁷⁰⁸ Lundbeck assessed this action as a breach of its agreement with Merck (GUK).⁷⁰⁹ The same Lundbeck document of 20 October 2003 noted that Merck Genericos was the first company in Portugal to receive reimbursement on generic citalopram and was expected to launch late October or beginning November 2003. Finally, with respect to France, the same document remarked that on 30 September 2003, Merck Génériques had had two generic citalopram registrations approved and was expected to launch in January 2004.⁷¹⁰
- (369) The agreement expired on 22 October 2003.
- (370) In total, over the entire period of operation of the agreement from 22 October 2002 to 22 October 2003, Lundbeck transferred a value to Merck (GUK) of EUR 12 million under the agreement regarding the EEA excluding the United Kingdom.

7.3.4. Subsequent events

- (371) In November 2003, Lundbeck obtained in Belgium a seizure of Natco citalopram that Merck Generics Belgium had started selling there.⁷¹¹
- (372) When Merck started to re-sell citalopram products in the EEA excluding the United Kingdom after the expiry of the agreement with Lundbeck, Lundbeck did not initiate infringement litigation against it.⁷¹² In January 2004, Merck Génériques became the first company to sell generic versions of citalopram in France.⁷¹³

7.4. Lundbeck's agreement with Arrow regarding the United Kingdom

7.4.1. The negotiation of the agreement

- (373) The Arrow Group of companies began its business of developing and marketing generic medicines in the EEA in 2001. Already in a preparatory phase leading up to the start of business, Arrow had identified citalopram "*as a major product that it would market shortly after it began trading.*"⁷¹⁴ Within the Arrow group of

⁷⁰⁶ ID 2006, page 2 and ID 673, page 511.

⁷⁰⁷ ID 2006, page 2. Note the internal change of position resulting from the agreement compared to June 2002 (see recital (334) above).

⁷⁰⁸ ID 904, page 76.

⁷⁰⁹ ID 903, page 24. Such breach, however, did not mean that GUK considered itself no longer bound by the agreement as of 10 October 2003, as Lundbeck argued in reply to the Statement of Objections (see ID 5394, page 161), as shown by recital (367) above: "...we have an agreement with Lundbeck not to sell in Europe until sometime around the end of October this year... there is no reason to expect an injunction to be granted against you in France, provided you launch after the expiry of the agreement."

⁷¹⁰ ID 904, pages 76-77.

⁷¹¹ ID 903, page 97.

⁷¹² ID 823, page 55.

⁷¹³ ID 892, page 19.

⁷¹⁴ ID 610, page 5.

companies, the project to develop and launch generic citalopram medicine in EEA markets was led by the United Kingdom company Arrow Generics Limited.⁷¹⁵ Arrow's plan was to launch generic citalopram in the United Kingdom market immediately after expiry of Lundbeck's compound and basic process patent on 5 January 2002, still in the month of January 2002.⁷¹⁶ Following the withdrawal of VIS' Drug Master File by Lundbeck in October 2000, Resolution Chemicals Ltd, another Arrow subsidiary at that time, started its own project to develop generic citalopram API. Arrow recognised, however, that Resolution would not have marketable citalopram products ready by January 2002.

- (374) A first indication of contacts between Arrow and Lundbeck dates from 15 December 2000. In an internal e-mail, Lundbeck reported that Arrow did not want to discuss citalopram before Lundbeck had entered into an agreement with Arrow regarding a different product.⁷¹⁷
- (375) On 22 May 2001, Arrow Group A/S, the Danish parent company of Arrow Generics Limited, entered into a contract with the German company Alfred E. Tiefenbacher for the purchase of marketing authorisations from Tiefenbacher and the possible supply of generic citalopram by Tiefenbacher, the API originating from Cipla or Matrix.⁷¹⁸ At that time, Tiefenbacher's request for a marketing authorisation in the Netherlands, mentioning both Cipla and Matrix as suppliers, was nearing approval.⁷¹⁹ Dutch approval would then be followed by Tiefenbacher making requests for approval to other national authorities in the EEA under the mutual recognition procedure or, in the case of France, through a national procedure.⁷²⁰ Under the contract, Arrow bought copies of (future) marketing authorisations from Tiefenbacher for the Netherlands, United Kingdom, Denmark, Finland, Sweden and France. Under clause 6.1 of the agreement, Arrow had the option upon written notice from time to time to:
- purchase the medicinal products in bulk exclusively from Tiefenbacher for five years after launch in each Member State;
 - manufacture the medicinal products itself or through third parties with API purchased from Tiefenbacher (with a (lower) royalty percentage for Tiefenbacher); or
 - manufacture the medicinal products itself or through third parties with API sourced from an Arrow affiliate (with a higher royalty percentage for Tiefenbacher).⁷²¹

In reply to the Commission's request for information of 9 March 2011, Arrow interpreted this contract with Tiefenbacher as follows: *"The contract did not contain an exclusive purchasing obligation (and indeed no obligation to purchase, only an option to do so)...Arrow Group did discuss a possible supply agreement with*

⁷¹⁵ ID 610, page 5.

⁷¹⁶ ID 610, page 6.

⁷¹⁷ ID 681, page 148.

⁷¹⁸ ID 619, pages 1 to 8. See also ID 847, page 61 and ID 280, page 5. See also IDs 1630 to 1633.

⁷¹⁹ The Dutch marketing authorisation was granted in September 2001, see recital (176) above.

⁷²⁰ ID 619, page 3.

⁷²¹ See Article 6.1 of the agreement, ID 619, page 4.

*Tiefenbacher, but as far as it can ascertain this was never concluded.*⁷²² *Under the terms of the contract, Arrow Group was expressly permitted to supply products sourced from third parties, subject to payment of a royalty to Tiefenbacher if it did so [x]% of gross sales if Arrow Group manufactured its own tablets with Tiefenbacher's API (which would have been sourced from either Cipla or Matrix...), or [y]% of gross sales if it manufactured its own tablets with API from a third party...*⁷²³

- (376) Arrow stated to the Commission that *"Arrow Group agreed to purchase tablets from Tiefenbacher, who Arrow understands made the decision to source its API from Matrix (in addition to Cipla) after Lundbeck acquired VIS."*⁷²⁴ According to Tiefenbacher, for the products or API sourced from Tiefenbacher, Arrow was free to specify to Tiefenbacher whether the citalopram should come from Cipla or Matrix.⁷²⁵ This having been said, initially, at least until the moment when Arrow and Lundbeck concluded their agreement regarding the United Kingdom, the citalopram products supplied by Tiefenbacher came from Cipla.⁷²⁶
- (377) Arrow has stated to the Commission that by "mid 2001",⁷²⁷ it became aware of Lundbeck's application for a crystallisation patent. This corresponds to the date of publication of Lundbeck's United Kingdom patent application GB 2357762 on 4 July 2001.⁷²⁸
- (378) In its reply to the Statement of Objections, Lundbeck has informed the Commission that between July 2001 and January 2002, it performed several analyses of Cipla's citalopram.⁷²⁹ According to Lundbeck: *"The results of these tests were all consistent and indicated the presence of 5-Chloro and 5-Bromo impurities and the absence of 5-Acetyl impurity, which showed that Cipla used the Cyanation 2002-1 Process. The low level of 5-Chloro and 5-bromo impurities and the rate between these two*

⁷²² Clause 6.2 of the agreement of 22 May 2001 provided that Arrow and Tiefenbacher would sign a related Supply Agreement in the course of the duration of the current agreement. However, Arrow reported to the Commission that *"Arrow Group considered entering into a supply agreement with Tiefenbacher in Autumn 2002, but as far as it is aware this was not concluded as agreement could not be reached on its terms."* See ID 1297, page 24.

⁷²³ ID 1297, page 44. That Arrow believed itself free under the contract with Tiefenbacher to buy API from any API supplier is shown by a contemporaneous document of 11 January 2002, which stated that *"[Arrow] told us when we met that under [Arrow's] agreement with Tiefenbacher [Arrow] are free to buy from anyone paying a [y]% royalty."* See ID 625, page 2.

⁷²⁴ ID 1297, page 33.

⁷²⁵ In Tiefenbacher's words: *"The customers were absolutely free to choose the API source. Tiefenbacher had no preference in that case" and "Some companies initially using Cipla material were injuncted and re-entered the market successfully with Matrix API. At a later stage, all customers preferred Matrix for patent reasons."* See ID 1713, page 1. Arrow argued in its reply to the Statement of Objections that *"the Tiefenbacher Agreement makes no reference to Tiefenbacher having multiple sources of citalopram API" and that "Arrow did not have an option to choose between different API sources; this was a matter entirely for Tiefenbacher."* See ID 6082, pages 15 and 16 respectively. However, Arrow's marketing authorisation authorised both Cipla and Matrix as API suppliers (see recital (424) below) and the contract with Tiefenbacher did not exclude that Arrow would choose the API supplier. The Commission refers to Article 6.1 of the agreement between Lundbeck and Arrow. See ID 619.

⁷²⁶ Matrix stated in the United Kingdom Lagap litigation that it began supplying citalopram to the EEA in March 2002. Lundbeck has stated to the Commission that it first became aware of Matrix's citalopram being sold on a market in the EEA (Denmark) in June 2002. See recital (153) above. See also ID 5394, page 163.

⁷²⁷ ID 610, page 7.

⁷²⁸ See recital (113) above.

⁷²⁹ ID 5394, page 166.

demonstrated that the specific impurity level could only have been obtained through the Crystallization Process, in violation of the Crystallization Patent."⁷³⁰ In its reply to the Statement of Objections, Lundbeck also stated that between June 2001 and January 2002, it performed several analyses of Matrix's citalopram. According to Lundbeck, *"...the impurity profile could only have been obtained through the Crystallization Process..."*⁷³¹

- (379) On 10 September 2001, Arrow Generics Limited ordered DM 2.8 million worth of citalopram tablets from Tiefenbacher.⁷³² In respect of this order, Arrow stated in its reply to the Statement of Objections: *"Arrow simply ordered products from Tiefenbacher and did not specify a particular API source."*⁷³³ These tablets were produced by the Icelandic company Omega Pharma for Tiefenbacher, using API from Cipla.⁷³⁴ They were packaged and labelled by the German company Dragenopharm.⁷³⁵ A first shipment of these tablets was delivered to Arrow in November 2001 and a second shipment in the second week of January 2002. The total number of tablets (in strengths of 10, 20 and 40 mgs was 9 222 000.⁷³⁶ These tablets were apparently stored in Germany.⁷³⁷
- (380) An e-mail of Lundbeck's [employee function]* dated 6 November 2001 shows that Lundbeck had apparently obtained copies of parts of Cipla's DMF. A Cipla document giving a brief outline of the process used by Cipla stated: *"Crude citalopram base is crystallised to get pure citalopram base."*⁷³⁸ On or around the same date, Lundbeck also obtained a copy of Matrix's DMF, which stated that *"Citalopram base of batch No. RD006/0101 was crystallized twice in Iso propyl alcohol and Methanol and prepared Citalopram Hydrobromide by using aq.HBr in Isopropylalcohol."*⁷³⁹ According to Lundbeck, this DMF had served as the basis for the marketing authorisation granted in the Netherlands on August 31, 2002.⁷⁴⁰
- (381) On 15 November 2001, Tiefenbacher prepared an analysis of the patents and patent applications Lundbeck had mentioned in its general warning letter to API producers and to certain generic suppliers in January 2001.⁷⁴¹ For Lundbeck's crystallisation utility model in the Netherlands (NL 1016435), which had been granted on 6

⁷³⁰ ID 5394, pages 166-167 and page 222. It should be noted that in the Lagap litigation, Lundbeck initially made a similar argument that chloro and bromo impurities in Matrix's product necessarily had to mean that Matrix had used Lundbeck's crystallisation process. After the inspection of Matrix's process, however, Lundbeck withdrew this argument. Lagap's expert stated in that case that *"Some of [Lundbeck's allegations], in particular those concerning so called 'fingerprints' for purification methods, are highly flawed..."* See recitals (156), (158) and (160) above.

⁷³¹ ID 5394, pages 171-172.

⁷³² ID 620, page 2.

⁷³³ ID 6082, page 16.

⁷³⁴ ID 623, page 3.

⁷³⁵ ID 2024, page 1.

⁷³⁶ ID 622, page 2.

⁷³⁷ See the preamble of the United Kingdom agreement: *"Whereas ARROW has threatened to import into the UK the said Citalopram from Germany"*. See ID 8, page 235.

⁷³⁸ ID 5439, page 5. In its reply to the Statement of Objections, Lundbeck argued that this statement of Cipla confirmed *"beyond any reasonable doubt that the process used by Cipla infringed the Crystallization Patent."* For Cipla's analysis, see recital (510) below.

⁷³⁹ ID 5394, page 172. In its reply to the Statement of Objections, Lundbeck argued that this statement of Matrix *"showed, again, that Matrix's process infringed the Crystallization Patent."*

⁷⁴⁰ ID 5394, page 172.

⁷⁴¹ See recitals (148) and (225) above.

November 2000, and the corresponding application in the United Kingdom (GB2357762), Tiefenbacher concluded: *"Describes the production of high purity Citalopram through the crystallisation of the base. In principle not applicable, as in our processes the base is not crystallised, but the product is cleaned through re-crystallisation of the hydrobromide. But: in some writings, protection for the production of high purity citalopram (>99.8%) is filed for. Will be monitored."*⁷⁴²

- (382) On 14 December 2001, a meeting took place between Arrow and Tiefenbacher, in which the patent situation was discussed.⁷⁴³ Lundbeck's PCT patent application WO 01/68627 for the crystallisation process⁷⁴⁴ was identified as problematic for Cipla. According to Arrow's report:

"The material destined for the UK is from Cipla and is purer than the VIS material. The purity level is in excess of 99.8%... In purifying their material Cipla have said that they take an acidic solution of the citalopram base and neutralize using ammonia to precipitate the base which is then converted to the salt. This method, they claim, corresponds to that shown in a 1977 patent. Matrix on the other hand do not isolate the base in crystalline form but convert the base as an oil to the oxalate (twice) and then convert the oxalate to the hydrobromide.

*A patent has been filed by Lundbeck, WO 01/68627, to purified base in crystalline form as an intermediate in the production of the hydrobromide salt. This patent has yet to grant in the UK so could not be used for injunction purposes. Matrix have taken steps to ensure that they do not isolate the base in a pure form but Cipla do isolate the base. Cipla's base is of unknown purity but could infringe this patent when granted."*⁷⁴⁵ Cipla's defence is that they employ a method of purification as disclosed in a 1977 patent.

⁷⁴² ID 673, page 174, translation from German. The original German text uses the word "Umkristallisation", here translated as "re-crystallisation". Tiefenbacher sent this analysis to Merck dura, one of its other clients, but it is unclear whether Arrow also received it. See recital (248) above. That Arrow shared the view that Lundbeck's patent only applied to crystallisation of the base, and not to crystallisation of the hydrobromide salt is clear from an internal e-mail of 24 June 2002 in which Arrow explored whether citalopram produced by the Chinese API producer Zhejiang Huahai Pharmaceuticals would be infringing or not. Arrow observed, in this respect, *"Lundbeck have been suing everyone in the EU on a patent which claims purification of the base by crystallization. From the flow sheet Huahai do not give any details on whether the base is crystallized or kept in solution and converted to the hydrobromide salt and crystallized. They do refer to the hydrobromide salt as "crude" which suggests that they purify the salt rather than the base. If this is the case then the process is non-infringing."* ID 641, page 2, quoted in recital (422) below.

⁷⁴³ ID 623, pages 3-4.

⁷⁴⁴ See recitals (149) and (151) above. It is recalled that this patent application included several claims for the crystalline base of citalopram as such.

⁷⁴⁵ The references in this meeting report (ID 623, pages 3-4) to Lundbeck's application for a patent *"to purified base in crystalline form as an intermediate"* and to *"Cipla's base is of unknown purity but could infringe this patent when granted"* imply that participants were, at this time, foremost concerned with possible infringement by Cipla of the product claims in Lundbeck's patent application WO 01/68627. As mentioned in recital (151) above, Lundbeck's product claims on the crystalline base of citalopram were later found by the EPO and the Dutch Industrial Property Office to lack novelty and therefore invalid. The United Kingdom crystallisation patent GB 2357762, however, was granted including these product claims (as well including claims regarding pharmaceutical formulations). This meant that the United Kingdom patent was on the one hand more likely to be infringed than without these claims, but on the other hand also more likely to be found at least partially invalid.

*A second patent filed by Lundbeck, WO 01/47877, claims a method of film distillation for purification of the salt form. Neither Matrix nor Cipla employ this method.*⁷⁴⁶

In view of the fact that Lundbeck will undoubtedly move for an injunction it seems best to prepare a defence position now in order to try and void such an injunction.

*The product bound for the UK employs Cipla raw material. Unfortunately, Cipla are not forthcoming with the actual detail on the process they use. This requires to be shored up if we wish to claim non-infringement. We could strike a deal with Cipla whereby the process could be shown to the court "in secret" without us seeing the detail. We will need this at least to avoid an injunction. Matrix are much more open with the detail of their process but presumably we cannot switch at this stage."*⁷⁴⁷

*Arrow's cover email to this report stated that "[an Arrow employee] has been through the issues surrounding purification of the base and Cipla and [sic] Matrix seem to be OK."*⁷⁴⁸

- (383) On 21 December 2001, Arrow purchased from Tiefenbacher a request for marketing authorisation Tiefenbacher had lodged earlier in the United Kingdom.⁷⁴⁹
- (384) On 27 December 2001 the United Kingdom Medicines Control Agency issued a positive opinion on Arrow's request for a marketing authorisation in the United Kingdom.⁷⁵⁰ However, as Arrow was to find out, because this request was based on a Tiefenbacher registration file and Lundbeck had opposed Tiefenbacher's file in the Netherlands⁷⁵¹, the United Kingdom Medicines Control Agency was not prepared to issue the United Kingdom marketing authorisation until Lundbeck's opposition in the Netherlands had been resolved. Arrow's United Kingdom marketing authorisation was in fact issued only in July 2002, after Lundbeck had lost its appeal in the Netherlands, more than six months later than expected by Arrow.⁷⁵² Based on the documents in the case file, it was only on 27 February 2002 that Arrow inquired with the United Kingdom Medicines Control Agency why the marketing authorisation had not been issued yet.⁷⁵³

⁷⁴⁶ Patent application WO 01/47877 corresponded to United Kingdom patent GB 2356199: Production of citalopram in pure form, by cyanide exchange; the film distillation patent. This United Kingdom patent, mentioned in Arrow's agreement with Lundbeck for the United Kingdom (see recital (393) below), was revoked by the United Kingdom Patent Office on 23 June 2004, the reason being that it covered the same invention as European Patent (UK) EP 1181272, with the same priority date. This action was not contested by Lundbeck. See ID 651, pages 2 to 5. In its reply to the Statement of Objections, Lundbeck stated with respect to the film distillation patent: "*Lundbeck, however, subsequently renounced enforcing that patent because it lent itself to invalidity claims and, most importantly, because Lundbeck had realized that it was possible for generic companies to design around the Film Distillation Patent...*". See ID 5394, page 162.

⁷⁴⁷ ID 623, pages 3-4.

⁷⁴⁸ ID 623, page 2.

⁷⁴⁹ ID 610, page 6, ID 1325, page 10.

⁷⁵⁰ ID 610, page 6, ID 636, page 2, ID 846, page 168.

⁷⁵¹ See recital (168) above.

⁷⁵² ID 642, page 2.

⁷⁵³ ID 610, page 6 and ID 636, page 2. [employee name]* declared in a statement prepared for the Commission, in reply to the Statement of Objections, that "*I was not aware of all the technical issues relating to the marketing authorisation but Arrow's management team was well aware that it had not been granted and that there were concerns of delays to the marketing authorisation being granted. We were aware of this prior to the settlement discussions with Lundbeck. My recollection is that the delay*

- (385) An e-mail of 11 January 2002 from Cipla's United Kingdom agent⁷⁵⁴ to Arrow reported that Cipla was "...supporting Tiefenbacher against Lundbeck. Apparently, Tiefenbacher's first registration was in Holland and it is against them that they are filing a claim, which Cipla are supporting Tiefenbacher in. As there are several other Indian producers of Citalopram, all of whom are infringing, [Cipla] is not willing to make available [its] process to other third parties, as you told us when we met that under your agreement with Tiefenbacher you are free to buy from anyone paying a [y]% royalty."⁷⁵⁵
- (386) An e-mail of 11 January 2002 from an American wholesaler acting on behalf of Ranbaxy to Arrow stated:
- "As discussed at the end of last year, we have forwarded to London...the Certificate of Analysis of the following APIs:*
- ...
- Citalopram*
- ...
- All are produced by Ranbaxy. May I also ask you if you could be available between Jan 21 and 23 for a meeting...?"*⁷⁵⁶
- (387) An e-mail of 15 January 2002 of Cipla's United Kingdom agent to Arrow stated:
- "I have had a further chat with [Cipla] and he in turn has talked to Tiefenbacher. Apparently, he would like you to talk to him as he is quite happy to defend you in court and will make the necessary information available to the appropriate authorities."*⁷⁵⁷
- (388) On 18 January 2002, Lundbeck's lawyers wrote to two Queen's Counsels in the United Kingdom to retain their services to "prepare for and appear in an application for an interim injunction" against Alpharma, Tiefenbacher, Omega and Arrow.⁷⁵⁸
- (389) On 21 January 2002, Lundbeck wrote to Arrow referring to a meeting with Arrow on 14 January 2002, in which Arrow had informed Lundbeck that it would in the very near future offer for sale in the United Kingdom a citalopram hydrobromide product from Tiefenbacher. There is no indication that Arrow identified the product as coming from Cipla.⁷⁵⁹ Lundbeck warned Arrow that Lundbeck believed Arrow's product would infringe two Lundbeck process patents in the United Kingdom: GB 2356199: Process for the preparation of pure citalopram, by cyanide exchange (the film distillation patent), granted on 3 October 2001, and GB 2357762: Crystalline

was due to proceedings brought by Lundbeck against the grant of the marketing authorisation for citalopram in The Netherlands. The UK authority were relying on the marketing authorisation in The Netherlands and as a result of the challenge in The Netherlands, we were aware in January 2002 that the grant of marketing authorisations in the UK would also be delayed." Nevertheless, "...Arrow still hoped to obtain a marketing authorisation within a reasonable period." See ID 6070, pages 6-7.

⁷⁵⁴ ID 670, page 5.

⁷⁵⁵ ID 625, page 2.

⁷⁵⁶ ID 624, page 2.

⁷⁵⁷ ID 626, page 2.

⁷⁵⁸ ID 5477.

⁷⁵⁹ As Tiefenbacher's marketing authorisation in the Netherlands covered both Cipla and Matrix as suppliers, Arrow's citalopram could in principle have come from either of them.

base of citalopram, to be granted on 30 January 2002.⁷⁶⁰ Lundbeck threatened to start infringement proceedings failing a satisfactory undertaking by Arrow not to infringe such patents.⁷⁶¹ Arrow wrote back on 22 January 2002 saying: *"We were alerted to these patents as a result of your action against the Dutch Health Authorities. We have looked at these in some detail and do not believe that we infringe these patents."* Arrow invited Lundbeck *"before you commence proceedings, if that is your intention" to "meet to discuss your allegations in more detail."*⁷⁶²

- (390) On 23 January 2002, Arrow's subsidiary Resolution Chemicals wrote in an e-mail to the company Neulands, a potential second citalopram API supplier, with respect to citalopram: *"We launch in UK next week and we are keen to qualify Neulands as a 2nd source."*⁷⁶³
- (391) In January 2002, Lundbeck expected Arrow imminently to become the first company to launch generic citalopram from Tiefenbacher in the United Kingdom.⁷⁶⁴ Lundbeck was unaware that through its administrative and legal proceedings against Tiefenbacher's marketing authorisation in the Netherlands, it was successful in considerably delaying the granting of Arrow's marketing authorisation in the United Kingdom, which was based on the Tiefenbacher file.⁷⁶⁵ Until as late as 8 February 2002, Lundbeck appears also to have been in doubt whether Arrow's citalopram came from Matrix or Cipla.⁷⁶⁶

7.4.2. The agreement

- (392) On 24 January 2002, the same day as Lundbeck's United Kingdom agreement with Merck (GUK), H. Lundbeck A/S concluded an agreement with Arrow Generics Limited and Resolution Chemicals Ltd (Arrow's API producer in the United Kingdom).⁷⁶⁷ The agreement covered the United Kingdom. Its term was *"from the date of signature until a final unappealable, enforceable UK-court decision has been rendered or until 31 December 2002, whichever event occurs first."*⁷⁶⁸ Arrow entered into the agreement *"on behalf of other members of its group of companies."*⁷⁶⁹

⁷⁶⁰ With respect to Lundbeck's patent application GB 2357762, the crystallisation patent, Lundbeck specifically mentioned in the letter to Arrow claims 1 and 12 to 16. It may be recalled that claim 1 of the corresponding patent at the EPO level was later deleted from the amended claims which were eventually upheld by the EPO in 2009. See recital (166) above. It may also be noted that claims 12 to 16 covered product claims and pharmaceutical composition claims. As mentioned in recital (151) above, Lundbeck's product claims on the crystalline base of citalopram as well as its claims regarding pharmaceutical compositions were later found by the EPO and the Dutch Industrial Property Office to lack novelty and therefore to be invalid.

With respect to Lundbeck's patent GB 2345199 (the film distillation patent), Lundbeck stated in the reply to the Statement of Objections that Lundbeck *"realized that it was possible for generic companies to design around the Film Distillation Patent"* and *"renounced enforcing that patent because it lent itself to invalidity claims."* See ID 5394, page 162.

⁷⁶¹ ID 627, pages 2-3.

⁷⁶² ID 628, page 2.

⁷⁶³ ID 1294, page 1.

⁷⁶⁴ ID 846, page 168. See also ID 823, page 20.

⁷⁶⁵ See recital (168) above. See also ID 904, page 182. Arrow received its United Kingdom marketing authorisation only on 26 July 2002.

⁷⁶⁶ ID 850, page 102. See also ID 8, page 198. See also recital (411) below.

⁷⁶⁷ ID 8, pages 234 to 240.

⁷⁶⁸ Article 4.1, ID 8, page 239.

⁷⁶⁹ ID 8, page 235.

(393) The preamble to the agreement stated:

"Whereas ARROW has obtained a licence from a third party to import into the UK Citalopram not manufactured by Lundbeck or with the consent of Lundbeck ("the said Citalopram", which definition shall for the avoidance of doubt comprise only Citalopram for marketing and sale in the UK and shall exclude Citalopram for marketing and sale in other countries)."

The preamble continued by stating that Lundbeck had performed a laboratory analysis of Arrow's citalopram and that Lundbeck believed that the importation by Arrow of the bulk citalopram in question violated Lundbeck's patent rights, in particular its patents GB 2357762 (preparation of crystalline base or salts of citalopram – the crystallisation patent), GB 2356199 (process for the preparation of pure citalopram, by cyanide exchange - the film distillation patent)⁷⁷⁰ and EP(GB) 171943 (novel intermediate and method for its preparation - the diol patent).⁷⁷¹ It then stated:

"Whereas ARROW does not consider that it infringes the Proprietary Rights and/or consider that the Proprietary Rights are valid or enforceable but accepts that Lundbeck has a reasonable belief that the Proprietary Rights may be valid and infringed and ARROW does not at present have any demonstrable incontrovertible evidence otherwise.

Whereas Lundbeck has threatened interim injunction proceedings and intends to pursue the alleged infringement in the Patents Court of the English High Court..."

(394) In Article 1.1 of the agreement *"ARROW on its own behalf and on behalf of all associated and related entities undertakes during the term of this Agreement...not in the UK to make, dispose of, offer to dispose of, use or, after the Second Delivery Date... import or keep for disposal or otherwise (1) the said Citalopram or (2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale pending a final unappealable decision in the Infringement Litigation..."*. Arrow later confirmed to the Commission that *"The Lundbeck Agreements cover citalopram in any form, including both as an API and a medicine."*⁷⁷² Arrow also agreed for the term of the agreement not to transfer, license or otherwise deal in any United Kingdom marketing authorisations relating to any such citalopram. In Article 1.2 Arrow agreed to give these undertakings to the court by way of a formal court order if requested to do so by Lundbeck.

⁷⁷⁰ Arrow reported to the Commission that this patent GB 2356199 was revoked by the United Kingdom Patent Office on 23 June 2004 because it had been granted for the same invention as EP patent 1181272 (which was granted on 28 August 2002). See ID 610 page 25 and ID 651.

⁷⁷¹ This last patent was granted in 1988. This patent covered the so-called diol process, which Lundbeck used itself to produce citalopram in this period. This patent expired in 2005. In its reply to the Commission's request for information of 19 March 2010, Arrow stated in respect of this patent: *"Although Lundbeck would ultimately assert its granted EP (GB) 171943 patent against Arrow, Arrow was aware of this patent but it was not a primary concern as Arrow believed that it was possible to manufacture around the intermediate that this patent claimed."* See ID 610, page 6.

⁷⁷² ID 610, page 25.

With respect to the words *"any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights"*, Arrow later explained to the Commission that *"The test established by Article 1.1 of the Agreement is a subjective test of alleged infringement, not actual infringement. Therefore, citalopram products that have not been found by a court to be non-infringing but do not actually infringe Lundbeck's patents could have been within the scope of Article 1.1, but that is entirely usual in agreements of this nature."*⁷⁷³

Article 1(1) implied that for the duration of the agreement Arrow not only committed itself not to import or sell any citalopram which Lundbeck alleged to be infringing, but also not to manufacture citalopram itself, through its subsidiary Resolution Chemicals, at least not if Lundbeck alleged such citalopram to be infringing.

- (395) Article 1.2 of the agreement stated that *"ARROW agrees during the Term to give the above undertakings to the Court by way of a formal Court Order if requested to do so by Lundbeck during the course of the Infringement Litigation."*
- (396) Article 2.1 stated that Lundbeck would commence legal infringement proceedings on the merits as soon as possible *"with the aim to establish whether ARROW has, is or would infringe Lundbeck's Proprietary Rights...Proceedings will be instigated in the Patents Court in the UK as soon as possible...The parties shall use their best endeavours to have the case on the merits set down for a speedy trial, if so requested by either of the parties."*
- (397) Article 2.2 stated:
- "In consideration of the undertakings in clause 1.1 and ARROW not seeking a cross-undertaking in damages in respect of the period comprising the Term, Lundbeck shall provide ARROW with a total of five million pounds sterling (GBP 5 million)."* This money was to be paid in four instalments covering the entire term of the agreement, the first payment being scheduled to take place seven days after the first delivery of Arrow stock to Lundbeck (which was to take place before 6 February 2002).⁷⁷⁴
- (398) Arrow later explained to the Commission that the amount of GBP 5 million represented *"a broad estimate of what Arrow would have received under a cross undertaking in damages in the event that the Lundbeck Process Patents were not infringed and/or were found to be invalid."*⁷⁷⁵ Another way of saying this is that the amount of GBP 5 million represented the amount of profit Arrow estimated it could have earned in the period concerned if it had successfully entered the United Kingdom market with its own generic product. In other words, by not selling Arrow now received a similar amount of money as it could have earned by selling in the market, but without any of the inherent commercial and litigation risks.
- (399) It is to be noted that the agreement did not contain any provision that if Lundbeck won the main proceedings on infringement, Arrow would have to pay back to Lundbeck part or the entirety of the money Lundbeck had paid to Arrow it up front.

⁷⁷³ ID 610, page 28.

⁷⁷⁴ In fact, the actual payments were later linked by Lundbeck to Arrow receiving a marketing authorisation and made in five instalments, see recital (412) below.

⁷⁷⁵ ID 610, page 8. See also ID 610, pages 28-29.

Arrow was therefore given the certainty by Lundbeck that in accepting the agreement it could keep the money, irrespective of any result of litigation on infringement.

(400) Article 2.3 stated:

"In the event that the final unappealable, enforceable UK-court decision in the Infringement Litigation rules that ARROW does not or has not infringed Lundbeck's Proprietary Rights the compensation granted by Lundbeck in accordance with clause 2.2 shall constitute full and final compensation from Lundbeck."

This also indicates that the amount of compensation was set based on Arrow's expected profits in the United Kingdom in the period concerned if it had successfully sold generic citalopram.

(401) Article 3 provided that Arrow would give 5 million tablets of the said citalopram in escrow to Lundbeck, as security. This stock was to be returned to Arrow if the final unappealable United Kingdom court decision ruled in favour of Arrow or upon the expiry of the agreement whichever event occurred first.

(402) In its explanations to the Commission, Arrow tried to justify entering into the agreement by saying that the concern that Cipla might be infringing Lundbeck's patents, *"placed Arrow, which was still a relatively newly-formed start-up company, in a commercially intolerable position: it had devoted considerable resources to its citalopram project and was now at serious risk of incurring very substantial costs in patent litigation and of being enjoined by Lundbeck..., thereby jeopardising the investment it had already made in trying to commercialise its citalopram product for the UK market... In these circumstances...Arrow sought to protect its position as best as it could, by reaching an agreement with Lundbeck on the best possible commercial terms it could secure."*⁷⁷⁶

7.4.3. Events during the implementation and extension of the agreement

(403) On 25 January 2002 Lundbeck lodged a claim form for infringement by Arrow of United Kingdom Patent GB 2356199 (the film distillation patent) in the United Kingdom High Court of Justice, Chancery Division, Patents Court, indicating that the *"Particulars of Claim will follow in due course"*.⁷⁷⁷

(404) On 25 January 2002, a Friday, at 13.09 hours, [employee name]*'s sent an e-mail to Tiefenbacher stating:

*"[Arrow employee] told me about the conversation she had with you last Tuesday [22 January 2002]. She said that you suggested that Cipla raw material possibly does infringe Lundbeck's patents, although you were not sure either way. You asked [Arrow employee] to check the patent. [Tiefenbacher employee], understand that we need to know how exactly Cipla produces the product. It does not help to look in patents in isolation. How are we going to defend ourselves? Please understand that there is much more at stake than just the UK. Please let me know what the position is with Cipla (who incidentally have refused to give us any information, claiming only that they do not infringe and will only deal with you) and what your plans are for defending the position."*⁷⁷⁸

⁷⁷⁶ ID 610, page 8.

⁷⁷⁷ ID 630, pages 1 to 4.

⁷⁷⁸ ID 631, page 5.

- (405) On the same day, at 13.13 hours, Arrow received an e-mail from Cipla's United Kingdom agent reporting about a contact with Cipla as follows:

"Since our meeting, I have discussed the matter once more with [Cipla]. He tells me that Tiefenbacher is well aware of Lundbeck's warning to issue an injunction against them and they are prepared and equipped to defend all those that they have sold licences to such as ...yourselves. [Cipla] was very surprised that Tiefenbacher was unable to help you when you asked for it.

I do not know where the truth lies in all of this. Whether Tiefenbacher is being awkward or whether [Cipla] has not given him the information. This I don't know.

*Anyway, I can confirm that [Cipla] is not willing to divulge the information to Arrow and that we have approached him as Cipla's UK agent for the supply of Cipla raw material."*⁷⁷⁹

- (406) On 28 January 2002, [employee name]* sent an e-mail to Tiefenbacher stating:

*"Thank you for your call of today and your e-mail reply. I note that you have no information from Cipla on the final purification steps that Lundbeck claims in their patents. Cipla have told us that they will only work through you (not directly with us). So, we are stuck! [Tiefenbacher employee] has just confirmed with [Arrow employee] that he is very nervous about the pending Lundbeck patents. Clearly you have not done your homework....We need specific answers – Do we infringe?"*⁷⁸⁰

Tiefenbacher's reply of the same day stated:

*"As you know Lundbeck is still publishing a lot of patents and nobody can give guarantees. We are currently checking the situation regarding one patent...It's not even clear whether the application came through or not and – if so – which claims came through or not. All I can say for today is that there is a certain likelihood that we have to react."*⁷⁸¹

- (407) On 29 January 2002, [employee name]* wrote to Tiefenbacher:

*"Cipla are refusing to talk to us, claiming that they will only give you [Tiefenbacher] the evidence and moreover, they are telling us, through their UK agent, that they have given you all the required information. We are going to be enjoined any day now. We have no ammunition other than to say to the court that we accept that we may be infringing. We do not know and we are unable to independently check the patent."*⁷⁸²

- (408) On 30 January 2002, as Lundbeck had already announced⁷⁸³, Lundbeck's United Kingdom crystallisation patent GB 2357762 was granted.⁷⁸⁴ Lundbeck did not, however, initiate infringement proceedings against Arrow on the basis of this patent, nor on that of the third patent mentioned in the agreement, EP(GB) 171943 (novel

⁷⁷⁹ ID 629, page 2.

⁷⁸⁰ ID 631, page 4.

⁷⁸¹ ID 631, page 3.

⁷⁸² ID 631, page 2. In the e-mail exchange with Tiefenbacher, Arrow made no mention of the agreement it had just concluded with Lundbeck.

⁷⁸³ See recital (389) above.

⁷⁸⁴ ID 723, page 19.

intermediate and method for its preparation; the diol patent).⁷⁸⁵ These patents were, however, mentioned in the consent orders with Arrow of 6 February 2002 and 30 January 2003.⁷⁸⁶

- (409) On 6 February 2002, a Master of the High Court of Justice, Chancery Division, Patents Court, granted at the request of the parties an order that Arrow be restrained from importing or selling "(1) *Citalopram not manufactured by Lundbeck or with the consent of Lundbeck* or (2) *any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights (including patent rights to inventions of Citalopram and to processes relating to the manufacture thereof, including but not limited to in particular GB patents no 2 357 762, 2 356 199 and EP(GB) 171943)* and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale..." "until a final unappealable, enforceable UK-court decision in this matter has been rendered or until 31 December 2002, which ever shall first occur." The Master also ruled that "This Court makes no further order on this application..."⁷⁸⁷ The text of this order had been drafted by the parties themselves (with minor amendments by the Master).⁷⁸⁸
- (410) With respect to the main proceedings, which in Article 2.1 of their agreement the parties had indicated they would pursue to find out whether Arrow infringed, it appears that in reaction to Lundbeck's initiation of the infringement proceeding⁷⁸⁹, Arrow had the intention by 21 February 2002 to claim the invalidity of the patent in suit (GB 2356199 – the so-called film distillation patent).⁷⁹⁰ However, from that moment on, neither Lundbeck's infringement claim nor Arrow's invalidity counter-claim was pursued further.⁷⁹¹ Arrow explained to the Commission that "neither Lundbeck nor Arrow took any steps to progress the proceedings until the proceedings were, by agreement, stayed by way of an order dated 30 January 2003... Lundbeck never issued Particulars of Claim. It would only have been if Lundbeck wished to reactivate the proceedings, for example by enforcement of the undertakings embodied in the consent order, that there would have been any necessity for Lundbeck to issue Particulars of Claim. Equally, in those circumstances, there was no basis for a substantive argument on the question of infringement of Lundbeck's patents GB235762, 2356199 and EP(GB)171943.

⁷⁸⁵ See recitals (393) and (403) above. Lundbeck only launched infringement proceedings based on the second patent mentioned in the agreement, GB 2356199: process for the preparation of pure citalopram, by cyanide exchange (the film distillation patent). While Lundbeck has stated in its reply to the Statement of Objections that "The notice of claim filed in the UK High Court against Arrow did not mention the Crystallization Patent, because the patent had not yet been granted at the time of filing" (see ID 5394, page 206), this does not explain why Lundbeck did not enlarge the infringement action to also cover the crystallisation patent after it had been granted. This is particularly strange given Lundbeck's claim in the reply to the Statement of Objections that "...the Crystallization Patent had always been the very essence of the dispute between Lundbeck and Arrow...". See ID 5394, page 206.

⁷⁸⁶ See recitals (409) and (429) below.

⁷⁸⁷ ID 683, page 109, ID 632, pages 4-5.

⁷⁸⁸ ID 683, pages 95 to 99.

⁷⁸⁹ See recital (403) above.

⁷⁹⁰ ID 1444, page 1.

⁷⁹¹ Lundbeck stated in its reply to the Statement of Objections that Lundbeck "realized that it was possible for generic companies to design around the Film Distillation Patent" and "renounced enforcing that patent because it lent itself to invalidity claims." See ID 5394, page 162.

Accordingly, and in line with the court rules, Arrow did not pursue the issue of invalidity of the patents in these proceedings as it would only have counterclaimed for invalidity after receiving the Particular of Claim for Lundbeck."⁷⁹² Arrow also stated to the Commission: "...Arrow consented to the extension of the time for the Particulars of Claim to be served that Lundbeck requested."⁷⁹³ To the Commission, Arrow explained its lack of drive to resolve the legal issues as caused by Cipla's refusal to reveal the details of their citalopram manufacturing process, the likelihood that Cipla was in fact infringing Lundbeck's crystallisation patent, and Arrow's claimed inability to challenge the validity of Lundbeck's crystallisation patent.⁷⁹⁴ There was never any ruling in the legal proceedings between Lundbeck and Arrow on the validity of Lundbeck's patents or on their infringement by Cipla's manufacturing process.

- (411) Lundbeck has reported to the Commission that on 7 and 8 February 2002, Lundbeck performed an analysis of Arrow's citalopram, as obtained pursuant to the United Kingdom agreement with Arrow. According to Lundbeck, *"The results were consistent with those of the previous analyses [of Cipla material], and Lundbeck therefore concluded that Arrow's products were based on API from Cipla..."*⁷⁹⁵
- (412) On 12 February 2002 Lundbeck confirmed to Arrow that it had received over 5 million citalopram tablets from Arrow.⁷⁹⁶ Lundbeck also announced it would transfer the GBP 5 million in three instalments over the period of the agreement, the first one taking place *"upon receipt of approved UK Marketing Authorisation"*.⁷⁹⁷ However, as Arrow's United Kingdom marketing authorisation was significantly delayed⁷⁹⁸, Lundbeck in fact agreed to make most of the payments already before Arrow's marketing authorisation was issued in July 2002. Lundbeck's payment of the GBP 5 million was in fact made in five instalments of GBP 1 million each, which took place on 14 March 2002, 15 April 2002, 27 May 2002, 25 June 2002 and 31 December 2002.⁷⁹⁹ Lundbeck also ensured that the 5 million tablets it had received from Arrow were not destroyed, as they might have to be given back to Arrow.⁸⁰⁰
- (413) On 13 February 2002, Tiefenbacher wrote to Arrow's [employee function]*: *"Lundbeck seems to be in the possession of the DMF's. We have no idea how they got it! In the Netherlands they cited few pages. Unfortunately it is written in the Cipla DMF – open part – that the base is crystallized. You have seen the papers on your*

⁷⁹² ID 1517, page 4.

⁷⁹³ ID 610, page 24.

⁷⁹⁴ ID 610, pages 8 and 24.

⁷⁹⁵ ID 5394, page 168.

⁷⁹⁶ ID 683, page 102, ID 634, page 2. With respect to that part of the stock that was not given to Lundbeck in escrow, Arrow explained to the Commission that *"The remainder of those stocks of Citalopram were sent by Arrow to jurisdictions where Lundbeck did not have patent protection such that infringement of Lundbeck's patents was not a concern."* See ID 610, page 26.

⁷⁹⁷ ID 634, page 3.

⁷⁹⁸ See recital (168) above.

⁷⁹⁹ See ID 1517, page 5. See also for instance ID 904, page 156, approving on 22 May 2002 a transfer of GBP 1 million to Arrow.

⁸⁰⁰ ID 683, page 64. By the time of the second addendum to the agreement, the stock was physically returned to Arrow, but Arrow was not allowed to dispose of it in any way. See ID 610, page 26 and recital (441) below.

patent meeting with [Tiefenbacher employee] on December 14th."⁸⁰¹ With respect to this e-mail, Arrow stated to the Commission: *"At the time that Arrow became aware of Cipla's process of manufacture, in February 2002...after it had already entered into the agreement with Lundbeck dated 24 January 2002, it realised that its product, developed from Cipla's API, infringed Lundbeck's patent GB 2357762, which had been granted on 30 January 2002."*⁸⁰²

- (414) A Lundbeck internal e-mail of 23 February 2002 indicates that Lundbeck expected Arrow to receive a marketing authorisation for generic citalopram in the United Kingdom in the next couple of days.⁸⁰³
- (415) On 27 February 2002, Arrow inquired with the United Kingdom Medicines Control Agency as to the reasons why its marketing authorisation had not yet been issued, following the positive opinion Arrow's application had received on 27 December 2001. The Medicines Control Agency replied on 13 March 2002 to confirm receipt. It stated that it would answer as soon as possible.⁸⁰⁴
- (416) On 4 April 2002, the American wholesaler acting for Ranbaxy⁸⁰⁵ sent a draft confidentiality agreement to Arrow *"to cover the technical and legal issues on Citalopram."* The e-mail proposed *"to discuss the Ranbaxy products in the presence of their representatives which are planning to tour Europe. They are most likely available during week 17 i.e. starting Monday April 22, 2002...Regarding the pricing...I will come back to you early next week."*⁸⁰⁶
- (417) On 17 April 2002, an Arrow e-mail to a contact person in Australia stated:
*"We are looking for a source of citalopram free of both process patents and purification patents for the different markets through out the world. We know that you have already sent use copy of the citalopram route of synthesis from [potential new API supplier]. What we would now like is pages from the DMF outlining details of any process steps especially to do with the purification steps involved. There are numerous patents granted across Europe claiming different purification steps from film distillation to simple recrystallisations! [Potential new API supplier] gets around all the later process patents however, we are not too sure about the purification patents."*⁸⁰⁷
- (418) On May 1, 2002, Tiefenbacher applied for a type I variation of its marketing authorisation in the Netherlands, the Reference Member State, to include its new washing process.⁸⁰⁸ Lundbeck stated in its reply to the Statement of Objections that Tiefenbacher obtained this type I variation to its MA in the Netherlands on 16 July 2002.

⁸⁰¹ ID 635, page 2. This is, of course, without prejudice to the question of the validity of Lundbeck's crystallisation patent. It is recalled that Cipla believed it was using technology that had already been disclosed in 1977 and that Lundbeck's crystallisation patent therefore lacked novelty. See recital (382) above.

⁸⁰² ID 610, page 28.

⁸⁰³ ID 904, page 182.

⁸⁰⁴ ID 636, pages 2-3.

⁸⁰⁵ See recital (386) above.

⁸⁰⁶ ID 1354, page 1.

⁸⁰⁷ ID 1293, page 1.

⁸⁰⁸ ID 5420.

- (419) On 14 May 2002, the American wholesaler acting for Ranbaxy sent an e-mail to Arrow informing Arrow that a Ranbaxy representative from India *"will be in Europe early June"*. The American wholesaler also confirmed that his company was *"doing follow up work on API's for the market in Europe with the authorisation of Ranbaxy's API export department."*⁸⁰⁹ In another e-mail to Arrow of the same day, the American wholesaler acting for Ranbaxy stated:
- "...we hereby transmit our offer: 500 to 1,000kg of Citalopram @ \$3,500/kg CIF Dublin.*
- Samples are available upon request.*
- [Ranbaxy representative] will be visiting Europe, beginning of June. He is available for a meeting with you either in London or Dublin on Thursday June 6th...*
- Besides Citalopram, most of the products we have discussed are Ex Ranbaxy..."*⁸¹⁰
- (420) According to information submitted by Arrow to the Commission, on 22 May 2002 Arrow made an application for a variation to its United Kingdom marketing authorisation to the United Kingdom authorities. This application was approved on 23 December 2002.⁸¹¹ This variation concerned Matrix's process.
- (421) On 31 May 2002, Tiefenbacher sent Arrow a detailed description of a new Matrix process for purifying the oily citalopram base, which avoided the appearance of base crystals. Tiefenbacher wrote: *"...we are convinced that the process is non infringing..."* The e-mail stated that Matrix had made a PCT filing to request a patent for this purification process. The text of the patent application was attached. Attached also was a protocol of a trial performed on the new process by the University of Hamburg from 26 to 28 March 2002. The conclusion of this trial was:
- "The trial demonstrates that with the purification method described known impurities of Citalopram hydrobromide obtained via the Bromptalide route can be reduced to a value below 0.1%. Formation of crystalline base was not observed. It was nor isolated neither used [sic] for any purification step."*⁸¹²
- (422) In an internal e-mail of 24 June 2002 Arrow explored whether citalopram produced by the Chinese API producer Zhejiang Huahai Pharmaceuticals would be infringing or not. Arrow observed, in this respect, *"...Lundbeck have been suing everyone in the EU on a patent which claims purification of the base by crystallization. From the flow sheet Huahai do not give any details on whether the base is crystallized or kept in solution and converted to the hydrobromide salt and crystallized. They do refer to the hydrobromide salt as "crude" which suggests that they purify the salt rather than the base. If this is the case then the process is non-infringing."*⁸¹³
- (423) According to information submitted by Arrow to the Commission, on 8 July 2002, Arrow again applied for a variation regarding Matrix's process. This application was approved by the United Kingdom authorities on 4 June 2003.⁸¹⁴

⁸⁰⁹ ID 1354, page 11.

⁸¹⁰ ID 1354, page 12.

⁸¹¹ ID 1297, page 38.

⁸¹² ID 640, page 24.

⁸¹³ ID 641, page 2.

⁸¹⁴ ID 1297, page 38.

- (424) On 26 July 2002, Arrow received United Kingdom marketing authorisations for the distribution of citalopram tablets of 10, 20 and 40 mg.⁸¹⁵ These marketing authorisations indicated both Cipla and Matrix as authorised API manufacturers.⁸¹⁶
- (425) On 12 August 2002, Tiefenbacher sent an e-mail to Arrow to inform it that *"Due to the patent situation it become necessary that also Cipla, the second API manufacturer for Citalopram changes the route of synthesis. The Dutch authorities checked the corresponding documentation and informed us that the change in the route of synthesis is a type I variation..."* Tiefenbacher asked Arrow to make the corresponding application in the United Kingdom.⁸¹⁷ According to information submitted by Arrow to the Commission, this application was made by Arrow on 30 September 2002 and was approved by the United Kingdom authorities on 3 February 2003.⁸¹⁸
- (426) In October and November 2002, further contacts took place between Arrow's subsidiary Resolution Chemicals and the Indian API supplier Neulands regarding certain orders of citalopram API Resolution had placed with Neulands for certification purposes.⁸¹⁹
- (427) On 14 November 2002, an internal Arrow e-mail considered concerning the process of the API supplier Reso: *"...the patent agent is reserving judgment on whether it's an infringement to go via a patented intermediate if it's only formed transiently in the process."*⁸²⁰
- (428) An internal Arrow e-mail of 26 November 2002 mentioned that the Indian producer Sun Pharmaceuticals produced citalopram.⁸²¹
- (429) With the expiry of the original court order coming up by 31 December 2002⁸²², Lundbeck and Arrow agreed on 19 December 2002 on the text of a new draft order to be issued by the Master of the High Court of Justice, Chancery Division, Patents Court.⁸²³ The Master issued the consent order with only marginal changes on 30 January 2003. He ruled that *"all further proceedings in this claim be stayed save for the enforcement of the undertaking given by the Defendants in this Order."* The undertaking given by Arrow *"on its own behalf and on behalf of all associated and related entities"* was that *"until a final unappealable enforceable UK Court decision in this matter has been rendered or until at least 1st April 2003, which ever shall occur first"*, Arrow would refrain from making, importing or selling in the United Kingdom *"(1) Citalopram not manufactured by Lundbeck or with the consent of Lundbeck or (2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights (including patent rights to inventions of Citalopram and to processes relating to the manufacture thereof, including but not limited to in particular GB patents no 2 357 762, 2 356 199 and EP (GB) 171 943) and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to provide*

⁸¹⁵ ID 682, page 7.

⁸¹⁶ ID 1632. See also ID 1297, page 48.

⁸¹⁷ ID 1359, page 1.

⁸¹⁸ ID 1297, page 38.

⁸¹⁹ ID 1294, pages 5 to 9.

⁸²⁰ ID 1291, page 1.

⁸²¹ ID 643, page 2.

⁸²² See recital (409) above.

⁸²³ ID 1449, pages 1 to 4 and ID 1450, pages 1 to 4.

Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale...". Also, Arrow committed not to transfer, license or otherwise deal in any United Kingdom marketing authorisations relating to such citalopram.⁸²⁴

- (430) From the two consent orders issued on 6 February 2002 and 30 January 2003, it appears that while these proceedings served to obtain enforceable court orders restraining Arrow from selling generic citalopram, there is no indication in the file that either of the two parties asked the High Court, Chancery Division, Patents Court to substantively examine the question whether any of the three Lundbeck patents mentioned in the agreement had been infringed or whether it was valid. As Lundbeck explained to the Commission, "*Lundbeck v. Arrow Generics Limited and Resolution Chemicals (HC 02 CO 216) was an action brought by Lundbeck against Arrow Generics Limited and Resolution Chemicals Limited for infringement of one of Lundbeck's patents (UK patent no 2, 356, 199). The Claim Form was issued on January 25, 2002. On the basis of undertakings given by the defendants to the court in two consent orders dated February 20, 2002 and December 19, 2002...respectively, the action was stayed.*"⁸²⁵
- (431) Apparently only by the end of January 2003⁸²⁶, after the original agreement had expired on 31 December 2002, did Arrow and Lundbeck formally agree to extend their agreement for the United Kingdom. The addendum, signed without a date by H. Lundbeck A/S and Arrow Generics Limited and Resolutions [sic] Chemicals Ltd, covered the United Kingdom for the period from 1 January 2003 to 31 March 2003.⁸²⁷ It extended the provisions of the original agreement, using virtually the same preamble and definitions. A new element in the preamble was the mention of the new consent order Lundbeck had obtained against Arrow (agreed between the parties on 19 December 2002 and issued by the court on 30 January 2003).
- (432) Article 1.1 of the extension agreement repeated the substantive obligations on Arrow already stated in Article 1.1 of the original agreement and in the consent order of 30 January 2003. In essence, in the United Kingdom Arrow was prohibited from making, importing or selling citalopram which Lundbeck alleged to be infringing or in dealing in any marketing authorisations pertaining to such citalopram.
- (433) Article 2.1 provided:
- "In consideration of the undertakings in clause 1.1 and ARROW not seeking a cross-undertaking in damages in respect of the period comprising the Term, Lundbeck shall provide ARROW with a total of four hundred and fifty thousand pounds sterling (GBP 450.000)..."*. The money was to be paid in three instalments of GBP 150 000 for each month of the duration of the term.

⁸²⁴ ID 645, pages 1 to 5.

⁸²⁵ ID 823, page 40. United Kingdom patent no; 2356199 was Lundbeck's patent for a process for the preparation of pure citalopram, by cyanide exchange (the so-called film distillation patent). See recital (393) above.

⁸²⁶ ID 904, pages 53 to 60.

⁸²⁷ ID 8, pages 241 to 245.

Arrow later explained to the Commission that the amount of GBP 150 000 per month in the first and second addenda *"represented a realistic (albeit broad) estimate of the likely damages that would be recovered under a cross-undertaking in damages..."*⁸²⁸

- (434) On 27 March 2003, Arrow received an e-mail from Ranbaxy, in which Ranbaxy stated:

"You would recall, during our meeting in London, we had discussed possible co-operation on some products like:

...

Citalopram

...

Citalopram

- (435) *You had expressed interest during the meeting, as you believe your current source is infringing. We believe, our product is clear of all such issues. Should you desire, we can send you a small sample for testing."*⁸²⁹

- (436) The negotiation of a second addendum also took considerable time. A draft was still exchanged on 4 May 2003, more than a month after the first addendum had expired. In the accompanying e-mail, Lundbeck told Arrow:

*"If lagab trial is withdrawn, you will have to invalidate the patent yourself – I believe that is fair."*⁸³⁰

- (437) On 28 May 2003, the Indian API supplier Neulands reported to Arrow's subsidiary Resolution Chemicals: *"From the current process, we cannot meet your target, especially in view of patent situation."*⁸³¹

- (438) A second addendum was agreed on 1 June 2003.⁸³² Its term was *"from the 1st April 2003 until 7 days from the date of the decision by the High Court of Justice, Chancery Division, Patents Court in the Lagap Litigation or the 31st January 2004, which ever occurs first."* The second addendum therefore tied the extension of the agreement to the fate of the on-going Lagap litigation (dealing with citalopram from Matrix) rather than to the litigation between Arrow and Lundbeck (dealing with citalopram from Cipla), which had been stayed and was never continued.

- (439) Article 1.1 of the second addendum was similar to Article 1.1 of the first addendum and Article 1.1 of the original agreement: Arrow's obligation not to make, import or sell in the United Kingdom citalopram which Lundbeck alleged to be infringing or to deal in any marketing authorisations pertaining to such citalopram was prolonged for the duration of the second extension.

- (440) In Article 1.2, *"In consideration of the undertakings in Clause 1.1 and ARROW not seeking a cross-undertaking in damages in respect of the period comprising the Term"*, Lundbeck agreed to pay Arrow GBP 1.5 million, again amounting to GBP

⁸²⁸ ID 610, page 29.

⁸²⁹ ID 1354, pages 17-18.

⁸³⁰ ID 845, page 23.

⁸³¹ ID 1294, page 10.

⁸³² ID 8, pages 246 to 252.

150 000 for each month of the ten months term. The money was to be paid in ten monthly instalments.

- (441) Article 3 of the second addendum was new and provided:

"As the time limit for sale of ARROW's stock expires before October 2003, Lundbeck agrees to purchase the stock from ARROW for destruction, if the High Court of Justice, Chancery Division, Patents Court finds in the Lagap Litigation that the Proprietary Rights are invalid. In such case Lundbeck shall pay an amount of GBP 750.000 (seven hundred and fifty thousand) to ARROW within 30 days from delivery of Arrow's stock and following the court's decision. If the High Court of Justice, Chancery Division, Patents Court in the Lagap Litigation gives judgement that the Proprietary Rights are not invalid Lundbeck shall obtain delivery of the stock, but shall not pay for the stock. If the Lagap Litigation is settled, withdrawn or where no ruling is made in the Lagap Litigation on or before 31 January 2004, time being of the essence, Lundbeck agrees to purchase 2/3 of the stock on the same conditions as set out above in this Clause 3, 2nd sentence against payment of GBP 500,000 (five hundred thousand)...During the Term of this Addendum and until the stock is delivered to Lundbeck, ARROW shall store the stock and may not dispose of such stock in any way."

According to exhibit 3.1 to the second addendum, the amount of GBP 750 000 represented the cost price of the over 5 million tablets, not the resale value.⁸³³ This amount included Arrow's packaging cost.⁸³⁴

- (442) An e-mail of Arrow's [employee function]* dated 5 August 2003 summarised the European citalopram situation over the last couple of years as follows: *"Towards expiry of the basic compound patent in Europe there was essentially only [one] source of raw material, VIS. The route that they employed was essentially that shown in the basic patent and this formed the basis for the generic registrations around Europe. In an attempt to restrict generic entry Lundbeck bought VIS and refused to supply material to generic companies. Lundbeck also started to file numerous patent applications aimed at blocking the "old" route of synthesis from being used. Of these by far the most troublesome was WO 01/68627 which covered a method of purifying citalopram base by recrystallization before conversion to the marketed hydrobromide salt. Lundbeck argued that material from the "old" VIS process was impure and required to be purified before use. Unfortunately, the raw materials available all employed a base crystallization and Lundbeck successfully managed to keep everyone off the market initially. There are essentially three raw materials we have worked with from Cipla, Matrix and [third API supplier]. Initially, all three were caught by the patent above. Since then they have modified their processes ... Since this step has been introduced there have been a series of non-infringement decisions in various European courts (Denmark, Sweden Norway, Netherlands and Germany)."*⁸³⁵
- (443) On 26 August 2003, Resolution Chemicals sent an e-mail to Arrow, stating: *"[employee name]* asked me to check if our process in India [that of the API supplier Neulands] was worth using. He says Matrix, Ranbaxy and Max are all free*

⁸³³ ID 8, page 252.

⁸³⁴ ID 846, page 170.

⁸³⁵ ID 649, page 2.

so only makes sense if there are no issues in Europe or the States." The answer from Arrow stated: *"Even if [Lundbeck] did injunct, we'd still have the other source [Tiefenbacher] registered so there's no way they could remove us from the market."*⁸³⁶

- (444) On 15 October 2003, Lundbeck wrote to Arrow to inform it that the Lagap litigation had been settled on 13 October 2003 and that Lundbeck consequently terminated the agreement with Arrow as of 20 October 2003.⁸³⁷ Although Lundbeck did not consider the settlement equivalent to a decision by the High Court of Justice⁸³⁸, it believed that, as it later explained to the Commission, *"because the Lagap settlement provided a licence to Lagap to sell citalopram in the UK, Lundbeck considered it was not practical to enforce its patent rights..."*⁸³⁹ Arrow acknowledged the termination and thanked Lundbeck for its cooperation.⁸⁴⁰ Lundbeck paid GBP 100 000 for the period from 1 October 2003 to 20 October 2003 and then stopped its regular monthly payments to Arrow.⁸⁴¹
- (445) On 4 November 2003 Lundbeck and Arrow agreed that Arrow would not deliver 2/3 of the stock to Lundbeck as foreseen in Article 3 of the second addendum, but that instead Lundbeck would pay Arrow GBP 350 000.⁸⁴² Lundbeck did not specify that these tablets should be destroyed and Arrow in fact sold them in the United Kingdom when it entered the citalopram market there. This entry, however, took place only in February 2004, following the expiration of the originally envisaged term of 31 January 2004 mentioned in the agreement with Lundbeck, despite the fact that Lundbeck had already terminated the agreement on 20 October 2003.⁸⁴³ To the Commission, Arrow explained this late entry by saying that *"In the absence of a High Court decision in the Lagap case, Arrow determined that the prudent course was to await the expiry of the Second Addendum before launching its citalopram products in the UK."*⁸⁴⁴ In this respect, Arrow did not indicate to the Commission that there was any link between Lundbeck's payment of GBP 350 000 and Arrow's decision to enter the United Kingdom market only in February 2004.
- (446) Arrow indicated to the Commission that for the first and second extensions of Arrow's agreement with Lundbeck, Lundbeck made the following payments to Arrow:
- GBP 150 000 on 7 February 2003;
- GBP 150 000 on 25 February 2003;
- GBP 150 000 on 26 March 2003;
- GBP 300 000 on 16 June 2003;

⁸³⁶ ID 1294, page 15.

⁸³⁷ ID 8, pages 497-498.

⁸³⁸ See recital (438) above.

⁸³⁹ ID 823, page 41.

⁸⁴⁰ ID 682, page 79.

⁸⁴¹ ID 8, page 497, ID 682, page 77.

⁸⁴² ID 904, page 48.

⁸⁴³ ID 610, pages 10, 25, ID 682, page 79. Arrow had obtained an extension of a year of the shelf life of the citalopram tablets in question from the United Kingdom Medicines Control Agency. See ID 610, page 27.

⁸⁴⁴ ID 610, page 10.

GBP 150 000 on 30 June 2003;
 GBP 150 000 on 31 July 2003;
 GBP 150 000 on 29 August 2003;
 GBP 150 000 on 30 September 2003;
 GBP 100 000 on 11 November 2003; and
 GBP 350 000 on 13 November 2003.⁸⁴⁵

- (447) In total, over the entire period of operation of the agreement from 24 January 2002 to 20 October 2003, Lundbeck transferred a value to Arrow of GBP 6.8 million (corresponding to approximately EUR 10.4 million)⁸⁴⁶ under the agreement regarding the United Kingdom, consisting of:
- GBP 5 million for the first year (until 31 December 2002);
 - 3 times GBP 150 000 in the first extension between January 2003 and March 2003 = GBP 450 000;
 - 6 times GBP 150 000 in the second extension between April 2003 and September 2003 = GBP 900 000;
 - GBP 100 000 in the second extension between 1 October 2003 and 20 October 2003;
 - GBP 350 000 in the second extension, related to Arrow's stock.

7.4.4. *Subsequent events*

- (448) When Arrow entered the United Kingdom market in February 2004 with its citalopram from Cipla, Lundbeck did not pursue Arrow for patent infringement.⁸⁴⁷

7.5. **Lundbeck's agreement with Arrow regarding Denmark**

7.5.1. *The negotiation of the agreement*

- (449) On 20 September 1999, the Danish company Nycomed, with which Lundbeck had concluded a co-marketing agreement⁸⁴⁸, started selling Lundbeck-manufactured citalopram in Denmark under the brand name Akarin, at prices comparable to Lundbeck's own-brand citalopram.⁸⁴⁹
- (450) On 11 February 2002, Lundbeck's crystallisation patent was granted in Denmark as patent DK 173903.
- (451) According to Arrow, early in March 2002, Lundbeck and Arrow met.⁸⁵⁰ Following this meeting, on 11 March 2002, Lundbeck sent a draft agreement for Denmark and Sweden to Arrow/Resolution Chemicals in the United Kingdom.⁸⁵¹

⁸⁴⁵ ID 1517, pages 5-6.

⁸⁴⁶ Using an average annual exchange rate for 2002 of 1 EUR = 0.62883 GBP and for 2003 of 1 EUR = 0.69199 GBP, source European Central Bank.

⁸⁴⁷ ID 610, page 25, ID 823, page 40.

⁸⁴⁸ ID 813, pages 48 and 62.

⁸⁴⁹ ID 813, page 84. See also ID 200. Another Lundbeck document mentions January 2000 as Nycomed's launch date of citalopram. See ID 903, page 3.

⁸⁵⁰ ID 1325, page 2.

⁸⁵¹ ID 1327, pages 1 to 5 and ID 1325, page 2.

- (452) In March 2002, the company A/S Gea (linked to Hexal) launched generic citalopram in Denmark, based on Cipla API.⁸⁵² Lundbeck started infringement proceedings before a Danish court 17 April 2002 and obtained an interim injunction on 5 July 2002.⁸⁵³
- (453) In May 2002, Biochemie launched generic citalopram in Denmark, also using Cipla API.⁸⁵⁴ Lundbeck started infringement proceedings on 12 June 2002 and obtained an interim injunction on 8 November 2002.⁸⁵⁵
- (454) On 8 May 2002, Tiefenbacher informed Arrow Scandinavia AB in Stockholm, Sweden (a holding company for Arrow Group's Scandinavian subsidiaries⁸⁵⁶), that it had obtained a marketing authorisation in Denmark for the company Jacobsen Pharma A/S on 2 May 2002.⁸⁵⁷ On 17 May 2002 Arrow Group A/S and Tiefenbacher agreed an appendix to their earlier contract of 22 May 2001.⁸⁵⁸ This appendix specified that Tiefenbacher agreed that Arrow could, instead of obtaining its own licence through the mutual recognition procedure, purchase a national licence granted to a third party in Denmark and Sweden based on Tiefenbacher's registration file (which covered citalopram sourced from Cipla or Matrix).⁸⁵⁹ This meant that Arrow could, in particular, buy the marketing authorisation obtained in Denmark by Jacobsen Pharma A/S.⁸⁶⁰ Arrow could then start selling generic citalopram in Denmark, whether from Cipla or Matrix.⁸⁶¹
- (455) On 23 May 2002, a new draft text of an agreement between Arrow and Lundbeck was sent from Lundbeck to Arrow Generics in the United Kingdom, foreseeing that Arrow would consent to an injunction for Denmark and Sweden in exchange for a compensation payment by Lundbeck of USD 500 000 for each Member State.⁸⁶² Arrow Scandinavia AB was also involved in the negotiation.⁸⁶³ In an e-mail of 27 May 2002, Arrow proposed that Arrow Group A/S in Copenhagen should be the party to the agreement for the Arrow group of companies and that "*all affiliates*" of Arrow Group A/S should be covered by the agreement. A new draft sent by Lundbeck on 31 May 2002 shows that the idea of a consent injunction for Sweden had been dropped.⁸⁶⁴

⁸⁵² ID 904, page 261.

⁸⁵³ The case was settled in 2005. See ID 234, page 6.

⁸⁵⁴ ID 904, page 261.

⁸⁵⁵ The case was settled in October 2003. See ID 234, page 5.

⁸⁵⁶ ID 1325, page 9.

⁸⁵⁷ ID 907, pages 95 to 97.

⁸⁵⁸ See recital (375) above.

⁸⁵⁹ ID 1329, pages 1 to 4.

⁸⁶⁰ Arrow informed the Commission that in fact Arrow did not buy any national marketing authorisation under this provision, including from Jacobson Pharma A/S. See ID 1325, pages 2, 3 and 5. It appears from the agreement that Lundbeck believed at the time of the conclusion of the agreement that Arrow could use or might come to use the marketing authorisation in Denmark of Jacobson Pharma A/S, see ID 8, page 255 and ID 823, page 45. Following the conclusion of the agreement with Lundbeck, there would have been no longer any incentive for Arrow, at least for the duration of the agreement, to buy a marketing authorisation for Denmark, as the agreement prohibited Arrow from selling there anyway.

⁸⁶¹ ID 8, page 199.

⁸⁶² ID 845, pages 54 to 68.

⁸⁶³ ID 907, page 66, ID 907, pages 94 to 97.

⁸⁶⁴ ID 907, page 166. The precise reasons why the parties did not pursue an agreement for Sweden are unclear. Denmark may have been more important to Lundbeck than Sweden because in Denmark

7.5.2. The agreement

- (456) On 3 June 2002 Arrow Group A/S and H. Lundbeck A/S concluded an agreement for Denmark.⁸⁶⁵ The preamble to the agreement noted that *"Arrow is in the process of obtaining a licence from a third party to import bulk Citalopram not manufactured by Lundbeck or with the consent of Lundbeck into the Territory" and that "Arrow intends to import bulk Citalopram into the Territory from Germany."* The preamble then stated that Lundbeck had performed laboratory analyses of Arrow's citalopram and that the results of these analyses gave Lundbeck *"substantial reason to believe"* that Arrow's citalopram infringed Lundbeck's patent DK 173903 (the Danish crystallisation patent) and DK patent application PA 2000 01943 8 (the Danish film distillation patent application)⁸⁶⁶. The preamble continued by saying that *"...Arrow has had no intention or knowledge of any infringement of Lundbeck's intellectual property rights and makes no admission of infringement, but acknowledges that Lundbeck is of the opinion that the findings by Lundbeck may lead to the conclusion that an infringement has taken place or would take place", that "Lundbeck represents that it would have pursued the said alleged infringement before the relevant courts", that Lundbeck had obtained a voluntary injunction in the United Kingdom against Arrow and that "...the parties are in agreement that further litigation between them should be avoided also taking into consideration the costs involved in such litigation and the risks for both parties concerning the outcome of same."*
- (457) Article 1.1 of the agreement provided:

"Arrow consents to cancel, cease and desist from any importation, manufacture, production, sale or other marketing of products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights in the Territory for the term of this Agreement, however only until a final, unappealable and enforceable, judicial decision in the Infringement Litigation, as defined above, has been rendered by the Courts in the UK. The obligation of Arrow under this clause 1.1 shall hereinafter be referred to as the "Consent Injunction"."

This provision also meant that Resolution Chemicals Ltd, as a subsidiary of Arrow Group A/S, was prohibited from manufacturing citalopram destined for sale in Denmark if Lundbeck alleged such citalopram to infringe its intellectual property rights in Denmark. Arrow later confirmed to the Commission that *"The Lundbeck Agreements cover citalopram in any form, including both as an API and a medicine."*⁸⁶⁷

Lundbeck had since February 2000 built up a considerable market share for its authorised generic supplier Nycomed selling Lundbeck-produced material, see ID 844, page 29. Arrow speculates that Sweden may have been dropped because several other generic companies had entered the Swedish market in February 2002 (see ID 1325, page 3), even though Lundbeck was, at least initially, successful in both Sweden and Denmark in obtaining interim injunctions (see ID 222, pages 18 to 22 and 29 to 32).

⁸⁶⁵ ID 8, pages 253 to 262.

⁸⁶⁶ This patent was granted in Denmark on 29 June 2002 as patent DK 2001 00386. Source: Espacenet.

⁸⁶⁷ ID 610, page 25. In a later response on the Danish agreement, Arrow confirmed that *"Subject the following qualifications, the substantive terms of the Danish Agreement are essentially the same as the UK agreement, and are explained fully in Arrow's First Response."* (ID 1325, page 5). The qualifications that then followed did not indicate any change to the coverage of citalopram both as an API and as a medicine in the Danish agreement.

It should be noted that Article 1.1 of the Danish agreement did not provide for any testing of samples on the basis of which Lundbeck would *"ascertain if there may be an infringement"* as Article 1.1 of the United Kingdom agreement stated.

(458) Article 1.2 of the agreement provided that *"During the term of this Agreement, Arrow shall maintain all licences and marketing authorisations and may not dispose of such licences or marketing authorisations neither as a sale, license or in any other way."*

(459) Article 2.1 provided that *"Lundbeck shall grant Arrow a compensation for the Consent Injunction under clause 1 of USD 0.5 million (USD 500,000.00)".* Jacobsen Pharma A/S was identified as *"holding the license on behalf of Arrow"*. The product was identified as *"a product supplied by Alfred E. Tiefenbacher."*

(460) Article 2.2 provided:

"In the event the final, unappealable and enforceable court decision in the Infringement Litigation rules that Arrow does not and has not infringed Lundbeck's intellectual property rights, the compensation paid by Lundbeck in accordance with clause 2.1 shall constitute full and final compensation from Lundbeck for any and all alleged and/or documented loss sustained or allegedly sustained by Arrow due to the Consent Injunction under this Agreement or otherwise resulting from this Agreement."

This indicates that the amount of compensation Lundbeck granted to Arrow for not selling generic citalopram to the market in Denmark was based on Arrow's expected profits in Denmark in the period concerned if Arrow had sold generic citalopram and had not been found to infringe Lundbeck's patents or if those patents had been found invalid.

(461) Article 3.1 provided:

"On payment of compensation as provided in clause 2 Lundbeck shall obtain delivery of Arrow's current stock of Citalopram tablets consisting of approximately 1 million tablets which shall comply with the marketing authorisation granted by the Danish authorities, at cost price being USD 147,000..."

(462) Article 4.1 provided:

"The term of this Agreement shall be from the date of signature until a final and unappealable court decision in the Infringement Litigation has been rendered or until 1 April 2003, whichever of these events occurs first." The term *"Infringement Litigation"* was defined in the preamble as the *"voluntary injunction against Arrow in the High Court of Justice, Chancery Division in London on 6 February 2002 ordering Arrow to be restrained until further order from infringing GB Patent 2 356 199B being equivalent to DK patent no. 173903."*⁸⁶⁸

⁸⁶⁸

Arrow explained to the Commission that in fact the United Kingdom patent and the Danish patent mentioned as equivalent here erroneously did not cover the same subject matter, GB patent 2 356 199B being the film distillation patent and DK patent no. 173903 being the Danish equivalent of GB 2 357 762, the crystallisation patent. Given that the United Kingdom proceedings concerned the film distillation patent, parties probably meant to refer to the equivalent Danish film distillation patent application, PA 2000 01943 8, mentioned earlier in the preamble. Arrow also informed the Commission that at the time the agreement was concluded, no patent litigation was taking place on citalopram between Lundbeck and Arrow in Denmark. See ID 1325, page 2.

- (463) Article 4.2 provided that if any third party tried to import, manufacture or sell generic citalopram in Denmark, Lundbeck was obliged to pursue such action based on its patents. If Lundbeck were unsuccessful in such litigation, Arrow had the right to annul the agreement, repay to Lundbeck that portion of the compensation for the Consent Injunction which applied to the period after generic entry and buy back its stock of tablets at the same cost price as for which it had sold them to Lundbeck.
- (464) A copy of Jacobsen Pharma's marketing authorisation was annexed to the agreement.
- 7.5.3. *Events during the implementation of the agreement*
- (465) In June 2002, United Nordic Pharma launched Matrix citalopram in Denmark.⁸⁶⁹ Lundbeck started infringement proceedings on 19 June 2002 and obtained an interim injunction on 21 March 2003.⁸⁷⁰
- (466) Lundbeck paid the USD 500 000 to Arrow Group A/S on 17 June 2002.⁸⁷¹
- (467) In September 2002 Ratiopharm launched generic citalopram from Matrix⁸⁷² in Denmark. Lundbeck started infringement proceedings on 18 November 2002. The court denied an injunction on 25 April 2003.⁸⁷³
- (468) In November 2002, Copyfarm launched generic citalopram from Matrix⁸⁷⁴ in Denmark. Lundbeck started infringement proceedings in January 2003. An interim injunction was granted on 17 June 2003. On 26 January 2004, the Appeals Court ordered the injunction lifted.⁸⁷⁵
- (469) Arrow explained to the Commission that *"It had not sold any citalopram in Denmark prior to the conclusion of the Danish Agreement, and did not attempt to do so during the lifetime of the Danish Agreement."*⁸⁷⁶
- (470) Arrow also informed the Commission that *"Arrow Group's tablets for Denmark were purchased from Tiefenbacher."* *"A UK stock reconciliation suggests that shipments were made to Denmark in the quantities contemplated by Clause 3.1 of the Danish Agreement."* Arrow *"has a copy of an invoice sent to Lundbeck for payment of the US\$147,000 under the terms of Clause 3.1 of the Danish Agreement..."*⁸⁷⁷ It therefore appears likely that the tablets transferred to Lundbeck were material which Arrow Generics Limited in the United Kingdom had purchased earlier from Tiefenbacher.⁸⁷⁸ The stock was shipped from Ireland to Lundbeck in Copenhagen.⁸⁷⁹ The invoice to Lundbeck was sent by Arrow Generics Limited and Lundbeck's payment for the stock was also made to Arrow Generics Limited.⁸⁸⁰

⁸⁶⁹ ID 904, page 261.

⁸⁷⁰ The injunction was upheld on 24 June 2003. See ID 234, page 6.

⁸⁷¹ ID 683, page 113.

⁸⁷² ID 903, page 3.

⁸⁷³ ID 234, page 7.

⁸⁷⁴ ID 903, page 3.

⁸⁷⁵ ID 234, page 5.

⁸⁷⁶ ID 1325, page 5.

⁸⁷⁷ ID 1325, page 5, ID 1334, page 1, ID 1434, pages 1 to 3.

⁸⁷⁸ ID 1325, page 6.

⁸⁷⁹ ID 683, page 113.

⁸⁸⁰ ID 1325, page 5.

- (471) Lundbeck confirmed to the Commission that *"Lundbeck initially stored the products purchased from Arrow and, following the expiry date, ultimately destroyed them."*⁸⁸¹
- (472) In total, over the entire period of operation of the agreement from 3 June 2002 to 1 April 2003, Lundbeck transferred a value to Arrow of USD 647 000 (corresponding to approximately EUR 684 000)⁸⁸² under the agreement regarding Denmark, consisting of:
- USD 500 000 for the duration of the agreement;
 - USD 147 000 for Arrow's stock.

7.5.4. Subsequent events

- (473) In the absence of a final and unappealable court decision in the *"Infringement Litigation"* between Lundbeck and Arrow before 1 April 2003, the agreement for Denmark expired on 1 April 2003. Lundbeck explained to the Commission: *"Because generic versions of citalopram had entered the market in Denmark by the end of the agreement with Arrow, Lundbeck did not seek to extend the agreement with Arrow beyond this date"*⁸⁸³ and *"In April 2003 there were several generic companies selling citalopram in Denmark. Lundbeck considered it was too costly to defend its citalopram intellectual property rights via further litigation or settlement agreement in Denmark."*⁸⁸⁴
- (474) Lundbeck also explained to the Commission that *"The agreements with Arrow only covered the UK and Denmark because these were the only Member States where Arrow, to Lundbeck's knowledge, intended to market citalopram."*⁸⁸⁵
- (475) Arrow, from its side, reported to the Commission that *"Arrow Group only entered the Danish market in June 2005."*⁸⁸⁶ These sales were not subject to infringement litigation by Lundbeck.⁸⁸⁷

⁸⁸¹ ID 823, page 45.

⁸⁸² Using an average annual exchange rate for 2002 of 1 EUR = 0.94557 USD, source European Central Bank.

⁸⁸³ ID 823, page 22.

⁸⁸⁴ ID 823, page 47.

⁸⁸⁵ ID 823, page 47.

⁸⁸⁶ ID 1325, page 5.

⁸⁸⁷ ID 823, page 45.

7.6. Lundbeck's agreement with Alpharma regarding the EEA

7.6.1. The negotiation of the agreement

- (476) On 25 August 2000, Alpharma entered into an agreement with Tiefenbacher and Omega Farma providing Alpharma with the rights to future marketing authorisations for generic citalopram Tiefenbacher would obtain (covering supplies from Cipla and Matrix).⁸⁸⁸ Tiefenbacher and Omega Farma had together developed registration files for finished dosage forms containing the active ingredient citalopram hydrobromide, in the form of film-coated tablets of 10, 20 and 40 mg. These registration files had been submitted in March 2000 to the Dutch health authorities. Following approval by the Dutch health authorities, Tiefenbacher would use the mutual recognition procedure to obtain as soon as possible a marketing authorisation for Germany. Tiefenbacher would license these marketing authorisations, after they had been obtained, on a non-exclusive basis to Alpharma. In addition, Alpharma obtained the right to either apply for marketing authorisations itself in all the remaining European countries using the registration files prepared by Tiefenbacher and Omega or to make Tiefenbacher extend its mutual recognition procedure to those countries (subject to additional payment). Alpharma also obtained the right to subsequently distribute the products concerned by the agreement in all European countries where it would have marketing authorisations. For a period of three years after launch in the United Kingdom, Alpharma would buy the product as tablets in bulk from Omega Farma and for an additional two years, Alpharma would buy the API exclusively from Tiefenbacher. Sales of the product by Alpharma would also be subject to a royalty payment to Tiefenbacher. The agreement stated that according to Tiefenbacher's best knowledge, there were no patents interfering with the project in Germany or, after 11 June 2002, in the Netherlands. However, neither Tiefenbacher nor Omega would "*warrant for damages of ALPHARMA due to patent infringements caused by the execution of the agreement*".⁸⁸⁹
- (477) On 11 January 2001 Lundbeck sent a letter to Alpharma in Denmark saying that it was aware that Alpharma was involved in activities in relation to "*our compound*" (that is to say citalopram) and warning it of possible infringement of Lundbeck's patents relating to the preparation of that compound. This letter listed the recently granted Dutch utility model 1016435 which covered not only a process to purify citalopram through crystallisation of the free base, but also, in the words of Lundbeck in the letter: "*The crystalline base of citalopram is claimed pr. se.*" The letter offered the possibility of "*discussions of these matters.*"⁸⁹⁰
- (478) On 2 February 2001 Alpharma sent an e-mail to Lundbeck saying that it was interested in investigating possibilities for cooperation with Lundbeck, in particular allowing Alpharma to introduce a generic version, possibly produced by Lundbeck, already before patent expiry on a profit-sharing basis.⁸⁹¹
- (479) On 12 February 2001 Lundbeck talked with Alpharma and agreed a meeting at Alpharma's premises on 29 March 2001.⁸⁹² Lundbeck stated in its reply to the

⁸⁸⁸ ID 746, pages 14 and 210 to 220.

⁸⁸⁹ See Article 9.1 of the agreement, ID 746, page 216.

⁸⁹⁰ ID 903, pages 66 to 69. Regarding the Dutch utility model 1016435 see footnote 226 above.

⁸⁹¹ ID 723, page 126.

⁸⁹² ID 723, page 125.

Statement of Objections that the [employee function]* of Alpharma ApS participated in this meeting.⁸⁹³

- (480) On 25 June 2001, in implementation of their earlier marketing authorisation purchase agreement of 25 August 2000, Alpharma and Tiefenbacher entered into a detailed supply agreement pursuant to which Alpharma would purchase exclusively from Tiefenbacher all finished dose citalopram products for sale in the EEA.⁸⁹⁴ These products were to be produced by Omega Farma based on API from the Indian producers Cipla or Matrix. The tablets would be supplied by Omega in bulk form and would be packaged into blister packs and labelled for Alpharma by the packaging company Dragenopharm. The supply agreement with Tiefenbacher simply provided the product specifications that Tiefenbacher had to comply with and left it to Tiefenbacher to select the API supplier.⁸⁹⁵ According to Tiefenbacher, for the products or API sourced from Tiefenbacher, Alpharma was free to specify to Tiefenbacher whether the citalopram should come from Cipla or Matrix.⁸⁹⁶ Certainly the agreement did not prevent this. This having been said, initially, at least until the moment when Alpharma and Lundbeck concluded their agreement regarding the EEA, the citalopram products supplied by Tiefenbacher came from Cipla.⁸⁹⁷
- (481) In its reply to the Statement of Objections, Lundbeck informed the Commission that between July 2001 and January 2002, it performed several analyses of Cipla's citalopram.⁸⁹⁸ According to Lundbeck: *"The results of these tests were all consistent and indicated the presence of 5-Chloro and 5-Bromo impurities and the absence of 5-Acetyl impurity, which showed that Cipla used the Cyanation 2002-1 Process. The low level of 5-Chloro and 5-bromo impurities and the rate between these two demonstrated that the specific impurity level could only have been obtained through the Crystallization Process, in violation of the Crystallization Patent."*⁸⁹⁹ In its reply to the Statement of Objections, Lundbeck also stated that between June 2001 and January 2002, it performed several analyses of Matrix's citalopram. According to Lundbeck, *"...the impurity profile could only have been obtained through the Crystallization Process..."*⁹⁰⁰

⁸⁹³ ID 5394, page 222.

⁸⁹⁴ ID 746, page 14 and ID1220, pages 11-12.

⁸⁹⁵ As Alpharma later explained to the Commission: *"Alpharma AS was not involved in the selection of the API supplier as this was dealt with by Tiefenbacher as the applicant for the marketing authorisation and Alpharma simply purchased the finished dose form of the product from Tiefenbacher."* See ID 746, page 14. Originally, Tiefenbacher had wanted to use the Italian API supplier VIS, but after this company had been acquired in October 2000 by Lundbeck, Tiefenbacher switched to Cipla and Matrix as possible suppliers. Cipla was the API supplier of the citalopram products purchased by Alpharma before Alpharma entered into the agreement with Lundbeck. See ID 4817, page 23.

⁸⁹⁶ ID 1713, page 1.

⁸⁹⁷ Matrix stated in the United Kingdom Lagap litigation that it began supplying citalopram to the EEA in March 2002. Lundbeck has stated to the Commission that it first became aware of Matrix's citalopram being sold on a market in the EEA (Denmark) in June 2002. See recital (153) above. See also ID 5394, page 163.

⁸⁹⁸ ID 5394, page 166.

⁸⁹⁹ ID 5394, pages 166-167 and page 222. It should be noted that in the Lagap litigation, Lundbeck initially made a similar argument [...]*, After the inspection of Matrix's process, however, Lundbeck withdrew this argument. Lagap's expert stated in that case that *"Some of [Lundbeck's allegations], in particular those concerning so called "fingerprints" for purification methods, are highly flawed..."* See recitals (156), (158) and (160) above.

⁹⁰⁰ ID 5394, pages 171-172.

(482) On 17 September 2001, Alpharma sent Tiefenbacher an e-mail stating:

*"We have not had the opportunity to review the route of synthesis for the Cipla API or the other alternative source which you have yet to name to us. We need to do this to assure ourselves that there is no risk of patent infringement."*⁹⁰¹

One day later, on 18 September 2001, Tiefenbacher replied:

"- the process of Cipla as well as the other supplier follows exactly the route described in the basic patent, UK 1526331, priority date January 14, 1976 and its family members like DE 2657013, F 7701079 etc. This was double-checked by patent attorneys and confirmed by the impurities that are found in the a.m. sources.

- we are also aware of the fact that a lot of additional patents and applications cover several routes of synthesis and intermediates, e.g. EP 171943, WO 01/02383, WO 98/19511, WO 98/19512, WO 98/19513, WO 00/13648, WO 00/11926, WO 99/30548, etc. etc. None of them leads to infringement by the process used by our suppliers.

*- furthermore, we are aware of the fact that several patents and applications cover the purification of Citalopram, e.g. GB 2 356 199, GB 2 357 762 and the corresponding national family members. We are concerned about some of the claims of the latter one, and will immediately take legal action against it in case they are granted."*⁹⁰²

(483) On 24 September 2001 Alpharma ordered a first stock of citalopram tablets from Tiefenbacher, to be delivered by 16 November 2001.⁹⁰³ Orders for more tablets followed on 11 December 2001 and 29 January 2002.⁹⁰⁴ These orders did not mention the producer of the API.

(484) Lundbeck later explained to the Commission that *"In September 2001, Lundbeck had seen evidence that Alpharma may attempt to enter in the Netherlands as early as January 2002, apparently based on a "licence" obtained from Tiefenbacher."*⁹⁰⁵

(485) An internal Alpharma document of 11 October 2001 indicates that Alpharma had the following expectations with respect to marketing authorisations and launch dates for its generic citalopram in EEA Contracting Parties:

⁹⁰¹ ID 4817, page 245.

⁹⁰² ID 4817, pages 243-244. See recital (151) above. Tiefenbacher was one of the companies that filed opposition before the EPO.

⁹⁰³ ID 8, page 278.

⁹⁰⁴ ID 8, pages 279-280.

⁹⁰⁵ ID 823, page 24.

"

	<i>AT</i>	<i>DK</i>	<i>FI</i>	<i>DE</i>	<i>NL</i>	<i>NO</i>	<i>SE</i>	<i>UK</i>
<i>Patent expiry</i>	04-03	01-02	01-02	- 94	01-02	01-02	12-01	01-02
<i>MA est</i>	03-02	02-02	02-02	04-02	<i>Appr</i>	02-02	02-02	02-02
<i>Launch Target</i>	-	03-02	05-02	04-02	01-02	04-02	03-02	02-02

"⁹⁰⁶

For all these countries together, plus Portugal, Alparma expected citalopram sales in 2002 of USD 3.8 million (approximately EUR 4 million).⁹⁰⁷

- (486) An e-mail of Lundbeck's [employee function]* dated 6 November 2001 shows that Lundbeck had apparently obtained copies of parts of Cipla's DMF. A Cipla document giving a brief outline of the process used by Cipla stated: "*Crude citalopram base is crystallised to get pure citalopram base.*"⁹⁰⁸ On or around the same date, Lundbeck also obtained a copy of Matrix's DMF, which stated that "*Citalopram base of batch No. RD006/0101 was crystallized twice in Iso propyl alcohol and Methanol and prepared Citalopram Hydrobromide by using aq.HBr in Isopropylalcohol.*"⁹⁰⁹ According to Lundbeck, this DMF had served as the basis for the marketing authorisation granted in the Netherlands on August 31, 2001.⁹¹⁰
- (487) On 15 November 2001, Tiefenbacher prepared an analysis of the patents and patent applications Lundbeck had mentioned in its general warning letter to API producers and to certain generic suppliers in January 2001.⁹¹¹ For Lundbeck's crystallisation utility model in the Netherlands (NL 1016435), which had been granted on 6 November 2000, and the corresponding application in the United Kingdom (GB2357762), Tiefenbacher concluded: "*Describes the production of high purity Citalopram through the crystallisation of the base. In principle not applicable, as in our processes the base is not crystallised, but the product is cleaned through re-crystallisation of the hydrobromide. But: in some writings, protection for the production of high purity citalopram (>99.8%) is filed for. Will be monitored.*"⁹¹²

⁹⁰⁶ ID 1595, page 2. Another internal Alparma document of the same date estimated the launch in Finland in March 2002 (rather than May 2002) and the launch in Norway in March 2002 (rather than April 2002). See ID 1596, page 7.

⁹⁰⁷ Using an annual exchange rate for 2002 of 1 EUR = 0.9456 USD, source European Central Bank. See ID 1595, pages 1 and 15.

⁹⁰⁸ ID 5439, page 5. In its reply to the Statement of Objections, Lundbeck argued that this statement of Cipla confirmed "*beyond any reasonable doubt that the process used by Cipla infringed the Crystallization Patent.*" For Cipla's analysis, see recital (510) below.

⁹⁰⁹ ID 5394, page 172.

⁹¹⁰ ID 5394, page 172.

⁹¹¹ See recitals (148) and (225) above.

⁹¹² ID 673, page 174, translation from German. The original German text uses the word "*Umkristallisation*". Tiefenbacher sent this analysis to Merck dura, one of its other clients, but it is unclear whether Alparma also received it. See recital (248) above.

(488) An internal Lundbeck e-mail of 4 December 2001 shows that Lundbeck expected Alpharma to launch a generic version of citalopram in Denmark by mid-February 2002.⁹¹³

(489) An internal e-mail from Alpharma's Dutch subsidiary reported on 21 December 2001 that Lundbeck had failed in its attempt in the Netherlands to obtain an interim injunction against the prospective launch of generic citalopram products from Tiefenbacher. The Dutch subsidiary expected to be able to launch generic citalopram in the Netherlands in the first or second week of February 2002.⁹¹⁴

(490) Another internal Alpharma e-mail of 21 December 2001 reported on the approval process for marketing authorisations:

*"We just got the approval for Citalopram in the Concerned Member States (CMS), and I have enclosed the email from Tiefenbacher with the approved SmPC below. Our regulatory people now work hard to get the papers into the local authorities today. We hopefully can launch in most countries no later than February, hopefully earlier in Sweden, where the patent has expired and in the big UK market, but that is down to supply and logistics."*⁹¹⁵

(491) On 9 January 2002 Lundbeck received the following information from an informed market player in the United Kingdom regarding Alpharma's planned launch there:

"Alpharma...have verbal confirmation of a citalopram licence for all strengths. It would have been granted by now but due to the current train strike not all the relevant individuals have been available in the MCA.

Alpharma's current delivery date is 14.01.02.

This is a complete surprise to the rest of the generic industry all who thought Generics UK (GUK) were the front runner to launch mid to end of January.

....

The open part of Alpharma DMF is confirmed as Tiefenbacher although the closed part is not currently known.

The current prices being offered to generic distributors are relatively high at:

	<u>Alpharma</u>	<u>Wholesaler price</u>	<u>Current NHS price</u>
<i>citalopram</i>	<i>10mg £6.96</i>	<i>£8.44</i>	<i>£9.64</i>
	<i>20mg £10.90</i>	<i>£14.02</i>	<i>£16.03</i>
	<i>40mg £19.57</i>	<i>£23.71</i>	<i>£27.10</i>

[market player] believes that the margin per pack for each supplier will be £1.50 per pack which means that the price to the retailer for 20mg will be £12.40. This

⁹¹³ ID 848, page 53.

⁹¹⁴ ID 4817, pages 232-233.

⁹¹⁵ ID 4817, page 231.

*compares with the current market price for parallel import which is £13.00 average price.*⁹¹⁶

- (492) On 17 January 2002, an internal Lundbeck e-mail stated:

"Just to show that Alpharma are expecting to launch imminent [in the UK] I attach a copy of their latest price list with citalopram on!

The prices are fairly high which would indicate that they only have limited supply.

Further [Merck (GUK)] today mentioned that Alpharma today had informed some of their customers that "due to an injunction" they could not deliver citalopram as promised. We do not believe that they have received their licence yet."⁹¹⁷

The attached official price list of Alpharma indicated *"Offer Prices available from 1 February 2002 – 28 February 2002."* The prices for a pack of 28 citalopram tablets were: 10 mg - £8.19, 20mg – £12.82 and 40 mg £23.08. These were prices at retail level.⁹¹⁸

- (493) On 18 January 2002, Lundbeck's lawyers wrote to two Queen's Counsels in the United Kingdom to retain their services to *"prepare for and appear in an application for an interim injunction"* against Alpharma, Tiefenbacher, Omega and Arrow.⁹¹⁹

- (494) On 21 January 2002, Alpharma's Dutch subsidiary reported to the [employee function]* of Alpharma ApS:

"We have received information of Lundbeck's lawyer that the process patents NL 1016435 (granted 6 nov. 2000) and NL 1017413 (granted 13 sept. 2001) are valid for 6 years after grant date and that our product (of Tiefenbacher) uses material which could be affected by those two patents.

They state these two patents describe the recrystallisation to 'clean' the citalopram base by precipitation of its crystalline form whereafter it is transformed into a salt f.e. the hydrobromide or hydrochloride salt and that it is likely we have used this route in synthesis of the active ingredient (they say especially as described under conclusion point 5, 7 and 9 of the NL 1016435 and point 1, 2, 3, 4, 9 of the NL 1017413."⁹²⁰

- (495) Also on 21 January 2002, an internal Alpharma e-mail from [employee function]* of Alpharma ApS reported:

"Subject: Lundbeck

⁹¹⁶ ID 904, pages 151-152. This shows that Alpharma intended to launch generic citalopram in the United Kingdom market with an initial price at retail level that would be slightly below the retail price level of parallel imports of Lundbeck's own citalopram. However, because of Lundbeck's appeal against the Dutch marketing authorisation, Alpharma's United Kingdom marketing authorisation was in fact delayed until 26 July 2002. See recital (540) below.

⁹¹⁷ ID 682, page 127.

⁹¹⁸ ID 682, page 128. Compare the official Alpharma price of £12.82 for a pack of 28 tablets of 20mg with the price of £12.40 estimated on 9 January 2002, see recital (491) above. It appears that, if Alpharma were to become the first generic undertaking to enter the United Kingdom citalopram market, it wanted its initial price to be just below the parallel import price level of £13.00 at retail level. This would provide sufficient incentive to pharmacists to buy the product from Alpharma, while maximising profits for Alpharma.

⁹¹⁹ ID 5477.

⁹²⁰ ID 4817, pages 219-220.

Have just had the US on the line...Apart from [initials], none of them is particularly keen on a deal – in any case, not unless there is significant advantage for us. [initials] thinks that things can be done legally, but he obviously needs details. We therefore agreed on the following (which resembles what we talked about).

Have another meeting/discussion and say that, in principle, we might be willing to discuss matters, but that we need more facts.

Flag up what we see as two or three possibilities:

a) only dollars for example, as we said 18-20;

b) combination of dollars and rights to a licence in Europe;

c) combination of dollars, licence rights in Europe and early entry to [third country].

If matters are taken further, [initials] will act very fast and have our legal position settled by means of a contract.

It will be very interesting to hear what they have to say."⁹²¹

(496) On 22 January 2002 Lundbeck's external lawyers sent a detailed warning letter to Alpharma alleging that if Alpharma were "*in the very near future*" to offer a generic citalopram hydrobromide product in the United Kingdom for sale, this would infringe Lundbeck's patents GB 2357762 (the crystallisation patent, to be granted on 30 January 2002) and GB 2356199: Production of citalopram in pure form, by cyanide exchange (the film distillation patent).⁹²² The letter stated, in particular: "*On this basis, we have advised our client that your citalopram hydrobromide product has been manufactured by the process of at least claim 1 of UK patent 2 357 762...*".⁹²³ The letter threatened an interim injunction. In its reply to the Statement of Objections Lundbeck stated that the allegations of infringement in this letter were based on several analyses Lundbeck had performed of Cipla-sourced citalopram between July 2001 and January 2002.⁹²⁴

(497) Also on 22 January 2002, the Dutch subsidiary of Alpharma reported that Dutch wholesalers had received letters of awareness from Lundbeck, which would "*disturb our sales introduction*."⁹²⁵ The Dutch subsidiary also reported:

*"I then spoke to [another generic company in the Netherlands], they received last week a letter of consciousness...They could inform me that [employee of the other generic company] first was told by [employee of Tiefenbacher] that there was no problem and they were aware of it. Yesterday (or so) however [employee of Tiefenbacher] informed them there is a problem with this two patents and the product is infringing."*⁹²⁶

(498) On 23 January 2002, at 11.08 hours in the morning, Alpharma's Dutch subsidiary reported the following:

⁹²¹ ID 4817, pages 217-218 (translation from Danish).

⁹²² ID 1004, page 304. With respect to United Kingdom patent 2356199, Tiefenbacher considered that neither Cipla nor Matrix used the process described in this patent, see recital (382) above.

⁹²³ It may be recalled that claim 1 of the corresponding patent at the EPO level was later deleted from the amended claims which were eventually upheld by the EPO in 2009. See recital (166) above.

⁹²⁴ See recital (481) above.

⁹²⁵ ID 4817, page 207.

⁹²⁶ ID 4817, page 215.

*"...this is to confirm the chosen strategy: we will today cancel the planned blisterpacking for NL at Dragenopharm (planned for Monday next). [Alpharma employee] can thus use the bulk for UK. Novartis phoned this morning&will object the NL patent. They offered to combine with Hexal. It is decided that Alpharma start own procedure...We keep of course in contact with the others. Same time I will follow up with Pharmachemie. I can offer this product to them, where Pharmachemie act as a distributor for us. They have 30% market share. We pack under private label&MA holder Alpharma b.v. printed on their packs. I keep you posted on this issue and will of course need [Alpharma employee]'s help later on for quick supply of bulk for us and hopefully Pharmachemie."*⁹²⁷

The reply of the [employee function]* of Alpharma ApS of the same morning was:

"Thank for the confirmation of our telephone conversation. Planning (SC) now need to see how the product freed up in NL can be applied elsewhere (UK, Scandinavia). Regarding the legal challenges by Lundbeck I expect that we will see the same in all countries (not just in NL) and I assume that [[employee function] of Alpharma ApS] will initiate the necessary measures to deal with them and keep the other countries updated on the developments."*⁹²⁸

In reaction to this, Alpharma UK replied at 13.00 hours of the same day:

*"Just to re-iterate that UK are very hungry for stock after a successful pre-sell."*⁹²⁹

- (499) At 11.26 hours of 23 January 2002, another string of internal Alpharma e-mails reported:

"Alpharma Holland...called me just now to tell me that they can't launch as planned for patent reasons. A new patent has been granted in Holland and is valid until 2006. However, they say it looks if the patent could be fought but this could take maybe 3 months. Therefore, they have to wait with the launch.

They said you can dispose of their quantities for the UK. The bulk was airshipped to Dragenopharm last Sunday. Therefore, it should have arrived at Dragenopharm meanwhile. The bulk is not yet packed. Therefore, if you need product to be packed for the UK, this would be your quickest option....

Of course, Alpharma Holland would most likely need product later if the patent falls. Therefore you could take their quantities and you give them the same quantities from your April shipment...

Concerning the patent itself, [employee of Alpharma's Dutch subsidiary] told me that it was applied for also in other EU countries but for the time being only granted in Holland. She has already informed [[employee function] of Alpharma ApS] as well. Hopefully, none of us will be affected also."*⁹³⁰

- (500) Another e-mail of Alpharma's Dutch subsidiary, sent at 13.10 hours of 23 January 2002 stated:

"Meantime I have phoned with Multipharma...: we will start our own procedure to try to invalidate the patents as will Hexal and Multipharma, but with close contacts

⁹²⁷ ID 4817, pages 199-200.

⁹²⁸ ID 4817, page 199.

⁹²⁹ ID 4817, page 199.

⁹³⁰ ID 4817, page 175.

*between the companies about the strategy (so we gain strength and harmonise our defence against Lundbeck)."*⁹³¹

- (501) At 15.41 hours of 23 January 2002, an e-mail from the Dutch Alparma subsidiary reported about a contact with Tiefenbacher:

*"Tiefenbacher...have contacted me about the patent issues. They informed me they were surprised by these two Dutch national ones, not having those checked as it were utility patents which are not proved on submission/granting by experts of the patent office. The[y] knew about the world patent application of these two, but he informed me experts had already a lot of comments and criticisms on those two so it was not likely they would be granted."*⁹³²

- (502) At 16.26 hours of 23 January 2002, an e-mail from [employee function]* of Alparma ApS stated:

"Lundbeck is getting more aggressive, as you probably all know, and I have spoken to [employee function at Alparma] to prepare our self for the future. Alparma B.V. is handling the case well in Holland through lawyer, but we need to address the situation in all other markets. Tiefenbacher [sic] is doing what they can, but we need to make arrangement for our own safety in the other countries. We might not need it, but I think its very prudent to have...We need to address defence strategy, cost and choice of counsellors, a.o.b."*⁹³³

In a response of 24 January 2002, the United Kingdom subsidiary of Alparma asked:

*"The U.K. Marketing Authority is expected to be granted early next week, please advise that once received, UK can proceed to sell/despach product??"*⁹³⁴

The answer of Alparma ApS of 24 January 2002, at 12.35 hours, was:

*"We cannot give a clear cut answer to your question today. We will come back as soon as we have any result of our investigations."*⁹³⁵

- (503) Another internal Alparma e-mail of 23 January 2002 reported as follows regarding the application for a marketing authorisation in the United Kingdom, following a conversation with the Medicines Control Agency:

*"Licence application proceeding well, we remain positive that we will still be the first Generic Company to launch...we know for fact, that no other licence has yet been awarded...I am optimistic of launching next week."*⁹³⁶

- (504) On 24 January 2002, the [employee function]* of Alparma ApS wrote the following to Tiefenbacher:

"I am sure, that you know all the Patents and Patent applications on Citalopram by heart, and will contribute to the defence of your own product. We, at Alparma on the other hand, cannot sit back and wait for the inevitable request for Injunctions

⁹³¹ ID 4817, page 196.

⁹³² ID 4817, page 194.

⁹³³ ID 4817, page 179.

⁹³⁴ ID 4817, page 178.

⁹³⁵ ID 4817, page 177.

⁹³⁶ ID 4817, page 193.

from Lundbeck. We need to prepare our own defence strategy. In order to do so, we will need the full and detailed route of synthesis for the Citalopram API.

*I am afraid I will have to insist on it, as I can hardly see any other option. The exception would be if Tiefenbacher would do all the legal battling on behalf of Alpharma, and that would be outside any contractual obligation. I fully understand why you have been reluctant to hand out the detailed information up until now, but our further defence work will be impossible, unless we have the information."*⁹³⁷

- (505) In response a couple of hours later, Tiefenbacher sent Alpharma *"our overview on the patent situation concerning Cipla's citalopram."* This document, which is not in the Commission's case file, is likely to have been an updated version of the patent overview document which Tiefenbacher had sent to Merck dura in November 2001.⁹³⁸ At the Commission's request, Tiefenbacher sent the Commission a document dated 8 February 2002 and entitled "Patent Overview Citalopram". This document, which according to Tiefenbacher is likely to be very similar to the one Alpharma received two weeks earlier from Tiefenbacher⁹³⁹, briefly analysed each of the Lundbeck's patents known to Cipla or Tiefenbacher. On the crystallisation patent, the document stated:

"Preparation of very pure Citalopram hydrobromide via crystallisation of the free base. However, claim 11 protects Citalopram hydrobromide with >99.8% purity without stating how it was obtained. This could be crucial because we might have the choice to infringe the patent or market AP/tablets with insufficient (= not "state of the art") purity. The applications are under investigation of our patent attorney.

Comment by Cipla:

The crystallisation of Citalopram free base is claimed (Claims 1,2).

In Cipla's process, the free base is obtained, not from the crude salt of mixture, but directly from the reaction work-up. Further, there is no step of 'initial purification' before the base is precipitated (claims 6, 7).

We do not practice claim 8&10.

Claim 9 is contingent on claims 1 to 8, which we do not practice.

Claim 13 is contingent on claim 12, which is contingent on claims 1 to 10, which we do not practice.

*Regarding claim 11, we feel that any repeated crystallisations even on material produced according to the basic patent would yield a product having a purity more than 99.8%. According to us it is very obvious for someone skilled in the art to develop and isolate pure Citalopram base by crystallisation."*⁹⁴⁰

⁹³⁷ ID 4817, page 169.

⁹³⁸ See recitals (248) and (487) above.

⁹³⁹ In its cover e-mail to the Commission, Tiefenbacher stated: *"I am sorry to inform you that we were not able to find the e-mail as such, but the pdf-file mentioned, dealing with the patent situation of Cipla's Citalopram. Although I would have preferred to have the e-mail to be 100% sure that the pdf-files (on file/sent) are identical, it can be assumed with reasonable safety that this is the attachment sent on 24.01.2002. No other version of this file could be found."* See ID 6486.

⁹⁴⁰ ID 6487, page 2. See also ID 6490. See also recital (510) below.

It should be noted that on October 18, 2001, Lundbeck had in fact filed an amended version of its patent application at the EPO, deleting claim 11 as referred to in this e-mail.⁹⁴¹

- (506) Later that same day, an internal Alparma e-mail of the [employee function]* of Alparma ApS reported:

*"Alparma UK have received a "letter of awareness" mentioning 2 patents. One of the patents are not likely to cause problems. The other one is actually an application to be granted 30 January...based on the same priority as the Dutch utility model [that is to say Lundbeck's crystallisation patent]... I have also spoken to Tiefenbacher, and they are still not willing to hand out the route of synthesis. They were quite open, besides that, and are willing to answer any specific questions related to the manufacturing process via Cipla in India (Cipla is the manufacture[r] of the API). It might very well be that we can seek the Lundbeck patent application invalidated without specific knowledge of the Cipla API process. Tiefenbacher strongly believe that they can invalidate the utility models and other applications related to that family. I too believe that. Further it is not possible to file for injunctions based on Utility models (has to do with the fact that they are non-examined)."*⁹⁴²

- (507) Another internal Alparma e-mail of the same day, 24 January 2002, reported that Alparma's subsidiaries in Norway and Denmark wanted more launch stock of citalopram. According to the report: *"If we can't find more goods for DK, they might have backorders already 1-2 months after launch. The reason for this is chain contracts which were received in December 2001, after launch orders were placed. DK expects to take 30% market share (volume). NO needs more goods because they this month have received positive signals from the largest pharmacy chain...Only the [name] contract is covered by launch stock."*⁹⁴³

- (508) An internal Alparma e-mail of the [employee function]* of Alparma ApS of 25 January 2002 stated:

"I have spoken to Alparma Holland this morning, and they don't intend to market Citalopram the first 2 months in NL, for strategic reasons. It might prove very difficult to sell in NL, because Wholesalers and Pharmacies are also threatened. This means that we don't have any infringement in NL. Novartis and Hexal together with Tiefenbacher, will be fighting the utility models in NL, and they will be clearing the path so to speak...I think our major efforts should be focused on UK and the Nordic countries, these are also, by far, the largest markets."

Later on, the same e-mail said:

⁹⁴¹ See ID 2773, page 4. Nevertheless, after having split off the product claims in a divisional, Lundbeck did obtain a patent on the crystalline form itself (EP 1 227 088). This patent was opposed before the EPO and subsequently revoked by the EPO (see recital (151) above), whereas Lundbeck's patent on the crystallisation process (EP 1169314) was significantly amended and the scope of its claims limited before the EPO. See recital (166) above. As for the British patent GB 2357762, this patent appears to have been granted with the product and pharmaceutical composition claims included.

⁹⁴² ID 4817, page 140. Lundbeck had utility models on the crystallisation process at least in Germany, Austria and the Netherlands. See recital (249) above and footnotes 226 and 390 above.

⁹⁴³ ID 4817, page 172.

*"My personal opinion, regarding the patent in question [that is to say Lundbeck's crystallisation patent], is that we shall go ahead and market our product. The patent is not likely to pass scrutiny on novelty and inventive step. I expect that they will end up, either with no patent or a very limited and narrow patent, which should not cause us problems. We do however need the supportive opinions of [external lawyers]. If they coincide, then I would recommend a "go ahead". We might loose and have to pay a limited damage fee, but not entering the market, could also lead to a significant loss."*⁹⁴⁴

(509) On 30 January 2002, an internal Lundbeck e-mail stated that Alpharma had obtained a marketing authorisation for Denmark.⁹⁴⁵ Alpharma had indeed obtained this marketing authorisation on 23 January 2002.⁹⁴⁶

(510) Also on 30 January 2002, Tiefenbacher sent Alpharma the following analysis by Cipla comparing its process with Lundbeck's crystallisation patent in the United Kingdom:

"We have studied the patent GB 2357762A. The patent claims the process for the manufacture of salt of Citalopram from crystalline citalopram base, which is isolated from crude salt of Citalopram or crude mixture of citalopram.

The experimental details show heptane as solvent used for the crystallisation of citalopram. In Cipla's method we do not isolate base from the isolated salt of citalopram but isolate crude citalopram base from aqueous acidic solutions of citalopram base by adjusting the pH with ammonia which is prior art and filtration of the precipitated product from water. This is crude citalopram base. This is the process described in the patent US 4136193 application date Jan. 1977. In this patent the base is an oil whereas we achieved solid by this process.

The crude solid base is then crystallised without using heptane as solvent. The pure citalopram base is then converted to the hydrobromide salt.

The patent describes a process to make citalopram base from crude mixtures of salts or crude mixture of base by first converting it into the salt eg sulphate, extracting the citalopram base by adjusting the pH with NaOH and extracting the base into toluene. The toluene solution is concentrated to give an oil which is dissolved in hot heptane and latter gradually cooled to give crystalline citalopram base.

*All the other claims in the patent especially claim 11 to 14 are based on the first two claims. Since they are contingent to claim 1 and 2 which we do not practice the purity of above 99.8% is specific to the methods described in this patent and should not be treated as generalised clai[m] for the product."*⁹⁴⁷

Tiefenbacher added to his:

⁹⁴⁴ ID 4817, pages 142-143.

⁹⁴⁵ ID 904, page 236.

⁹⁴⁶ ID 1244, page 21.

⁹⁴⁷ As mentioned in recital (151) above, Lundbeck's product claims on the crystalline base of citalopram as well as its claims regarding pharmaceutical compositions were later found by the EPO and the Dutch Industrial Property Office to lack novelty and therefore to be invalid. The United Kingdom crystallisation patent GB 2357762, however, was granted including these claims. This meant that the United Kingdom patent was on the one hand more likely to be infringed than without these claims, but on the other hand also more likely to be found at least partially invalid.

*"Please find also attached the claims of GB 2357762 B which has been granted today, as well as the examination and comments of the EPO for the corresponding EP application of Lundbeck. Based on this, we are a bit surprised that the national applications are granted so quickly. We are also quite confident that it will be possible to get rid of them due to lack of novelty."*⁹⁴⁸

- (511) On 31 January 2002, one day after its crystallisation patent had been granted in the United Kingdom, Lundbeck filed a patent infringement lawsuit in the United Kingdom High Court of Justice Chancery Division seeking an injunction against Alpharma's envisaged⁹⁴⁹ sale in the United Kingdom of products containing citalopram for allegedly infringing Lundbeck's patents GB 2356199 (the so-called film distillation patent) and GB 2357762 (the crystallisation patent). The claim was also directed against Omega Farma and Tiefenbacher.⁹⁵⁰ In the application, Lundbeck's head of chemistry stated in an expert witness statement on behalf of Lundbeck: *"Although we have as yet been unable to acquire any citalopram hydrobromide from the first defendant ("Alpharma"), either in the UK or (from its associated companies) elsewhere in Europe, we have been able to analyse material placed on the market elsewhere in Europe by other companies (such as Hexal) who are also believed to be sourced by the second defendant ("Tiefenbacher"). We believe the raw material for all of these products is to be produced in India by Cipla Limited. Such material has the fingerprints associated with the 2002-1 [cyanation] process, but at the reduced levels which are consistent to the best of my own knowledge only with purification using the processes disclosed in UK Patents 2 356 199 B and 2 357 762 B."*⁹⁵¹
- (512) An internal Lundbeck e-mail of 4 February 2002 reported that Alpharma expected to launch its own generic citalopram product in Norway between April and July 2002.⁹⁵²
- (513) An internal Lundbeck update on generic citalopram of 7 February 2002 reported: *"Alpharma deal is being negotiated – license for N, downpayment, consent to injunction in all EU + N."*⁹⁵³ An internal Lundbeck e-mail of 12 February 2002 indicates that Lundbeck was considering granting Alpharma a licence to sell Lundbeck citalopram in Norway, as part of a wider deal covering other, larger European markets.⁹⁵⁴
- (514) On 8 February 2002, Alpharma Inc.'s [employee function]* wrote in an internal Alpharma e-mail:

⁹⁴⁸ ID 4817, pages 107-108. See footnote 947 above.

⁹⁴⁹ ID 8, page 264. According to Actavis: *"as far as we are aware, ...no sales of citalopram were recorded by the Alpharma Human Generics Business prior to the conclusion of the Settlement Agreement on 22 February 2002."* See ID 746, page 13. According to Lundbeck, *"With Alpharma's launch imminent, Lundbeck sued Alpharma to obtain an injunction in the UK..."* See ID 823 page 24. In fact, Alpharma obtained a marketing authorisation in the United Kingdom only on 26 July 2002. See recital (168) above.

⁹⁵⁰ ID 1004, pages 382 to 427.

⁹⁵¹ ID 1004, page 415.

⁹⁵² ID 723, page 58.

⁹⁵³ ID 903, page 42.

⁹⁵⁴ ID 723, page 60.

*"In two weeks we should have a much better understanding of how strong our invalidity case is against the patent. Once we understand this, we can decide on a plan of action (some options we will consider are whether to launch in the face [of] the patent before the injunction hearing, approach Lundbeck for a license, wait until we have new supply)."*⁹⁵⁵

- (515) An internal Lundbeck e-mail of 14 February 2002 raised the question: *"Should we pursue the case against Alpharma in the UK even if we reach agreement with them?"*

The internal advice given by the head of the patent department was: *"I don't think we should pursue the injunction case to the end if we reach an agreement and if there is a risk that we might lose. In a few days we will have an overview of Alpharma's arguments. After that, we can assess what our chances are. If Alpharma don't mind losing and our chances of winning are good, it would be good for any subsequent cases if we were to win."*⁹⁵⁶

- (516) An internal Alpharma e-mail from the [employee function]* of Alpharma ApS of 14 February 2002 stated:

"Currently we are riding two horses:

*Planning the launch of citalopram for UK, DK, NL, D, S, N, Fin
Negotiating with Lundbeck*

*However, next week we probably have to make a decision. To make the best possible decision I will like to get a short description of the legal situation in each of the seven markets and the risk exposure we have: I.e. risk of injunction, strength of Lundbeck's patent, can Lundbeck demand damage compensation if they win a subsequent court case, likelihood that we can invalidate the patent, timelines..."*⁹⁵⁷

- (517) On 19 February 2002, an internal Alpharma e-mail sent to the [employee function]* of Alpharma ApS on the subject of *"the legal and patent-related situation regarding Citalopram in the seven launch countries"* stated:

*"With regard to injunctions, it is reasonably clear that Lundbeck will be able to seek similar measures in all the countries in order to prevent us from selling the product. They seem also to have shown an intention to use this to keep us out for as long as possible. We could, if need be, counter their action in the same way as in the UK but, as we know, that is a time-consuming and expensive process. If we started to sell the product, and their patent was valid, we would be liable to pay compensation. However, it would take a long time for liability to be demonstrated if, in our defence, we were to maintain that the patent was invalid. Moreover, it would in any event take a year for the case to be heard, and an appeal could be lodged. A final decision would not, therefore, be in place for a number of years. Worst case scenario: if we were to lose the case and we had been selling the product all that time, the compensation payable would of course be fairly substantial."*⁹⁵⁸

⁹⁵⁵ ID 4817, page 55.

⁹⁵⁶ ID 723, pages 15-16.

⁹⁵⁷ ID 4817, page 35.

⁹⁵⁸ ID 4817, page 26 (translation from Danish).

- (518) Later on the same day, 19 February 2002, an internal Alparma e-mail from the [employee function]* of Alparma ApS gave the following assessment of the situation:

"Currently we plan to launch Citalopram in UK, NL, DE, DK, NO, SE, FI within the next 2 – 6 weeks. However, the legal situation is complicated by the infringement of a key Lundbeck patent.

It is basically one family of patents, which Lundbeck currently are using in their defence of Cipramil. The name of the family is "Crystalline base of Citalopram", and it is present in one or more forms, in all HPI countries. The patent is already approved/granted in several countries in record time...

The product produced by Cipla (API) – Omega (tablets) – Tiefenbacher is, to the best of all knowledge, infringing on the Lundbeck patent. This is the product currently on stock in most of our affiliates. (Stocking would be considered infringement).

Lundbeck has applied for Preliminary Injunction in NL and UK, and is likely to do so in all countries where they get the patent approved (a prerequisite for injunction).

We are currently establishing defence in UK and NL. An injunction hearing is set for 26 March in London high court, and we have to submit our defence by 4 March. Our defence will be to convince the court that the Lundbeck patent is foreseeable and therefore none inventive. It is likely that we can avoid an injunction, and we have a reasonable case to win a case of invalidation of the Lundbeck patent.

It can be lengthy and probably costly, but we should be able to get a substantial part back in damage fee, if we win! On the other hand Lundbeck can claim substantial damage compensation if they win!!

The second API supplier Matrix is, also to the best of all knowledge, using a none infringing process and this API could be used without the risk of infringement. It would mean a lot of scrapping and launch delay of roughly 3-4 month.⁹⁵⁹

If we halt all launch activities now, to clarify the legal situation and launch later in the spring/summer with the non infringing API from Matrix, we will have lost the competitive (time) advantage we have by launching the next 2 – 6 weeks and we have scrappings of USD 2 million. This will significantly influence the business case which has an NPV of USD 10 million.

Our recommendation is to pursue a deal with Lundbeck if a reasonable settlement can be achieved serving our legal and commercial interests.⁹⁶⁰

- (519) On 20 February 2002 an internal Alparma e-mail proposed to add the following paragraph to the preamble of the draft agreement with Lundbeck:

⁹⁵⁹ In its reply to the Statement of Objections, Lundbeck stated that "It was only in April 2002 that Lundbeck learned for the first time that Matrix might claim a modification in its production process..." and "United Nordic Pharma's launch in the Danish market on June 14, 2002, was the first time when Lundbeck learned that Matrix-based citalopram had been launched on the market" and "Lundbeck obtained more information about Matrix's additional washing step only at the end of September 2002...". See ID 5394, page 163.

⁹⁶⁰ ID 4817, pages 22-23.

"WHEREAS, Lundbeck has agreed not to injunc [sic] or otherwise prosecute Alpharma for manufacturing, importing, selling, etc. Citalopram containing product after the termination of this contract."

The reason given for this proposal was that *"...I miss something stating that Lundbeck don't carry on with the same old argument after June 2003. If we for instance change to Matrix API and we are free of the Lundbeck patent, then I don't want to be dragged round the circus once more."*⁹⁶¹

This paragraph was not retained in the agreement as actually concluded with Lundbeck.

- (520) By the time Alpharma and Lundbeck entered into an agreement for the EEA on 22 February 2002, Alpharma had through Tiefenbacher obtained marketing authorisations for generic citalopram in the Netherlands (6 September 2001), Finland (21 January 2002), Denmark (23 January 2002) and Sweden (22 February 2002). After concluding the agreement with Lundbeck, and during its operation, Alpharma obtained again through Tiefenbacher further marketing authorisations in Norway (8 March 2002), Germany (18 April 2002), Austria (24 June 2002) and the United Kingdom (26 July 2002).⁹⁶²

7.6.2. *The agreement*

- (521) On 22 February 2002 H. Lundbeck A/S and Alpharma ApS concluded an agreement covering the Union and Norway for a period expiring on 30 June 2003.⁹⁶³ The preamble mentioned that Lundbeck believed that the production method used to produce Alpharma's citalopram infringed Lundbeck's patents rights, including in particular those listed in appendix A. This appendix listed for different European countries the national equivalents of Lundbeck's crystallisation patent (patent GB 2357762 in the United Kingdom) and of Lundbeck's patent for a process for the preparation of pure citalopram, by cyanide exchange; the film distillation patent (patent GB 2356199 in the United Kingdom).⁹⁶⁴
- (522) The preamble mentioned that *"Alpharma has manufactured, produced and/or purchased pharmaceutical products containing Citalopram with the intention of marketing such products in the Territory."* The *"Territory"* was defined as *"all EU countries, Norway and [third country]."* The preamble then stated that Lundbeck had performed laboratory analyses of Alpharma's citalopram and that the results of these laboratory analyses gave Lundbeck *"substantial reason to believe"* that the production methods used to produce Alpharma's products infringed Lundbeck's intellectual property rights. The preamble continued by saying that Lundbeck had started infringement proceedings against Alpharma in the United Kingdom and that Alpharma *"has acknowledged that the findings by Lundbeck are correct and has undertaken to refrain from marketing of such products"*. The preamble then said that

⁹⁶¹ ID 4817, page 12.

⁹⁶² ID 1244, page 21.

⁹⁶³ ID 8, pages 263 to 291.

⁹⁶⁴ Lundbeck explained in its reply to the Statement of Objections that film distillation removed different impurities than crystallisation of the free bases, so that theoretically it was possible for a manufacturing process to infringe both process patents. See ID 5394, footnote 14. Lundbeck also stated in its reply to the Statement of Objections that Lundbeck *"realized that it was possible for generic companies to design around the Film Distillation Patent"* and *"renounced enforcing that patent because it lent itself to invalidity claims."* See ID 5394, page 162.

"Lundbeck has agreed to compensate Alpharma in order for Lundbeck to avoid a costly and time-consuming patent litigation, the outcome of which cannot be predicted with absolute certainty" and "in order to settle the dispute Lundbeck has furthermore agreed to purchase all of Alpharma's stock of products containing Citalopram and to compensate Alpharma for such products."

- (523) In Article 1.1 of the agreement Alpharma ApS agreed to cease importing and selling *"pharmaceutical products containing Citalopram"* in the territory covered by the agreement for the duration of the agreement, including through any of its affiliates or through any third party (including any licensees). "Affiliate" was defined as *"any company which, directly or indirectly, controls or is controlled or is under common control"* with Alpharma ApS. Lundbeck, in return, agreed to dismiss the pending infringement lawsuit against Alpharma in the United Kingdom. Article 1.1 also provided that *"This Article 1.1 shall not apply to any product containing escitalopram."*
- (524) Article 1.2 stipulated that *"In the event of any breach of the obligation set forth in Article 1.1 or at the request of Lundbeck, Alpharma and Alpharma's Affiliates will voluntarily submit to an interim injunction by any competent court in any applicable country in the Territory. Lundbeck shall be entitled to obtain such injunction without providing any kind of security. Alpharma and Alpharma's Affiliates waives any confirmatory action pursuant to any law or regulation in any applicable country in the Territory relating to such injunction proceedings and shall upon request from Lundbeck sign any document necessary to obtain such injunctions."* The same Article provided that in the event of any wilful or negligent material breach of the obligation set forth in Article 1.1, Alpharma had to pay Lundbeck damages equal to the payments made by Lundbeck under this Agreement.
- (525) Article 1.3 provided that *"As compensation for Alpharma's obligations set forth in this Agreement and in order for Lundbeck to avoid the cost and time of litigation, Lundbeck shall pay to Alpharma USD 12 million (USD 12,000,000.00), of which USD 11 million (USD 11,000,000.00) shall be for Alpharma's products containing Citalopram."* This amount would be paid in three instalments of USD 4 million each, on 31 March 2002, 31 December 2002 and 30 June 2003 respectively, subject to Lundbeck receiving a copy of Alpharma's marketing authorisation for the United Kingdom.
- (526) Lundbeck later explained to the Commission that *"Under the agreement with Alpharma, and in lieu of any damages that might be available to Alpharma in the event that its citalopram products were not infringing, Lundbeck provided Alpharma with \$12 million - \$11 million of which was payment for Alpharma's stock of products containing citalopram."*⁹⁶⁵
- (527) In article 2.2 Alpharma agreed to deliver, not later than 31 March 2002, its entire current stock of products containing citalopram (specified as *"approximately 25,400,000 tablets"*) to Lundbeck. Of this total number of tablets, 9,400,000 were

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ID 823, page 24.

already in Alpharma's possession, whereas the rest was on order. The tablets already received by Alpharma were stocked in the United Kingdom and Sweden.⁹⁶⁶

- (528) Appendix A to the agreement listed a number of Lundbeck patent applications and patents in the different countries covered by the agreement. Appendix B listed the product specifications of the Alpharma tablets and Appendix C listed Alpharma's purchase orders. The tablets in question had been produced by Omega Farma in Iceland for Tiefenbacher. The documents did not indicate whether the API came from Matrix or Cipla. Appendix C also contained a "*Citalopram tablets status report*" of Alpharma which indicates that Alpharma paid EUR 3.7 million for the 25.4 million tablets which Lundbeck purchased for USD 11 million (EUR 11.6 million).⁹⁶⁷ This shows that Lundbeck paid Alpharma roughly the expected resale value of the tablets in the market, not the purchase cost.⁹⁶⁸

7.6.3. Events during the implementation of the agreement

- (529) In the evening of 22 February 2002, the day the agreement with Lundbeck was signed, Alpharma informed its external counsel that "*we will withdraw from the case against Lundbeck.*"⁹⁶⁹
- (530) A Lundbeck internal e-mail of 23 February 2002 indicates that Lundbeck expected Alpharma and Arrow to receive a marketing authorisation for generic citalopram in the United Kingdom in the next couple of days. This e-mail also stated: "*Of course our fear is that a third and a fourth company will also receive a registration at the same time. If this is the case we will take legal action and sue for patent infringement on the spot – our problem will be how to find out if anybody has received registration. (The one company that we fear most is Lagab [sic]).*"⁹⁷⁰ Another internal Lundbeck e-mail of the same date reported that according to Lundbeck's information Alpharma had received a marketing authorisation in Sweden on 22 February 2002.⁹⁷¹
- (531) On 13 March 2002, the United Kingdom Patents Court, at the request of Tiefenbacher and Omega, struck out a claim of joint tortfeasance Lundbeck had against these two companies as part of the infringement proceedings initiated on 31 January 2002. According to the United Kingdom judge, who noted that Lundbeck had settled with the first defendant, Alpharma: "*...the patents granted in this country*

⁹⁶⁶ ID 8, page 277. In its reply to the Statement of Objections, Lundbeck stated: "*...had Lundbeck wished to market the tablets, it could not have done so since the Agreement did not provide for Alpharma to transfer its MA to Lundbeck.*" See ID 5394, page 232.

⁹⁶⁷ Using an average annual exchange rate for 2002 of 1 EUR = 0.94557 USD, source European Central Bank. See ID 8, page 277.

⁹⁶⁸ See also ID 681, page 42. In this internal e-mail of 18 April 2002 Lundbeck calculated the value, based on cost prices, of 16 million tablets which had been ordered by Alpharma, but not yet delivered to Lundbeck, at approximately USD 2.3 million. If one compares this figure to the figure of USD 11 million Lundbeck agreed to pay for 25.4 million Alpharma tablets, then it confirms that Lundbeck paid to Alpharma the resale value in the market of those tablets and not the cost price. After all, if 16 million tablets have a cost price of USD 2.3 million, then 25.4 million tablets would have a cost price of approximately USD 3.7 million, not USD 11 million. Indeed, using the price in the agreement, the resale value of 16 million tablets was USD 6.9 million (16/25.4 times USD 11 million), which is exactly three times the cost price of USD 2.3 million. See also ID 904, page 172.

⁹⁶⁹ ID 4817, page 289.

⁹⁷⁰ ID 904, page 182.

⁹⁷¹ ID 681, page 147. See also recital (520) above.

*only have national effect. We cannot stop importers into this country from going to get their stocks or supplies from sources outside this jurisdiction...In my view, there is nothing on the pleadings which goes any way beyond showing, at the most, that the Second and Third Defendants are knowingly assisting the First Defendant in importing into the United Kingdom. In my view, this is not an arguable case of joint tortfeasance...."*⁹⁷²

- (532) Also on 13 March 2002, an e-mail exchange between Lundbeck and external legal counsel identified Lagap as *"the potential new defendant"* in the United Kingdom.⁹⁷³
- (533) An e-mail of 22 March 2002 from Alparma to Lundbeck reported the delivery of over 6 million Alparma citalopram tablets to Lundbeck on 21 March 2002.⁹⁷⁴
- (534) An internal Lundbeck e-mail of 25 March 2002 mentions that Lundbeck made a payment of USD 2 million to Alparma and that USD 2 more million were still to be paid.⁹⁷⁵
- (535) By 4 April 2002, Alparma had delivered a total of 8.5 million tablets to Lundbeck.⁹⁷⁶
- (536) By the middle of April 2002, Lundbeck and Alparma agreed to enter into a consent order under which the judge would rule *"that all further proceedings in this claim be stayed"* taking into account that Alparma had agreed to refrain from importing, making or selling *"pharmaceutical products containing citalopram made utilising any of the processes claimed under GB patents 2 357 762 B and GB 2 356 199 B or any equivalent patent granted or applied for in relation to any of the Relevant Territories..."*.⁹⁷⁷ As Lundbeck later explained to the Commission, *"In UK civil litigation, a consent order merely records an agreement reached between the parties...the consent order...was designed to give Lundbeck the means to enforce the Alparma Agreement. The consent order enabled Lundbeck, as claimant, to enforce the undertakings given by Alparma without the need to commence a fresh action. Under English law, had Alparma breached this consent order, it would have been liable for contempt of court. Moreover, Lundbeck could have immediately obtained a preliminary injunction against Alparma. Therefore, Lundbeck would have enforced the consent order, rather than the Agreement, in case of breach by Alparma of its undertakings."*⁹⁷⁸ Parties agreed that Lundbeck would only be entitled to enforce the consent order if Lundbeck had complied with its (payment) obligations in the agreement.⁹⁷⁹
- (537) On May 1, 2002, Tiefenbacher applied for a type I variation of its marketing authorisation in the Netherlands, the Reference Member State, to include Matrix's

⁹⁷² ID 5449, page 4.

⁹⁷³ ID 5480.

⁹⁷⁴ ID 681, page 32 and ID 684.

⁹⁷⁵ ID 904, page 155. See also ID 681, pages 34-35.

⁹⁷⁶ ID 688.

⁹⁷⁷ ID 396, pages 175 to 181. This wording in the draft consent order had been drawn up by the parties themselves. In this kind of consent order, a so-called Tomlin order, parties can keep the precise terms of their agreement, including in this case the payment from Lundbeck to Alparma, confidential. Also, the terms of the agreement can include matters outside of the jurisdiction of the court or the scope of the case in hand.

⁹⁷⁸ ID 5394, pages 231-232.

⁹⁷⁹ ID 396, pages 175 to 181.

new washing process.⁹⁸⁰ Lundbeck stated in its reply to the Statement of Objections that Tiefenbacher obtained this type I variation to its MA in the Netherlands on 16 July 2002.

- (538) On 2 May 2002, the High Court of Justice, Chancery Division, Patents Court granted upon the application of the parties a consent order to stay all further proceedings in Lundbeck's infringement claim, subject to Alpharma's contractual commitment to Lundbeck (without undertaking the same to the court) to desist until 30 June 2003 from importing or selling in all Union countries and Norway *"pharmaceutical products containing citalopram made utilizing any of the processes claimed under GB patents 2 357 762 B and GB 2 356 199 B or any equivalent patent granted or applied for in relation to any Relevant Territories."*⁹⁸¹ Moreover, according to a contemporaneous Lundbeck document: *"As to the infringement case against Tiefenbacher and Omega, the judge in view of the settlement with the primary defendant, i.e. Alpharma, dismissed the case."*⁹⁸²
- (539) By 26 June 2002, Alpharma had delivered a total of 22.4 million tablets to Lundbeck.⁹⁸³
- (540) On 26 July 2002, Alpharma received a United Kingdom marketing authorisation for the distribution of citalopram tablets of 10, 20 and 40mg.⁹⁸⁴
- (541) On 9 August 2002, Lundbeck ordered the tablets it had received from Alpharma to be destroyed.⁹⁸⁵
- (542) In September 2002, the type I variation to cover Cipla's patent free purification method (the Cipla II process) was submitted in the Netherlands and approved two and a half months later.⁹⁸⁶
- (543) An e-mail exchange between Lundbeck and Alpharma of 7 November 2002 shows that Lundbeck asked Alpharma whether part of the tablets which had been on order at the time of conclusion of the agreement with Lundbeck and which were supplied to Alpharma by Tiefenbacher and then supplied from Alpharma to Lundbeck, were "Matrix new", thereby referring to the Matrix II process.⁹⁸⁷
- (544) On 18 November 2002, Lundbeck wrote to Alpharma saying that it had still not received 3 million tablets (out of the agreed total of 25.4 million tablets, which should have been supplied to Lundbeck not later than 31 March 2002) and would, if no further deliveries were received, hence reduce the purchase price of USD 11 million with USD 1.3 million. This correction would be made with the second

⁹⁸⁰ ID 5420.

⁹⁸¹ ID 1004, pages 447-448. See also ID 723, page 89.

⁹⁸² ID 846, page 47. See recital (531) above.

⁹⁸³ ID 904, pages 149-150.

⁹⁸⁴ ID 682, page 4.

⁹⁸⁵ ID 681, page 25. This instruction was repeated on 26 November 2002. See ID 683, page 64. See also ID 682, page 1.

⁹⁸⁶ ID 1713, page 1.

⁹⁸⁷ In fact, Lundbeck stated in the e-mail: *"I'm going on the basis that it is the Matrix new."* Alpharma replied that it would deliver 1.4 million tablets. See ID 681, page 53. See also ID 6782, page 9.

instalment payment, the due date of which was 31 December 2002.⁹⁸⁸ Alpharma did actually make at least one further delivery (which was also destroyed).⁹⁸⁹

- (545) On 13 December 2002 Lundbeck wrote to Alpharma saying that, based on the total number of tablets received until then (23.3 million tablets instead of the agreed 25.4 million tablets), it would withhold USD 900 000 from the agreed USD 11 million for Alpharma's stock of citalopram.⁹⁹⁰ This deduction was made to the second instalment payment which was due on 31 December 2002.⁹⁹¹
- (546) The third and last instalment of USD 4 million was paid by Lundbeck towards the end of June 2003.⁹⁹² The agreement expired as foreseen on 30 June 2003. It was not extended.
- (547) In total, over the entire period of operation of the agreement from 22 February 2002 to 30 June 2003, Lundbeck transferred a value to Alpharma of USD 11.1 million (corresponding to approximately EUR 11.7 million)⁹⁹³ under the agreement regarding the EEA, consisting of:
- USD 10.1 million for Alpharma's stock;
 - USD 1 million for Lundbeck's saved litigation costs.

7.6.4. Subsequent events

- (548) After the expiry of the agreement with Lundbeck, Alpharma started selling citalopram in the EEA, beginning with Germany in August 2003.⁹⁹⁴ Sales in the Netherlands started in October 2003⁹⁹⁵. The United Kingdom followed in April 2004⁹⁹⁶, Denmark in July 2004, Finland in August 2004⁹⁹⁷ and Sweden and Norway in July 2005.⁹⁹⁸ Those sales appear to have been made with Matrix product.⁹⁹⁹ None of these sales were subject to infringement litigation by Lundbeck.¹⁰⁰⁰

⁹⁸⁸ ID 904, page 239.

⁹⁸⁹ ID 682, page 1.

⁹⁹⁰ ID 1224, page 1.

⁹⁹¹ ID 904, pages 237 and 241, ID 723, page 82.

⁹⁹² ID 723, page 82.

⁹⁹³ Using an average annual exchange rate for 2002 of 1 EUR = 0.94557 USD, source European Central Bank.

⁹⁹⁴ ID 746, page 13.

⁹⁹⁵ ID 1244, page 4.

⁹⁹⁶ ID 2616.

⁹⁹⁷ ID 1244, page 4.

⁹⁹⁸ ID 1244, page 4. This information is based on data provided by Actavis. According to the sales information provided by Xellia Pharmaceuticals, Alpharma's sales of generic citalopram in Norway started in October 2004. See ID 1226, page 1.

⁹⁹⁹ ID 746, pages 241 to 267. This would have been Matrix product produced with the new and process including the washing step. In its reply to the Statement of Objections, Lundbeck stated: "*Alpharma started selling in the UK only in April 2004, and launched even later in other EEA countries, presumably because of fear of preliminary injunctions.*" However, Lundbeck also stated in the same reply: "*Alpharma encountered, at the time, difficulties to supply itself with API because Tiefenbacher refused to maintain commercial relations with Alpharma following the latter's admission that Tiefenbacher's Cipla-based products infringed Lundbeck's patents.*" See ID 5394, page 233.

¹⁰⁰⁰ ID 823, page 36.

7.7. Lundbeck's agreement with Ranbaxy regarding the EEA

7.7.1. The negotiation of the agreement

- (549) On 11 January 2001, Lundbeck wrote a warning letter to Ranbaxy in India saying it was aware that Ranbaxy was developing a process for the manufacture of citalopram and pointing out that Lundbeck had a large portfolio of patents relating to the preparation of citalopram.¹⁰⁰¹
- (550) In February 2001, Ranbaxy and Lundbeck opened discussions on the idea that Lundbeck might buy citalopram supplies from Ranbaxy.¹⁰⁰²
- (551) By May 2001, following a Ranbaxy visit to Lundbeck, the discussions had advanced to the stage where Ranbaxy asked Lundbeck: "*On Citalopram, can we agree that the contract would be signed subject to Ranbaxy demonstrating non-infringing technology. Can we fix timelines for this?*"¹⁰⁰³
- (552) In July 2001, Lundbeck informed Ranbaxy that after all it did not want to go ahead with the supply project.¹⁰⁰⁴ Ranbaxy complained to Lundbeck that "*...the entire strategy of Ranbaxy on Citalopram revolved around this relationship. We had consciously not pursued other opportunities coming our way as we opted to work with M/s Lundbeck.*" Ranbaxy asked Lundbeck to purchase at least 400 kg citalopram before the end of 2001.¹⁰⁰⁵ The price for 400 kg citalopram would be around USD 1 to 1.5 million.¹⁰⁰⁶ Lundbeck refused to buy any citalopram from Ranbaxy and concluded internally: "*That was exactly what we were playing for when we started the dialogue*".¹⁰⁰⁷
- (553) An internal Alpha Pharma e-mail of 12 December 2001 stated:
- "Ranbaxy claim to have developed non-infringing API with full supporting documentation. Unable to find out if they have finished product. Will keep you updated."*¹⁰⁰⁸
- (554) An e-mail of 11 January 2002 from an American wholesaler representing Ranbaxy to Arrow in the United Kingdom shows that Ranbaxy had started to explore selling own-manufactured citalopram API in Europe. The e-mail stated:

¹⁰⁰¹ ID 850, pages 144 to 147. See also recitals (180) to (183) above.

¹⁰⁰² ID 904, page 129.

¹⁰⁰³ ID 848, page 51. Lundbeck stated in its reply to the Statement of Objections that at this time Lundbeck suffered from capacity constraints for the production of citalopram and was therefore interested in recruiting new contract suppliers. See ID 5394, page 236. Neither Lundbeck nor Ranbaxy explained satisfactorily to the Commission why it would be important in this context for Ranbaxy to show that it was able to produce citalopram without infringing Lundbeck's process patents. If Ranbaxy was to work as a contract supplier to Lundbeck, could Lundbeck not have licensed its own patented production technology?

¹⁰⁰⁴ In its reply to the Statement of Objections, Lundbeck stated that at this time Lundbeck had solved its capacity constraint problem by other means and no longer needed Ranbaxy as a contract supplier. See ID 5394, page 237.

¹⁰⁰⁵ ID 848, page 50.

¹⁰⁰⁶ ID 904, page 129.

¹⁰⁰⁷ ID 904, page 129, translation from Danish. In reply to the Statement of Objections, Lundbeck argued that this e-mail would at least also show that its discussions regarding supplies from Ranbaxy had also the purpose of ensuring "*... Lundbeck a buffer of stock*", whereas "*... the situation had changed and we were no longer interested*" (see ID 904, page 129, Lundbeck's translation from Danish). See ID 5394, pages 237-238.

¹⁰⁰⁸ ID 4817, page 235.

"As discussed at the end of last year, we have forwarded to London...the Certificate of Analysis of the following APIs:

...

Citalopram

...

*All are produced by Ranbaxy. May I also ask you if you could be available between Jan 21 and 23 for a meeting...?"*¹⁰⁰⁹

- (555) An internal e-mail of Ranbaxy's patent department of 21 March 2002 entitled *"Citalopram patent applications of concern"* stated:

"Some recent PCT/EP application on citalopram are of concern to us as they try to cover compounds/processes which are part of prior art and we fall under the scope of such claims."

With respect to Lundbeck's crystallisation patent, the e-mail stated:

*"Crystalline base of citalopram was obtained/set free/isolated in EP 347066 (Example 3, application published in March 1995) and converted to the hydrobromide salt. The process is therefore disclosed earlier and not novel in any way. Our process does not involve any purification/recrystallization of the citalopram base, however it is set free at one stage and the product is a thick oil which tends to solidify on cooling (at the bottom of the reactor). In order to overcome any potential infringement issue on account of claim 1, the citalopram base oil is directly dissolved in a solvent (without allowing any solidification) and then converted to the hydrobromide salt. No handling or analysis of the citalopram base is done."*¹⁰¹⁰

Moreover, the e-mail stated:

"The patent application also claims a crystalline base of citalopram, or a hydrochloride or a hydrobromide salt of citalopram characterized in that it has a purity of more than 99.8% w/w preferably more than 99.9% w/w (claim 11). The claim being independent covers citalopram hydrobromide of purity 99.8% w/w irrespective of the process of preparation. ... Citalopram hydrobromide obtained by our process is also greater than 99.8% w/w but we follow a different process (two patent applications have been filed on the same). Thus Citalopram hydrobromide of purity 99.8% w/w is not limited to the claimed process. We would obviously like to market the product of purity more than 99.8%."

The reply of Ranbaxy's management in the same exchange of e-mails stated:

*"We shall oppose the British patent after consulting the file wrapper. Action in other European countries will be decided accordingly."*¹⁰¹¹

¹⁰⁰⁹ ID 624, page 2.

¹⁰¹⁰ ID 5178, pages 1-2. Patent EP 347066 was an earlier Lundbeck patent on new enantiomers and their isolation, which had been applied for on 20 December 1989. Source: Espacenet. It is recalled that claim 1 of the crystallisation patent was deleted in the amended version eventually accepted by the EPO in 2009. See recital (166) above.

¹⁰¹¹ ID 5178, pages 1-2.

It should be noted that on October 18, 2001, Lundbeck had in fact filed an amended version of its patent application at the EPO, deleting claim 11 as referred to by Ranbaxy in this e-mail.¹⁰¹² However, this product claim remained present in the United Kingdom patent for the crystallisation patent (patent GB 2357762) as granted in the United Kingdom on 30 January 2002. There is no indication that Ranbaxy, after having concluded the agreement with Lundbeck, actually opposed this United Kingdom patent.

- (556) The same e-mail of Ranbaxy's patent department also analysed another process patent application for citalopram of Lundbeck's, WO 01/68631. It stated that *"none of the process claims...are of any concern"*, but observed that the application also claimed an intermediate which Ranbaxy had in its process. According to the e-mail, this intermediate *"has been reported in literature"* in 1977 and thus *"We believe that this compound should be excluded from this claim."*¹⁰¹³

The reply of Ranbaxy's management stated:

*"The concerned product claims of the patent application are not of concern in view of the prior art and would not be valid in case of grant."*¹⁰¹⁴

- (557) On 4 April 2002, the American wholesaler acting for Ranbaxy¹⁰¹⁵ sent a draft confidentiality agreement to Arrow *"to cover the technical and legal issues on Citalopram."* The e-mail proposed *"to discuss the Ranbaxy products in the presence of their representatives which are planning to tour Europe. They are most likely available during week 17 i.e. starting Monday April 22, 2002...Regarding the pricing...I will come back to you early next week."*¹⁰¹⁶

- (558) On 17 April 2002 a meeting took place between Lundbeck and Ranbaxy at the latter's offices in London. Ranbaxy's [employee function]* led the discussion from Ranbaxy's side. Ranbaxy's position, as reported in Lundbeck's e-mail, was:

- *"We have a non-infringing process*
- *Not crystallising the free base*
- *[Lundbeck] knows our process*
- *We will file now for UK & Germany, where we have our own subs – expect registration in 8 months*

¹⁰¹² See ID 2773, page 4. Nevertheless, after having split off the product claims in a divisional, Lundbeck did obtain a patent on the crystalline form itself (EP 1 227 088). This patent was opposed before the EPO and subsequently revoked by the EPO (see recital (151) above), whereas Lundbeck's patent on the crystallisation process (EP 1169314) was significantly amended and the scope of its claims limited before the EPO. See recital (166) above. As for the British patent GB 2357762, this patent appears to have been granted with the product and pharmaceutical composition claims included. There is no indication in the case file that Ranbaxy opposed this patent, as it intended to do before it concluded the agreement with Lundbeck. See recital (151) above.

¹⁰¹³ This PCT patent application for a method for the preparation of citalopram by alkylation was published by the European Patent Office on 18 December 2002. The application was withdrawn by Lundbeck on 13 September 2005. The patent was granted only in New Zealand. Sources: WIPO Patentscope and EPO Espacenet.

¹⁰¹⁴ ID 5178, pages 1-2.

¹⁰¹⁵ See recital (554) above.

¹⁰¹⁶ ID 1354, page 1.

- *We are discussing with a partner for Northern Europe, who will be able to bring our product to the market in 3-4 months – signature is close*
- *Q: Is that Tiefenbacher? A: No, we are also talking to Tiefenbacher, but it is not them [Most likely it is Tiefenbacher/Delta – however it could also [be] Merck Generics if Natco really is infringing]*
- *Annual capacity for [third countries] & EU – 4.5 ton*
- *Do you want a deal? Please let us know before end of April!"*¹⁰¹⁷

Below this, the Lundbeck representative wrote:

*"Do we want a deal? I guess a deal will be \$10M-\$20M or even more. My opinion is that it will be difficult – antitrust wise, costs and value for money..."*¹⁰¹⁸

- (559) On 14 May 2002, the American wholesaler acting for Ranbaxy sent an e-mail to Arrow informing Arrow that a Ranbaxy representative from India *"will be in Europe early June"*. The American wholesaler also confirmed that his company was *"doing follow up work on API's for the market in Europe with the authorisation of Ranbaxy's API export department."*¹⁰¹⁹ In another e-mail to Arrow of the same day, the American wholesaler acting for Ranbaxy stated:

"...we hereby transmit our offer: 500 to 1,000kg of Citalopram @ \$3,500/kg CIF Dublin.

Samples are available upon request.

[Ranbaxy representative] will be visiting Europe, beginning of June. He is available for a meeting with you either in London or Dublin on Thursday June 6th...

*Besides Citalopram, most of the products we have discussed are Ex Ranbaxy..."*¹⁰²⁰

- (560) On 16 May 2002, Lundbeck became aware that Ranbaxy had filed two patent applications in India for processes for manufacturing citalopram. In the e-mail reporting this, Lundbeck's [employee function]* wrote: *"Both these processes can be in conflict with our process patents."*¹⁰²¹

- (561) An internal Lundbeck Business Development document entitled "Generic citalopram update 21 05 2002" stated:

"Ranbaxy

- *Meeting 8 May in Paris*
- *12 months ceasefire – possible patent infringement against*
 - *UK distribution: 10% volume at a 40% margin - £1-2M*
 - *Cash sum \$5.3M*
 - *Total cost – appr. \$7-8M*

¹⁰¹⁷ ID 681, page 88. In reply to the Letter of Facts, Ranbaxy argued : *"...it usually took around two years for it to obtain marketing authorizations [...]. For citalopram, Ranbaxy obtained them in [...] 17 months..."* See ID 6802, page 6.

¹⁰¹⁸ ID 681, page 88.

¹⁰¹⁹ ID 1354, page 11.

¹⁰²⁰ ID 1354, page 12.

¹⁰²¹ ID 8, page 339, translation from Danish. See also ID 5394, page 240.

- *Alternative: Piggy-bag Tifi [Tiefenbacher] and hit the market in August 2002.*"¹⁰²²
- (562) Lundbeck sent a draft of a "Settlement Agreement" to Ranbaxy (UK) Limited on 24 May 2002. This draft mentioned Ranbaxy (UK) Limited as a party to the agreement together with Ranbaxy Laboratories Limited in India.¹⁰²³
- (563) On 27 May 2002, Ranbaxy UK sent an e-mail to Lundbeck describing a production process for the manufacture of citalopram.¹⁰²⁴ Lundbeck claimed in its reply to the Statement of Objections that this e-mail described Ranbaxy's production process for citalopram and that "*the process described in these schemes was clearly covered by Lundbeck's patented Iodo Process, with an additional purification step based on the patented Amide Process*".¹⁰²⁵
- (564) An internal Lundbeck document of 31 May 2002 analysed "*the Ranbaxy process as it appears from the reaction schemes that we have received*" and concluded that there were arguments for considering that it infringed Lundbeck's patent application EP 1159274: Method for the preparation of citalopram (the iodo process patent)¹⁰²⁶ and Lundbeck's patent EP 1015416: Method for the preparation of citalopram (the amide process patent).¹⁰²⁷ Regarding the former, Lundbeck's [employee function]* considered in this document: "*EP 1159274 has a claim 11 covering the intermediate 5-iodo-citalopram per se. Since such a claim may be considered analogous with a process claim, importation of a product which is a direct result of conversion of 5-iodo-citalopram to citalopram may be considered infringement of EP 1159274.*"¹⁰²⁸ Regarding the latter, he took the view that "*...it is possible that the conversion of 5-carboxamido-citalopram to citalopram in step two of the Ranbaxy process will be regarded as an infringement of EP 1015416.*"¹⁰²⁹
- (565) A Lundbeck e-mail to Ranbaxy (UK) Limited of 7 June 2002 explained:
- "According to our contract to be signed in June – the mechanism for allocating quantities to Ranbaxy will be as follows:*
- While the contract is in force – Ranbaxy can in a month purchase up [to] 10% of Lu-UK last month's volume of*
- *Cipramil 10mg 28 tabs*
 - *Cipramil 20 mg 28 tabs*
 - *Cipramil 40 mg 28 tabs*
- Prices are as mentioned in the contract [...] less 40%.*"¹⁰³⁰

¹⁰²² ID 847, page 32.

¹⁰²³ ID 904, pages 159 to 169. The actually concluded agreement was with Ranbaxy Laboratories Limited in India only.

¹⁰²⁴ ID 5397.

¹⁰²⁵ ID 5394, pages 15 and 49. See also recital (564) below.

¹⁰²⁶ This patent was granted by the EPO on 26 March 2003, see Espacenet and ID 5176, page 15.

¹⁰²⁷ ID 8, pages 336 to 338. Lundbeck had filed these two process patents (referred to by Lundbeck as its iodo process patent and amide process patent respectively, see ID 5394, page 12) in 1998 and 1999 respectively, see recital (144) above.

¹⁰²⁸ ID 8, pages 336-337.

¹⁰²⁹ ID 8, pages 336-337. This patent is referred to by Lundbeck as the amide process patent.

¹⁰³⁰ ID 681, page 98.

- (566) By the time Ranbaxy and Lundbeck entered into an agreement for the EEA on 16 June 2002, Ranbaxy had already produced around 500 kg of citalopram API and had already sold citalopram API to Sweden and Italy.¹⁰³¹ On 14 June 2002, Ranbaxy had filed a Drug Master File for its citalopram API with the United Kingdom authorities. At the same time, the dossier necessary for Ranbaxy's application for a marketing authorisation to sell citalopram medicines itself was sent from India to Ranbaxy's United Kingdom office.¹⁰³² Ranbaxy sent a technical data package or the open part of its Drug Master File to potential API customers in Italy, Portugal, Greece and France, both before conclusion of the agreement with Lundbeck and during its operation.¹⁰³³ By 16 June 2002, Ranbaxy had not yet filed for any marketing authorisations in EEA Contracting Parties to distribute citalopram medicines itself.¹⁰³⁴

7.7.2. The agreement

- (567) On 16 June 2002, H. Lundbeck A/S and Ranbaxy Laboratories Limited in India concluded an agreement covering the then EEA (as well as a number of third countries, collectively referred to as "the Territory") for a period of 360 days.¹⁰³⁵ The preamble noted that *"...Ranbaxy has filed two process patent applications in India (264/DEL/2001 and 779-DEL/2001) relating to the manufacture of Citalopram and has, furthermore, manufactured pharmaceutical products containing Citalopram with the intention of marketing such products in the Territory through affiliates, licensees or customers of Ranbaxy."* The preamble then stated that Lundbeck had performed laboratory analyses of Ranbaxy's products and that based on the results of these laboratory analyses Lundbeck believed that *"the production methods used to produce Ranbaxy's products infringe Lundbeck's intellectual property rights, in particular EP patent No 1015416¹⁰³⁶ and EP Patent Application No 1159274"¹⁰³⁷*. Ranbaxy noted in the preamble that it *"disputed the claim of Lundbeck that the Patent filed by Ranbaxy and the production method used by Ranbaxy infringe Lundbeck's intellectual property rights."* Finally, the preamble noted that Lundbeck and Ranbaxy had *"arrived at a Settlement in order to avoid costly and time-consuming patent litigation, the outcome of which cannot be predicted with absolute certainty."*

It should be noted that when the agreement was concluded, no litigation between Lundbeck and Ranbaxy on citalopram was taking place anywhere in the EEA.¹⁰³⁸

¹⁰³¹ ID 601, page 8, ID 597, page 1. The amount sold in Sweden was negligible, but in Italy Ranbaxy sold 16 kg of citalopram API to the Italian company Pharmacare before the agreement was concluded at a price of USD 3.1 million, see ID 597, page 1. Ranbaxy stated in its reply to the Statement of Objections *"that this company acted as a broker in the past and may well have been doing so in this instance in which case the API would have been destined for a market outside the EEA."* See ID 5176, page 37. It appears that Ranbaxy later issued credit notes to the Italian company against the invoices concerned. According to Ranbaxy, this meant that the product never found an ultimate buyer. See ID 5176, page 37.

¹⁰³² ID 1748, page 2, ID 5176, page 27 and ID 5182.

¹⁰³³ The Italian company Pharmacare received a technical data package in December 2001. The French company GNR Pharma received a technical data package in January 2002. See ID 1748, page 3.

¹⁰³⁴ Ranbaxy filed its United Kingdom application for a marketing authorisation in early August 2002.

¹⁰³⁵ ID 8, pages 292 to 299.

¹⁰³⁶ Referred to by Lundbeck as the amide process patent.

¹⁰³⁷ Referred to by Lundbeck as the iodo process patent.

¹⁰³⁸ ID 823, page 62, ID 601, page 7.

(568) Article 1.1 of the agreement stated:

"Subject to the terms and conditions of this Agreement and subject to payment of the Settlement Amount by Lundbeck, Ranbaxy shall not in the Territory claim any rights on the Patent Application or any production method used by Ranbaxy and shall cancel, cease and desist from any manufacture or sale of pharmaceutical products based hereon, in the Territory through itself, its Affiliates and/or any third party during the term of the Agreement." Affiliate meant any company directly or indirectly controlled by Ranbaxy Laboratories Limited or Ranbaxy (UK) Limited.

Ranbaxy signed the agreement on 11 June 2002, whereas Lundbeck signed it on 16 June 2002. Further to a Lundbeck letter of 14 June 2002, Ranbaxy sent Lundbeck on 17 June 2002 a signed side letter to the agreement which stated:

*"The Agreement is signed by Lundbeck and returned to Ranbaxy subject to the explicit proviso that the term "pharmaceutical products" also covers bulk and any other form containing the active ingredient and that products delivered to Ranbaxy under Article 1.3 are only for sale in the UK."*¹⁰³⁹

(569) Article 1.2 provided that *"In the event of any breach of the obligation set forth in Article 1.1 or at the request of Lundbeck, Ranbaxy Laboratories Limited, Ranbaxy (UK) Limited and Ranbaxy's Affiliates will voluntarily submit to an interim injunction by any competent court in the Territory."* Ranbaxy would *"waive any confirmatory action pursuant to any law or regulation in the Territory relating to such injunction and shall upon request from Lundbeck sign any document necessary to obtain such injunctions."*¹⁰⁴⁰

(570) In Article 1.3, *"in consideration of the Settlement arrived at"* Lundbeck agreed to pay Ranbaxy an amount of USD 5 million, *"being the Settlement Amount"*, payable in five instalments spread over the duration of the term of the agreement, the last instalment being due on the last day of operation of the agreement.

(571) Also in Article 1.3, Lundbeck agreed to sell citalopram tablets (10 mg, 20 mg and 40 mg) to Ranbaxy in the United Kingdom during the term of the agreement, in quantities to be negotiated. Appendix B specified the sales price from Lundbeck to Ranbaxy as the current Lundbeck ex-factory price less 40%. Lundbeck estimated the cost of this arrangement to Lundbeck at GBP 1.5 million.¹⁰⁴¹ As for the quantities, it was agreed that Ranbaxy would be entitled to sell in the United Kingdom every month up to 10% of Lundbeck's last month's sales volume of citalopram in the United Kingdom.¹⁰⁴² Ranbaxy would *"use its dispensing doctor field force at its own expenses to promote the product in the UK."* Finally, Article 1.3 provided that Ranbaxy and Lundbeck would be free to choose their customers and wholesalers in the United Kingdom market.

(572) Article 1.4 of the agreement provided: *"During the term of this Agreement, Lundbeck and Ranbaxy undertake not to initiate legal proceedings against each other based on any of the patents set out above."*

¹⁰³⁹ ID 246, pages 1 to 3.

¹⁰⁴⁰ There is no indication in the file that any voluntary interim injunction was put into force by the parties in the EEA in the period covered by the agreement. Ranbaxy assured Lundbeck that following the agreement it did not export any citalopram to the EEA, see recital (577) below.

¹⁰⁴¹ See recital (561) above and recital (576) below.

¹⁰⁴² See recital (565) above and recital (576) below.

7.7.3. Events during the implementation and extension of the agreement

- (573) On 19 June 2002, Lundbeck made the first payment of USD 1 million to Ranbaxy (UK) Limited.¹⁰⁴³
- (574) In July 2002, Ranbaxy filed a PCT application WO 02/007872 for the process for which it had already filed DEL '779 application in India. For Ranbaxy's DEL '264 application in India, a PCT application had already been filed as WO 02/072565 in March 2002.¹⁰⁴⁴
- (575) In early August 2002, Ranbaxy filed an application for a marketing authorisation to sell medicines in the United Kingdom.¹⁰⁴⁵
- (576) A Lundbeck Business Development document with the title "Generic citalopram update 04 09 2002" stated:

"Ranbaxy

- Greater Europe*
- 12 month deal*
- Until 10 June 2003*
- Distribution of 10% Cipramil volume in the UK plus cash settlement"*¹⁰⁴⁶

The same document states on the final two pages:

"What have we spent out of the pocket?

<i>Company</i>	<i>Market</i>	<i>Time</i>	<i>Cost</i>	<i>M DKK</i>
<i>Merck Generics</i>	<i>UK</i>	<i>24.1.03</i>	<i>£3M</i>	<i>40</i>
<i>Arrow</i>	<i>UK</i>	<i>31.12.02</i>	<i>£5M</i>	<i>65</i>
<i>Alpharma</i>	<i>EU</i>	<i>30.6.03</i>	<i>\$12M</i>	<i>100</i>
<i>Arrow</i>	<i>DK</i>	<i>15.5.03</i>	<i>\$0.7M</i>	<i>5</i>
<i>Ranbaxy</i>	<i>EU</i>	<i>10.6.03</i>	<i>\$5M</i>	<i>40</i>
<i>Out of the pocket</i>				<i>250</i>

¹⁰⁴³ ID 681, page 102.

¹⁰⁴⁴ ID 5176, page 46.

¹⁰⁴⁵ ID 5176, page 26.

¹⁰⁴⁶ ID 904, page 304.

"What have we spent totally?"

<i>Company</i>	<i>Market</i>	<i>Margin</i>	<i>Cost</i>	<i>M DKK</i>
<i>Out of the pocket</i>				250
<i>Distribution Merck Generics</i>	<i>UK</i>	<i>£419K per mth</i>	<i>£5M</i>	65
<i>Distribution Ranbaxy</i>	<i>UK</i>	<i>10% vol at 40%</i>	<i>£1.5M</i>	20
<i>Less UK discount anyway</i>			?	(35)
<i>Total spend</i>				300

„1047

- (577) On 25 October 2002, Ranbaxy Laboratories Limited in India wrote to Lundbeck: *"This is to confirm that we have not sold any citalopram, not only in Europe but in the entire world after June 02"*. The Lundbeck email which distributed this news to key players within the undertaking Lundbeck warned: *"Strictly confidential – please do not forward this e-mail!"*¹⁰⁴⁸
- (578) An internal Lundbeck e-mail of 28 January 2003 shows that Lundbeck took the necessary measures to pay Ranbaxy's instalment of USD 1 million foreseen for 10 March 2003.¹⁰⁴⁹
- (579) On 19 February 2003, Lundbeck and Ranbaxy agreed to extend the agreement until 31 December 2003.¹⁰⁵⁰ Article 2 of the addendum to the agreement provided that *"In consideration of the prolongation of the term of the Agreement, Lundbeck shall pay to Ranbaxy or its affiliates USD four point five million (USD 4,500,000)."* This money would be paid in two instalments spread over the duration of the term of the extension, the last instalment being due on the last day of the operation of the agreement. Article 3 provided that Ranbaxy's right to distribute Lundbeck citalopram in the UK was also extended until 31 December 2003.
- (580) On 27 March 2003, Ranbaxy Laboratories Limited sent an e-mail to Arrow, stating: *"You would recall, during our meeting in London, we had discussed possible co-operation on some products like:*

...

Citalopram

¹⁰⁴⁷ ID 904, pages 305-306.

¹⁰⁴⁸ ID 681, page 151.

¹⁰⁴⁹ ID 904, page 64.

¹⁰⁵⁰ ID 8, pages 300 to 302.

...

Citalopram

You had expressed interest during the meeting, as you believe your current source is infringing. We believe, our product is clear of all such issues. Should you desire, we can send you a small sample for testing."¹⁰⁵¹

- (581) On 14 May 2003, Ranbaxy concluded an in-licensing agreement with the Spanish company Farmaprojects S.A. and the French company Laboratoire RPG Aventis to in-license the latter's future marketing authorisation for citalopram in France, together with future supplies of citalopram via Farmaprojects S.A. This citalopram did not originate with Ranbaxy. The request for a marketing authorisation was filed in France on 23 October 2003 and granted on 20 July 2004.¹⁰⁵²
- (582) On 29 September 2003, Lundbeck internally considered the strategy it would follow in case of a "Total victory" in the Lagap litigation. A total victory would mean a "Court case outcome: Patent validated; Matrix infringes".

"Agreements

Merck Generics (Natco) – seeks to prolong agreement

Arrow (Cipla & Matrix) and [...] (Cipla) – agreements terminate automatically, do nothing

Alpharma (Cipla & Matrix) – agreement has terminated, do nothing

*Ranbaxy (Ranbaxy) – agreement terminates 31 Dec 2003 – do nothing or consider prolonging the agreement"*¹⁰⁵³

- (583) On 5 November 2003, Ranbaxy wrote to Lundbeck informing it, as a matter of courtesy, "that Ranbaxy will be launching its Citalopram product in the United Kingdom and elsewhere in Europe, as soon as practicable after 31 December 2003."¹⁰⁵⁴
- (584) Throughout the term of the extended agreement with Lundbeck, that is to say between 16 June 2002 and 31 December 2003, Ranbaxy did not sell any own-produced citalopram in any Contracting Party to the EEA Agreement, with the exception of 2.5 kg of citalopram API in Italy in July 2002, one month after the agreement with Lundbeck had been concluded (presumably a small violation of the agreement). This material was sent to the same client who had already received 16 kg of citalopram API in 2002 before the agreement with Lundbeck.¹⁰⁵⁵
- (585) During the term of the extended agreement, between 16 June 2002 and 31 December 2003, Lundbeck sold to Ranbaxy for re-sale in the United Kingdom 135 561 packs of 28 citalopram tablets of 10 mg at a price of GBP 5.06 per pack, 446 278 packs of 28 citalopram tablets of 20 mg at a price of GBP 8.42 per pack and 70 023 packs of 28 citalopram tablets of 40 mg at a price of GBP 14.23 per pack. The total purchase cost

¹⁰⁵¹ ID 1354, pages 17-18.

¹⁰⁵² ID 1748, page 4, ID1216, page 11. See also ID 1217.

¹⁰⁵³ ID 846, page 7.

¹⁰⁵⁴ ID 599, page 1.

¹⁰⁵⁵ ID 601, page 8, ID 597, page 1, ID 1216, pages 5-6, ID 1748, page 2. See footnote 1031 above.

of these tablets amounted to GBP 5.4 million.¹⁰⁵⁶ Their re-sale value in the United Kingdom market would, based on the terms of the agreement, have been around GBP 8.5 million.¹⁰⁵⁷ Lundbeck's losses on these sales and the value it transferred to Ranbaxy were therefore around GBP 3 million.¹⁰⁵⁸ Lundbeck's prices to Ranbaxy remained stable over the entire duration of the agreement.

- (586) The agreement between Lundbeck and Ranbaxy expired on 31 December 2003.
- (587) In total, over the entire period of operation of the agreement from 16 June 2002 to 31 December 2003, Lundbeck transferred a value to Ranbaxy of USD 9.5 million and GBP 3 million (together corresponding to approximately EUR 12.7 million)¹⁰⁵⁹ under the agreement, consisting of:
- USD 5 million for the first year;
 - USD 4.5 million for the extension until the end of 2003;
 - GBP 3 million in estimated profit loss for Lundbeck under the distribution agreement.

7.7.4. Subsequent events

- (588) A letter of 9 January 2004 from Lundbeck to a law firm representing Ranbaxy shows that Lundbeck was considering granting Ranbaxy a licence to its process patent EP (UK) 1159274, at terms to be discussed.¹⁰⁶⁰ This indicates that Ranbaxy was considering at that time to enter the United Kingdom market with its own product.
- (589) Ranbaxy obtained a marketing authorisation in the United Kingdom in January 2004, just after expiry of the agreement with Lundbeck.¹⁰⁶¹ On 3 February 2004, based on the mutual recognition procedure taking the United Kingdom as reference Member State, Ranbaxy submitted applications for marketing authorisations for Ranbaxy citalopram in the Netherlands, Ireland, Germany, Austria and Spain. The mutual recognition procedure for these applications ended on 20 September 2004.¹⁰⁶² In Italy, Ranbaxy applied for a marketing authorisation in November 2004 and obtained it in October 2005. Moreover, Ranbaxy had already obtained marketing authorisations to sell generic citalopram based on other companies' Drug Master Files in Spain on 29 June 2004 and in France on 20 July 2004.¹⁰⁶³ Ranbaxy has

¹⁰⁵⁶ See ID 1937. See also ID 1748, pages 1-2.

¹⁰⁵⁷ ID 8, page 299.

¹⁰⁵⁸ It should be noted that the value Lundbeck transferred to Ranbaxy does not necessarily correspond to the net profit Ranbaxy made on these sales. The latter amount depends on the distribution costs of Ranbaxy. In a different context, Lundbeck estimated that "*distribution costs* [in the United Kingdom] *are of the order of 1% of sales*", see ID 394, page 37. Ranbaxy, on the other hand, claimed in its reply to the Statement of Objections that its distribution costs in the United Kingdom were anywhere between 15% and 25% of sales revenue, see ID 5176, page 57. According to Ranbaxy, its net profit from the distribution arrangement was anywhere between GBP 1 million and GBP 1.8 million (see ID 5176, page 57).

¹⁰⁵⁹ Using an average annual exchange rate for 2003 of 1 EUR = 1.13116 USD and 1 EUR = 0.69199 GBP, source European Central Bank.

¹⁰⁶⁰ ID 682, page 104.

¹⁰⁶¹ ID 1748, page 3.

¹⁰⁶² ID 1748, page 6.

¹⁰⁶³ ID 1217. For Spain, Ranbaxy signed the in-licensing contract on 27 May 2005 and the two marketing authorisations concerned were transferred to Ranbaxy in June 2005. It is unclear if and when Ranbaxy started selling citalopram in Spain under this agreement. See ID 1748, page 5.

confirmed to the Commission that it started selling in-licensed citalopram (that is to say purchased from another company) in France in December 2004.¹⁰⁶⁴ With respect to own-manufactured citalopram, after having obtained the marketing authorisations, Ranbaxy started selling its own generic citalopram medicines in the United Kingdom in May 2004¹⁰⁶⁵, followed by Germany in 2005¹⁰⁶⁶ and Ireland and Italy in 2006.¹⁰⁶⁷ Some sales of Ranbaxy citalopram also took place in northern Europe in 2005.¹⁰⁶⁸ None of these sales were subject to infringement litigation by Lundbeck.¹⁰⁶⁹

8. APPLICATION OF ARTICLE 101 OF THE TREATY AND ARTICLE 53 OF THE EEA AGREEMENT

8.1. Relationship between the Treaty and the EEA Agreement

(590) The EEA Agreement between the Union Member States and the EFTA countries came into force on 1 January 1994. In its Article 53, the EEA Agreement contains provisions on competition analogous to Article 101 of the Treaty. Infringements that cover only the territory of one or more Union Member States are governed exclusively by the Treaty. This is the case for the two agreements concluded between Lundbeck and Arrow, which concerned the United Kingdom and Denmark and which, as explained further below¹⁰⁷⁰, should together be considered to constitute a single and continuous infringement. Infringements that cover both the territory of one or more Union Member States and of one or more EFTA countries are governed by the Treaty in so far as competition in and trade between Union Member States is concerned and by the EEA Agreement in so far as competition in and trade between EFTA countries or between Union Member States and EFTA countries is concerned. This is the case for the two agreements concluded between Lundbeck and Merck, which concerned the United Kingdom and other EEA Contracting Parties than the United Kingdom and which, like the two agreements between Lundbeck and Arrow, should together be considered to constitute a single and continuous infringement. This is also the case for the agreement between Lundbeck and Alpharma, covering the EEA, and for the agreement between Lundbeck and Ranbaxy, also covering the EEA, which are separate infringements.

8.2. Jurisdiction

(591) In the present case the Commission is the competent authority to apply both Article 101 of the Treaty and, on the basis of Article 56 of the EEA Agreement, Article 53 of the EEA Agreement since the infringements in question had an appreciable effect on trade between Member States.¹⁰⁷¹

¹⁰⁶⁴ ID 1216, page 11, ID 1217. Although Ranbaxy had, as mentioned, also in-licensed in June 2004 a marketing authorisation to sell citalopram in Spain, Ranbaxy has not provided information on any such sales made in Spain. In-licensing is not free and Ranbaxy would normally have had every incentive to seek a return on its investment by starting sales in Spain soon after having obtained the in-licensed marketing authorisation. See ID 1748, page 5.

¹⁰⁶⁵ ID 3176.

¹⁰⁶⁶ Ranbaxy claims sales in Germany started in December 2005. See ID 1216, page 6.

¹⁰⁶⁷ ID 601, page 9, ID 598, pages 1 to 3. See also ID 823, page 63 and ID 1216, page 5.

¹⁰⁶⁸ ID 598, page 2.

¹⁰⁶⁹ ID 601, page 9, ID 823, page 63.

¹⁰⁷⁰ See section 12.8 below.

¹⁰⁷¹ See chapter 13 below.

8.3. Article 101 of the Treaty and Article 53 of the EEA Agreement

(592) This Decision examines the application of Article 101 of the Treaty and Article 53 of the EEA Agreement to the agreements that are the subject of this Decision. The product concerned by these agreements was citalopram.¹⁰⁷² Because of the regulatory framework, with marketing authorisations and pricing and reimbursement decisions being taken on a national basis¹⁰⁷³, the geographic markets concerned were national in scope and were specifically indicated in each of the agreements.

(593) Article 101 of the Treaty prohibits as incompatible with the internal market "*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 (...), and in particular those which :*

(a) ...

(b) *limit or control production, markets, technical development, or investment;*

(c) *share markets or sources of supply*

(d) ..."

provided the conduct does not meet the conditions of an exemption pursuant to paragraph (3) of Article 101 of the Treaty. The Court of Justice has clarified that "*the types of agreements covered by Article 81(1)(a) to (e) EC do not constitute an exhaustive list of prohibited collusion.*"¹⁰⁷⁴

(594) The conclusion of the legal assessment in chapter 12 below is that the agreements that are the subject of this Decision had the object of restricting competition within the internal market or a substantial part thereof, in that the generic undertaking concerned accepted against payment from Lundbeck to restrict for the duration of the agreement its independent efforts to enter one or more Union or EEA markets.

(595) Unless specifically indicated otherwise, the legal assessment in chapters 12 to 14 below is limited to the provisions of Article 101 of the Treaty, as the corresponding provisions of Article 53 EEA are identical, with the only difference that the reference in Article 101(1) of the Treaty to trade "*between Member States*" is replaced by a reference in Article 53 EEA to trade "*between contracting parties*" and the reference in Article 101 of the Treaty to competition "*within the common market*" is replaced by a reference in Article 53 EEA to competition "*within the territory covered by the ...[EEA] Agreement.*" The legal assessment below under Article 101 of the Treaty therefore also applies to Article 53 EEA, unless specifically indicated otherwise.

9. THE NATURE OF THE INFRINGEMENTS

9.1. Introduction

(596) This chapter analyses the nature of the infringements addressed by this Decision. When the agreements in question were concluded, Lundbeck's compound patent

¹⁰⁷² See chapters 5 and 7 above.

¹⁰⁷³ See chapter 3 above.

¹⁰⁷⁴ Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd (BIDS) and Barry Brothers (Carrigmore) Meats Ltd*, [2008] ECR I-08637, paragraph 23.

(including the two original production processes) had already expired, but Lundbeck still had a number of process patents which covered some, but not all, processes to manufacture citalopram that met regulatory requirements in Europe. Each of the agreements was characterised by the fact that it contained a transfer of value from Lundbeck to a potential or actual generic competitor, which was related to the latter's agreement not to market generic citalopram in the geographic area concerned for the duration of the agreement.

- (597) Based on the jurisprudence of the Court of Justice of the European Union, this chapter will first set out the relationship between patents and competition law. An important conclusion from this section 9.2 below is that agreements between undertakings regarding patents, including agreements dealing with or settling patent disputes, are not immune from competition law scrutiny. Section 9.3 below briefly recalls the jurisprudence of the Court of Justice on the notions of "undertaking" and "agreement" within the meaning of Article 101(1) of the Treaty. Finally, section 9.4 deals with the concept of potential competition, which is important in this case, as most of the generic undertakings in question had not yet entered markets in the EEA when they signed the agreements with Lundbeck.

9.2. Patents and competition law

9.2.1. The relationship between patents and competition law

- (598) In Case 15/74, *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc*, the Court of Justice had to examine the application of the Treaty rules on the free movement of goods and on competition in the context of patent rights. The Court of Justice stated in this context:

"...whilst the Treaty does not affect the existence of rights recognized by the legislation of a Member State in matters of industrial and commercial property, yet the exercise of these rights may nevertheless, depending on the circumstances, be affected by the prohibitions in the Treaty.

Inasmuch as it provides an exception to one of the fundamental principles of the Common Market, Article 36 in fact only admits of derogations from the free movement of goods where such derogations are justified for the purpose of safeguarding rights which constitute the specific subject matter of this property.

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 parties, as well as the right to oppose infringements."¹⁰⁷⁵

With respect to the rules on competition, the Court of Justice stated in the same case:

"Although 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.

¹⁰⁷⁵ Case 15/74, *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc*, reference for a preliminary ruling, [1974] ECR 1147, paragraphs 7 to 9.

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."¹⁰⁷⁶

(599) The "*right to oppose infringements*" is a unilateral right of the patent holder, flowing directly from the intellectual property of which it is the owner. The right to oppose infringements 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 market entry and requests for damages to repair any injury already caused. A patent however can be challenged and a court might find it invalid. The power to confirm a patent valid and infringed or find it invalid and non-infringed lies exclusively with a court. In Case 193/83 *Windsurfing International v Commission*, 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..."¹⁰⁷⁷ This is particularly relevant for the pharmaceutical sector, where generic competition (often) explicitly or implicitly entails the challenge of originator patent rights, which an originator undertaking, rightfully or not, invokes against generic entry, as will be further explained in section 9.4.

(600) The conclusion of an agreement settling a patent dispute¹⁰⁷⁸ does not provide immunity from competition law simply because the agreement relates to patent law. A patent holder only has the right under patent law to enforce its patent rights unilaterally, if necessary through infringement action before the court. Patent settlement agreements are, just like any other civil law contracts, voluntarily concluded by a meeting of the free will of two or more parties. Such agreements are fully subject to the discipline of competition law. In this respect, the General Court stated in Case 65/86, *Bayer AG and Maschinenfabrik Hennecke v Heinz Süllhöfer*, dealing with a no challenge clause in a licence agreement:

*"[i]n its prohibition of certain "agreements" between undertakings, Article 85(1) [now 101(1) 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."*¹⁰⁷⁹

This also applies to agreements whose purpose is to put an end to or otherwise deal with patent litigation or, more broadly, patent disputes. Thus, while companies in principle have the right to reach an agreement on their patent disputes, just as they have the right in principle to conclude other kinds of agreements, even if they are actual or potential competitors, in doing so they must respect Union competition law.¹⁰⁸⁰

¹⁰⁷⁶ Case 15/74, *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc*, reference for a preliminary ruling, [1974] ECR 1147, paragraphs 39 and 40.

¹⁰⁷⁷ Case 193/83, *Windsurfing International v Commission*, [1986] ECR 611, paragraph 52.

¹⁰⁷⁸ See footnote 6 above.

¹⁰⁷⁹ Case 65/86, *Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Süllhöfer*, [1988] ECR 5249, paragraph 15.

¹⁰⁸⁰ Both Cases *Windsurfing International* and *Bayer AG and Maschinenfabrik Hennecke GmbH* show that private agreements restricting competition cannot meet the legal conditions of a justified "*derogation from EU [...] competition rules*" in the sense examined by *Centrafarm* (see recital 9.2.1 above), as argued by Merck KGaA in its reply to the Statement of Objections (see ID 5960, pages 116 and 129-).

- (601) That agreements concerning intellectual property rights between undertakings are subject to Union competition law has also been held by the Courts of the European Union in several other cases dealing with intellectual property.

With respect to the assessment whether licensing agreements between parties restricted competition, the Court of Justice held in Case 193/83 *Windsurfing International v Commission* 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 [now Articles 101 and 102 of the Treaty] [...] the Commission must be able to exercise its powers in accordance with the provisions of Regulation no 17 [now Regulation 1/2003]."¹⁰⁸¹

In the same case, the Court of Justice stated with respect to a contractual obligation on a licensee not to challenge the validity of licensed patents, 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, 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.*"¹⁰⁸² The Court of Justice prohibited thus 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.¹⁰⁸³

132) simply because they are concluded in the context of "[t]he protection of IP rights". The risk of completely exempting private agreements from the application of Articles 101 and 102 of the Treaty simply because they relate to "[t]he protection of IP rights" would be that undertakings would invoke uncertainty with respect to the scope of patents to engage in rent sharing arrangements that restrict competition between themselves. As mentioned in recital (599) above, when it comes to the question of patent infringement, the Court of Justice ruled in Case 193/83 *Windsurfing International v Commission* (paragraph 52) that a licensor cannot substitute "...its discretion for the decisions of national courts, which were the proper forum for actions..." See also Case 193/83, *Windsurfing International v Commission*, [1986] ECR 611, paragraph 36 and the discussion by Advocate General Jacob in paragraph 30 of his opinion in Case C-316/95 *Generics BV v Smith Kline & French Laboratories* [1997] ECR I-03929, where he considered limitations of the *Centrafarm* definition of the "subject matter" of a patent right for other contexts. In support of its argument, Merck KGaA specifically pointed to the Court's ruling in Case C-316/95, *Generics BV v Smith Kline & French Laboratories Ltd* [1997] ECR I-03929, paragraph 20, where the Court of Justice stated: "*the Community Patent Convention [...] confer[s] the right to prevent third parties [...] using the product obtained directly by the process which is the subject-matter of the patent.*" (See ID 5960, pages 116 and 129-132) This corresponds to the right to oppose. However, that judgment did not deal with the relevant question of whether an agreement between competitors that share rents in relation to a commitment of one party to limit or postpone a patent challenge or entry constitutes a competition restriction.

¹⁰⁸¹ Case 193/83, *Windsurfing International v Commission*, [1986] ECR 611, paragraph 26. In paragraphs 27 and 28, the Court of Justice also clarified that "[t]he findings of the Commission relating to the scope of a patent do not in any way pre-empt the determinations made later by national courts within their spheres of jurisdiction and are subject to review by the Court of Justice. That review must be limited to determining whether, in the light of the legal position existing in the state in which the patent was granted, the Commission has made a reasonable assessment of the scope of the patent."

¹⁰⁸² Case 193/83, *Windsurfing International v Commission*, [1986] ECR 611, paragraph 92.

¹⁰⁸³ The Court of Justice did not examine whether such challenge would have actually happened and would have been successful.

- (602) With respect to trademarks, the Court of Justice held in Case 35/83, *BAT Cigaretten-Fabriken GmbH v Commission*, that "agreements known as 'delimitation agreements' are lawful and useful if they serve to delimit, in the mutual interest of the parties, the spheres within which their respective trademarks may be used, and are intended to avoid confusion or conflict between them. That is not to say, however, that such agreements are excluded from the application of Article 85 of the Treaty [now Article 101 of the Treaty] if they also have the aim of dividing up the market or restricting competition in other ways... 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.' "¹⁰⁸⁴

9.2.2. Specific characteristics of the pharmaceutical sector

- (603) Union competition law must be respected by parties concluding a patent settlement agreement. As will be further analysed in section 10.1 below, even if the limitations included in the patent settlement remain within the scope of the patent, a settlement agreement may, under certain circumstances, have to be considered as contrary to competition law. It should be noted that in the case of process patents, it will often be very difficult to determine in advance, in the absence of any court ruling, whether a particular product has been produced in a manner that falls within the scope of a process patent or not. While both the generic undertakings and Lundbeck claim in these proceedings that the citalopram the generic undertakings had in their possession when they concluded the respective agreements was "*infringing*"¹⁰⁸⁵, in reality one can only describe the products in question at that point in time as "*potentially infringing*", given that the competent court had not given a ruling on infringement yet and that the burden of proving infringement would have been on Lundbeck and would have been difficult to meet.¹⁰⁸⁶ With respect to in-scope limitations obtained through transfers of value, it is not because the patent holder might (or might not) have obtained the same result by seeking an infringement ruling from a court that it must necessarily be free at a time when the outcome of a court ruling is unknown to achieve that same potential result in any other manner conceivable. The means used matter.¹⁰⁸⁷
- (604) In particular, in the case at hand, if a generic undertaking is paid by an originator undertaking to cease its independent efforts to enter the market with a potentially infringing product, the situation to be analysed under competition law is very different from that if the originator undertaking had succeeded in obtaining an infringement ruling from a court. If infringement is established by a court, the means used to achieve exclusion are the right to oppose based on the objective strength of the patent. Such means fall within the specific subject matter of the patent. If a settlement is agreed without any transfer of value, such an agreement is subject to the scrutiny of competition law, but is likely to be found in compliance therewith as long as the agreement has been reached based on each party's competing assessment of the

¹⁰⁸⁴ Case 35/83, *BAT Cigaretten-Fabriken GmbH v Commission*, [1985] ECR 363, paragraphs 27 and 28.

¹⁰⁸⁵ See the individual legal assessments in chapter 12 below.

¹⁰⁸⁶ In its reply to the Statement of Objections, Lundbeck stated that, in practice, proof of infringement of a process patent is "*very difficult*" (ID 5394, page 29, see also page 183).

¹⁰⁸⁷ As the Court of Justice stated in the Irish Beef case: "*In addition, the means put in place to attain the objective of the BIDS arrangements include restrictions whose object is anti-competitive.*" Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd*, judgment of 20 November 2008, paragraph 36.

patent situation. But when the generic undertaking's incentives to seek market entry are reduced or eliminated because of a transfer of value by the originator undertaking, the generic undertaking may willingly accept market exclusion which it would not accept without the inducement, and the result of market exclusion is therefore not achieved by the strength of the patent, but by the amount of the value transfer. This remains true whether or not the same exclusion might have been achieved if the originator undertaking had gone to court. By paying the generic undertaking to give up its competitive challenge, the originator undertaking obtains certainty that the generic undertaking will not enter the market for the period of the agreement, and, because the generic undertaking will no longer have the incentive to try to enter or litigate given that it cannot sell, there is a high probability that the generic undertaking will not seek a ruling of non-infringement or a ruling of invalidity of the invoked patent, even without any non-challenge clause in the agreement. From the perspective of the originator undertaking, it is the uncertainty of possible generic market entry, including through patent litigation, which reflects potential competition. This potential competition is eliminated through the transfer of value and transformed into the certainty of no competition.¹⁰⁸⁸ This is in particular the case when the amount of the value transfer matches the profit that the generic producer would have made if it had entered the market.¹⁰⁸⁹

- (605) If the exclusion agreed in a patent settlement agreement covers not just the allegedly infringing process used by the generic undertaking at that point in time, but extends to future processes which may not even exist yet and which may or may not be covered by the patent holder's patents, then it becomes all the more clear that the generic undertaking's willingness to give up its efforts to seek market entry was not based on any analysis of possible patent infringement but on the financial incentives offered by the originator undertaking. As a result, possibilities to compete are foreclosed that the generic undertaking would in the absence of the payment have no incentive to accept: Even if the generic undertaking was utterly convinced that its product was infringing and that the invoked patent was valid, in the absence of a payment, why would the generic undertaking accept to bind itself for future products or products from other suppliers that might be non-infringing? Nor could the originator undertaking have obtained such a result by initiating before a court infringement action against the generic undertaking's currently held product, which would have been limited to the latter.

9.3. Agreements between undertakings

- (606) Article 101(1) of the Treaty prohibits certain "*agreements between undertakings*". The concept of 'undertaking' in Union law has an economic scope and a different meaning than the notion of corporate legal personality in national law. As the Court of Justice held in Case C-97/08 P, *Akzo Nobel v Commission*,

*"the concept of an undertaking covers any entity engaged in an economic activity, regardless of its legal status and the way in which it is financed" "even if in law that economic unit consists of several persons, natural or legal."*¹⁰⁹⁰ In this respect it has

¹⁰⁸⁸ On potential competition, see further section 9.4 below.

¹⁰⁸⁹ See chapter 12 below, where the Commission finds for each agreement covered by this Decision that the value transferred from Lundbeck to the generic undertaking at least roughly matched the profit the generic undertaking could only have hoped to obtain by entering the market.

¹⁰⁹⁰ Judgment of 10 September 2009, paragraphs 54-55.

*"been consistently held that any activity consisting in offering goods and services on a given market is an economic activity."*¹⁰⁹¹

- (607) In Case T- 41/96, *Bayer AG v Commission*, the General Court held, based on well-established jurisprudence:

"It is also clear from the case-law in that in order for there to be an agreement within the meaning of Article 85(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..."

As regards the form in which that common intention is expressed, it is sufficient for a stipulation to be the expression of the parties' intention to behave on the market in accordance with its terms....

*It follows that the concept of an agreement within the meaning of Article 85(1) of the Treaty [now Article 101(1) of the Treaty], as interpreted by the case-law, centres around the existence of a concurrence of wills between at least two parties, the form in which it is manifested being unimportant so long as it constitutes the faithful expression of the parties' intention."*¹⁰⁹²

- (608) An agreement can be said to exist when there is a concurrence of wills between two or more parties. Such concurrence of wills allows parties to co-ordinate their behaviour: together they agree on what one or both of them should do. The type of coordination of behaviour between undertakings that falls within the scope of Article 101(1) of the Treaty is that which limits or is likely to limit the individual commercial autonomy of at least one of these undertakings in the future, whether by action or abstention of action. 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."*¹⁰⁹³ *"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."*¹⁰⁹⁴

- (609) The agreements that are the subject of this Decision, including the extensions of those agreements, are clearly *"agreements between undertakings"* within the meaning of Article 101(1) of the Treaty. Each of these agreements contained a concurrence of wills between the undertaking Lundbeck on the one hand and a

¹⁰⁹¹ Case C-180/98, *Pavel Pavlov and Others v Stichting Pensioenfonds Medische Specialisten*, reference for a preliminary ruling, judgment of 12 September 2000, paragraph 75.

¹⁰⁹² Case T- 41/96, *Bayer AG v Commission*, judgment of 26 October 2000, paragraphs 67 to 69.

¹⁰⁹³ Commission Notice: Guidelines on the application of Article 81(3) of the Treaty, OJ C 101, 27.4.2004, page 97, point 14.

¹⁰⁹⁴ Commission Notice: Guidelines on the application of Article 81(3) of the Treaty, OJ C 101, 27.4.2004, page 97, point 15.

generic undertaking on the other hand with respect to the future commercial behaviour of the generic undertaking in question in exchange for a transfer of value from Lundbeck. As the analysis of each agreement in chapter 10.2 will show, the obligations which the generic undertaking accepted in each agreement restricted its ability to enter the market and thereby its autonomy of commercial decision-making and eliminated or substantially reduced commercial uncertainty for Lundbeck with respect to the competitive behaviour of that generic undertaking for the term of the agreement.

9.4. Potential competition

9.4.1. The concept of potential competition

(610) As will be assessed for each generic undertaking in detail in chapter 12 below, the agreements in the case at hand were agreements between undertakings that were at the time of events at least potential competitors. According to well-established jurisprudence 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 enter the relevant market and compete with established undertakings."*¹⁰⁹⁵

(611) In *Visa*, the General Court stated:

"In the second place, as regards the legal tests which should be applied in order to determine whether Morgan Stanley was a potential competitor in the market in question, it follows from the case-law cited in paragraphs 68 and 69 above that the Commission was required to determine whether, if the Rule had not been applied to Morgan Stanley, 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

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Joined Cases T-374/94, T-375/94, T-384/94 and T-388/94, *European Night Services and Others v Commission* [1998] ECR II- 3141, paragraph 137.

competitive pressure on the undertakings currently operating in that market, a pressure represented by the likelihood that a new competitor will enter the market if the market becomes more attractive."¹⁰⁹⁶

- (612) With respect to the time frame within which potential entry should take place, the Court of Justice 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..."¹⁰⁹⁷ The Court of Justice held, in this respect, that a period of one year mentioned in the Commission's Guidelines on horizontal cooperation agreements was merely illustrative.¹⁰⁹⁸
- (613) In *Hitachi*¹⁰⁹⁹, dealing with potential competition in the context of a market-sharing agreement in which Japanese undertakings agreed to stay out of the EEA, the General Court, considering the arrangement to constitute a restriction by object under Article 101, stressed that the key point for the existence of potential competition was that the alleged potential competitors (in that case, the Japanese producers of gas insulated switchgear) were "*regarded*" and "*perceived*" as "*potential credible competitors*" by the incumbents in the market (in that case, the European producers).¹¹⁰⁰ The General Court confirmed that the Japanese producers were indeed potential competitors. Another key point in that judgment was that despite the "*objective entry barriers*" (recognised by the General Court and uncontested by the Commission), the Japanese producers were technically able to enter the European market.¹¹⁰¹ Key items of evidence "*did not state that it was impossible to enter that market, but merely that such entry was difficult*".¹¹⁰² By contrast, whether the Japanese producers actually had a commercial interest in entering the European market was considered "*irrelevant*".¹¹⁰³ In this respect, "the possible lack of commercial interest for the Japanese producers in entering the EEA ..."*does not render* [the market-sharing arrangement] *devoid of purpose*" as the agreement primarily serves to "*eliminate the residual risk of a future entry* [in the] long

¹⁰⁹⁶ Case T-461/07, *Visa Europe Ltd and Visa International Service v European Commission*, judgment of 14 April 2011, not yet reported, paragraphs 166 to 169. In its reply to the Statement of Objections, Alpharma argued that based on this jurisprudence, the Commission must show that entry by Alpharma would have been "*economically viable*." See ID 6056, pages 27-33. However, the General Court in fact stated in the quote to which this footnote refers that market entry must be "*an economically viable strategy*". The word "strategy" implies that the Commission does not have to show that an undertaking would actually have entered the market in the absence of the agreement, nor that if it had entered the market, such entry would necessarily have been a commercial success. Secondly, the word "*Accordingly*" in the quote implies that if the Commission demonstrates, supported by evidence or an analysis of the structures of the relevant market, that in the absence of the agreement "*there would have been real concrete possibilities for [the undertaking] to enter that market and to compete with established undertakings*", entry into that market was indeed a commercially viable strategy for the company concerned.

¹⁰⁹⁷ Case T-461/07, *Visa Europe Ltd and Visa International Service v European Commission*, judgment of 14 April 2011, paragraph 189.

¹⁰⁹⁸ 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.

¹⁰⁹⁹ Case T-112/07, *Hitachi v Commission*, judgment of 12 July 2011, not yet reported.

¹¹⁰⁰ Case T-112/07, *Hitachi v Commission*, judgment of 12 July 2011, paragraphs 90, 226 and 319.

¹¹⁰¹ Case T-112/07, *Hitachi v Commission*, judgment of 12 July 2011, paragraphs 157 and 160.

¹¹⁰² Case T-112/07, *Hitachi v Commission*, judgment of 12 July 2011, paragraph 111.

¹¹⁰³ Case T-112/07, *Hitachi v Commission*, judgment of 12 July 2011, paragraph 160.

term".¹¹⁰⁴ 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]".¹¹⁰⁵

- (614) It is only logical that the perception of market incumbents should play a role in the assessment of whether potential competition exists. If a market incumbent like Lundbeck perceives a competitive threat from generic undertakings that have not yet entered the market, as witnessed for instance by Lundbeck's warning letter of January 2001 to API producers and generic suppliers, this perception is likely to form a competitive constraint on its behaviour in the market. In Lundbeck's case, for instance, Lundbeck could have decided (and did decide in Denmark) to introduce its own authorised generic product to pre-empt generic competition.¹¹⁰⁶ Lundbeck also accelerated the development of its successor product escitalopram. Indeed, in the case at hand, the fact that Lundbeck transferred considerable value to a number of generic suppliers in exchange for their acceptance not to enter the market shows that Lundbeck believed them to be potential competitors.

9.4.2. Specific characteristics of the pharmaceutical sector

- (615) The Commission's Guidelines on the application of Article 81(3) of the Treaty state that *"in assessing whether the parties to an agreement are actual or potential competitors the economic and legal context should be taken into account"*¹¹⁰⁷. In this respect, the pharmaceutical sector presents several specific features: The upcoming expiry of exclusivity on a compound patent generally triggers a highly dynamic competitive process, whereby different generic undertakings rush and compete to be first to bring to the market their generic version of the originator medicine.¹¹⁰⁸ This process of "getting-ready-for-generic-entry" starts generally well before compound patent expiry in view of the time required for preparing entry. If a generic undertaking manages to be the first to enter, it can often benefit from high profit margins until such time as generic competition intensifies through the entry of more generic competitors.¹¹⁰⁹ This explains why API producers and generic suppliers are willing to make considerable investments and accept certain risks (including the risk of infringing process patents that the originator undertaking may have or may still be applying for and that a claim of invalidity may not succeed in removing) to be among the first to enter a newly available generic product market.¹¹¹⁰ Once several generic

¹¹⁰⁴ Case T-112/07, *Hitachi v Commission*, judgment of 12 July 2011, paragraph 158.

¹¹⁰⁵ Case T-112/07, *Hitachi v Commission*, judgment of 12 July 2011, paragraph 226.

¹¹⁰⁶ See also recitals (622) and (623) below.

¹¹⁰⁷ Commission Notice: Guidelines on the application of Article 81(3) of the Treaty, OJ C 101, 27.4.2004, page 97, point 18.

¹¹⁰⁸ See recital (69) above.

¹¹⁰⁹ For instance, in negotiating a settlement with Neolab, Lundbeck accepted that if Neolab had sold its generic product during the period of the consent injunction, it would have made a profit of 70%. See ID 394, page 37. In October 2002, Neolab and Lagap had been the first two generic companies to enter the United Kingdom market.

¹¹¹⁰ Compare point 29 of the Technology Transfer Guidelines: *"The parties are considered to be potential competitors on the product market if in the absence of the agreement and without infringing the intellectual property rights of the other party it is likely that they would have undertaken the necessary additional investment to enter the relevant market in response to a small but permanent increase in product prices."* See 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 29.

competitors are present in the market, prices will tend to drop fast and the originator undertaking's market share may drop significantly if it chooses not to lower its prices. In this period, profits for generic undertakings still tend to be considerable. The process generally loses its dynamics only once the market has become saturated and prices have dropped to a fraction of what they used to be at the time the originator undertaking enjoyed exclusivity.¹¹¹¹ This saturation of the market with generic products and the bottoming out of prices can take up to five years.¹¹¹² The very significant price reductions that normally and irreversibly result from widespread generic entry means that the mere ability of suppliers of generic medicines to enter a market following expiry of the compound patent in itself poses a significant competitive threat to the incumbent originator undertaking, irrespective of the precise intentions of specific generic undertakings and irrespective of whether one or more of them are more likely to infringe any remaining process patents than others.

- (616) The competitive process leading to generic entry consists of two main stages. Potential competition starts when generic API producers that want to launch a generic medicine upon expiry of the exclusivity on the compound patent begin developing a commercially viable production process leading to a product that meets regulatory requirements. This process may already begin several years before expiry of exclusivity on the compound patent. In preparing for launch of a new generic product, it will often be the case that the API producer will have to overcome potential intellectual property barriers deriving from not yet expired process patents. In the second phase of potential competition, suppliers of generic medicines to the targeted markets (which, as in the case of Ranbaxy, may also be the API producer itself) will prepare for actual generic entry by applying for marketing authorisations, by ordering supplies, and by developing strategies for commercial market entry in one or more markets in the EEA, by obtaining price levels (where required by the national authorities) and reimbursement levels in the target markets, by creating a sales force and, as a last step before actual entry, by issuing price lists. Instead of applying itself for a marketing authorisation, a supplier of generic medicines may also be able to purchase or license a marketing authorisation already obtained by another undertaking.¹¹¹³ It may then either buy the product covered by that marketing authorisation or apply for a variation of the marketing authorisation to buy from another API producer.
- (617) In relation to overcoming potential intellectual property barriers, API producers have different options to compete. Firstly, an API producer may produce the molecule relying on disclosures regarding the manufacturing process contained in the initial molecule patent or in other expired patents. Should any process patent still be a potential obstacle, they can oppose or try to invalidate such a patent or try to "invent

¹¹¹¹ In February 1999, Lundbeck wrote: "*when generic citalopram is launched on a market, there is enormous price competition with the maker of the original product*". See recital (128) above.

¹¹¹² With respect to market shares, Lundbeck estimated in February 1997 that, in a realistic scenario, it would lose 28% market share to generic competition in the first year of generic entry, climbing to 70% in year five. Between year four and five, the market share loss would still amount to 4%. See recital (124) above.

¹¹¹³ A former executive of the generic industry explained: "*'in-licensing' is still normal business practice today in the generics industry.*" (See ID 6070, page 2)

around" such a patent (thus avoiding the scope of the patent).¹¹¹⁴ The likelihood of invalidation may be high or low. In turn, it may be easy or difficult to invent around a patent (with a low or high likelihood of not infringing remaining patents¹¹¹⁵). In the course of preparing for market entry, API producers can and often will further amend particular steps in their production process to increase the likelihood that they avoid any possible infringement of process patents. Generic undertakings often pursue different paths in parallel. However, either way, API producers generally face as part of the competitive process uncertain patent law questions and potential intellectual property barriers.¹¹¹⁶ In the case of process patents, it usually does not take long for API producers to find some way to produce a medicine which is no longer patent-protected in a way that does not infringe any process patents.¹¹¹⁷

- (618) As already mentioned in section 4.1, upon expiry of exclusivity of the compound patent, suppliers of generic medicines also have a number of options to compete with originator undertakings to enter the market with their generic product in the face of process patent obstacles created by the originator undertaking. Like the API producer (or together with the API producer), they can oppose or try to invalidate a patent. They can also seek a declaration of non-infringement from a court or take other measures to "clear the way" before actual entry (such as informing the originator undertaking of the manufacturing process used and inviting it to "sue us now").¹¹¹⁸ Or they can launch at risk and face a possible patent challenge by the originator undertaking head on, defending themselves against allegations of infringement and with the option to counter-claim patent invalidity. Concerns about possible patent infringement can also be met by working with the API producer to further amend the production process to reduce or eliminate the risk of patent infringement. Finally, switching to another API producer with less risk of patent infringement is also a possibility that can normally be accomplished within a matter of months.¹¹¹⁹
- (619) For the reasons set out in recitals (615) to (618), generic undertakings can become a competitive threat to an originator undertaking at least several years before expiry of the exclusivity on a compound patent is due. In *AstraZeneca*, the Court of Justice considered that SPCs can have significant exclusionary effects after the expiry of the basic patents, but that *"they are also liable to alter the structure of the market by*

¹¹¹⁴ See already recitals (72) and (73).

¹¹¹⁵ "Inventing around" implies that remaining patents are not infringed. In this case, for example, the process that a generic manufacturer has developed is out of the scope of the originator's patents. However, whether or not the originator's remaining patents are infringed is often unclear and entails litigation.

¹¹¹⁶ In its reply to the Statement of Objections, Merck KGaA pointed out that in a situation of *"a bundle of patents, the identification of the protected zone of exclusivity becomes, however, blurry and opaque."* (See ID 5960, page 113)

¹¹¹⁷ See recital (634) below.

¹¹¹⁸ See footnote 312 above.

¹¹¹⁹ According to a March/April 2002 publication of the United Kingdom Medicines Control Agency in the United Kingdom, the Agency processed all type II variations within 90 days from the acknowledgement letter (and 85% within 60 days), resulting either in an approval or a request for supplementary information. A type II variation would normally be required for a switch to a different API supplier. For type I variations, the corresponding figures were 100% in 30 days and 84% in 20 days. A type I variation could be appropriate if the existing API supplier modified its already approved production process. See ID 1910, page 16. See also recital (86) above. Whether an applicant actually obtained approval within these time periods depended on the completeness and accuracy of the information it supplied to the agency.

adversely affecting potential competition even before that expiry."¹¹²⁰ 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 patent, even if process 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.¹¹²¹

- (620) When an originator undertaking issues allegations of infringement of process patents against a generic undertaking, this normally provides a solid indication that there is potential competition, in particular if the generic undertaking has already sunk considerable resources and time into the development or marketing of the generic product to which the dispute relates. The absence of a marketing authorisation does not mean that the product is not capable of reaching the market in the near future, as long as the generic undertaking was pursuing its efforts to obtain regulatory approval before it entered into an agreement with the originator undertaking.¹¹²²

9.4.3. *Potential competition in the case at hand*

- (621) As the facts in chapter 7 have shown, at the time Lundbeck and the generic undertakings concluded the agreements in question, Lundbeck's basic patent on the citalopram compound (which included the two original processes to produce the compound) had lapsed by January 2002 in most EEA Contracting Parties. This meant that citalopram markets in those Contracting Parties of the EEA were open to generic competition, as generic citalopram medicine could henceforth be sold provided it met regulatory requirements as to quality, safety and efficacy, as confirmed by a marketing authorisation.¹¹²³ Generic undertakings with a business plan to sell generic

¹¹²⁰ Case C-457/10 P, *AstraZeneca v Commission*, judgment of 6 December 2012, paragraph 108.

¹¹²¹ Case C-457/10 P, *AstraZeneca v Commission*, judgment of 6 December 2012, paragraph 108.

¹¹²² See by analogy Case T-50/00, *Dalmine SpA v Commission* [2004] ECR II-2395, paragraph 186: "*As for Dalmine's arguments concerning the practical obstacles which prevented it from directly selling premium and standard OCTG on the United Kingdom market, those obstacles are not sufficient to show that it would never have been able to sell those products on that market had it not been for the supply contract it entered into with Corus and subsequently with Vallourec. On the assumption that conditions on the United Kingdom market for OCTG improved, it cannot be precluded that Dalmine would have been able to obtain a licence to sell premium thread pipes on that market or that it might have increased its production of standard OCTG in order to sell those products in that market. It follows that, by signing the supply contract in question, it in fact accepted constraints on its commercial policy, as described in paragraphs 182 to 185 above.*"

¹¹²³ See section 4.2 above. Lundbeck internally rightly concluded at the time that "[g]eneric competition is foreseen on markets where the product patent has expired". See recital (127) above. The open nature in principle of citalopram markets in the EEA at the time the agreements were concluded is a fundamental difference with the situation in Case T-360/09, *E.ON Ruhrgas AG and E.ON AG v Commission*, judgment of 29 June 2012, where the French and German markets were, for legal and factual reasons, 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. However, 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).*" 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 that entering the market would have been "*an economically viable strategy*" (paragraph 114). The Court found that "*In particular, there is no 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*

citalopram in markets in the EEA and a realistic prospect to obtain supplies of generic citalopram medicines and an accompanying marketing authorisation in the near future were potential competitors to Lundbeck and to each other.

- (622) In the case of citalopram, Lundbeck considered at the time that "[g]eneric competition is foreseen on markets where the product patent has expired", that is to say in most EEA Contracting Parties at the latest as of January 2002.¹¹²⁴ Fully in line with Lundbeck's forecast, there is abundant evidence that the dynamic competitive process for generic citalopram entry had started with full force before the agreements were concluded, and was on-going and not concluded during their term. The facts show that a number of specialised API companies were investing and teaming up with generic companies trying to be amongst the first to bring generic citalopram to the market.¹¹²⁵ The facts, however, also show that only few API producers and generic companies were so advanced that they were able to compete for being "*in pole position*" for generic entry. In the United Kingdom, among these companies vying for pole position were Arrow, Alpharma (both had teamed up with the API producers Cipla and Matrix) and Merck (GUK) (which had teamed up with the API producer Natco).¹¹²⁶ Merck called the time period shortly before conclusion of the agreements "*the race against Tiefenbacher*" (which had licensed its Cipla and Matrix marketing authorisations to Arrow and Alpharma).¹¹²⁷ This dynamic race with changing positions of "*front runner[s]*"¹¹²⁸ stopped or was in any case significantly slowed down, particularly in the United Kingdom, because of the agreements that Lundbeck concluded with Merck (GUK), Arrow, Alpharma and Ranbaxy.
- (623) With respect to Lundbeck's contemporaneous views on the existence of potential competition on citalopram, already in November 1998 Lundbeck wrote: "*Generic competition is foreseen on markets where the product patent has expired or where generic suppliers may invent a new manufacturing process. In some EU markets the patent has already expired.*"¹¹²⁹ In December 1999 Lundbeck wrote: "*By 2002, however, generics are expected to have captured a substantial share of Cipramil sales.*"¹¹³⁰ In January 2001, Lundbeck wrote a general warning letter about the risk of

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).

¹¹²⁴ See recital (127) above. For patent expiry dates see recitals (109)-(111). The exception is Austria, where the compound patent expired only in April 2003.

¹¹²⁵ Including VIS, CF Pharma, Norpharma, Cipla, Dai-ichi, Hauhai, Herero, Max Pharma, Merck, Matrix, Natco, Neuland, Ranbaxy, Resolution Chemicals (Arrow), RPG Life Science, Sekhsaria, Sumika and Sun. See recitals (148), (150), (173)-(183), (219), footnote 300, ID 673, pages 42 and 85 and ID 6082, page 29. However, only some of these companies continued their project (also due to circumstances described in section 6 above).

¹¹²⁶ See recital (257) above.

¹¹²⁷ ID 5960 (Merck KGaA's reply to the Statement of Objections), pages 25 and 80-81. See also recital (257) above.

¹¹²⁸ See, for example, recital (495) above.

¹¹²⁹ See recital (127) above.

¹¹³⁰ See recital (129) above.

patent infringement to a number of generic API producers and generic suppliers of medicines.¹¹³¹ In December 2001, Lundbeck wrote in its "Goal, Activity and Budget Plan 2002" with respect to the United Kingdom market: *"The UK is the market that Lundbeck expects to be hit most severely by generic competition. Immediately following patent expiry in January 2002, generic sales are expected to take 60% of the citalopram business."*¹¹³² Given this assessment of the immediate and strong impact of generic competition on Lundbeck's market share (previously at 100%), there can be no doubt that potential generic competition exerted competitive pressure on Lundbeck well in advance of the expiry of the compound patent in January 2002 in most EEA countries. As has been described in chapter 6, faced with the threat of generic competition on citalopram, representing during exclusivity 85% of Lundbeck's turnover, Lundbeck accelerated development of its successor product escitalopram with a view to introducing it into the market as long as possible in advance of widespread generic entry on citalopram. Lundbeck also took a number of actions to delay generic entry on citalopram, including the purchasing of VIS and Norpharma's patented process, submitting a large number of patent applications for manufacturing processes for citalopram and intervening in marketing authorisation procedures, introducing its own authorised generic distributor in Denmark, Nycomed, and, last but not least, concluding the agreements with generic suppliers that are the subject of this Decision.

9.4.4. *Challenging patents is an expression of potential competition in the pharmaceutical sector*

- (624) It should be noted that non-infringement of a patent is not a requirement to obtain a marketing authorisation in the EEA.¹¹³³ Nor does a generic undertaking have to prove that it is not infringing any patent before it can market its products in the EEA.¹¹³⁴ On the contrary, it is only when an originator undertaking has proven to a national court, at least in a *prima facie* fashion, that a generic product infringes a patent that the generic undertaking may be enjoined by the court not to sell the product.¹¹³⁵ Should that happen, the generic undertaking in question will no longer

¹¹³¹ See for instance recitals (148), (225), (477) and (549) above.

¹¹³² See recital (196) above.

¹¹³³ See section 4.2 above. It should be noted that whenever Lundbeck and the generic undertakings in this case claimed to the Commission that the generic products in question were "infringing", in fact what they should have said was that these products were "potentially infringing" or that they thought that the products would be infringing. In reality, at the point in time when the agreements covered by this Decision were concluded, none of the generic undertakings in question had been found to be infringing any of Lundbeck's process patents by a court of law in any of the territories covered by the agreements.

¹¹³⁴ Even in the United Kingdom, following the *Paroxetine* ruling (see footnote 312 above), a generic undertaking has the legal right to launch at risk, even if, when faced with an interim injunction, the balance of convenience would tilt in favour of granting the injunction if the generic could not have ignored that the patent holder would sue for patent infringement if it entered the market and it did nothing to "clear the way". Also in the United Kingdom, therefore, the generic undertaking does not have to prove that it is non-infringing. The burden of proof in this respect remains, in principle, with the originator undertaking.

¹¹³⁵ In reply to the Statement of Objections Lundbeck confirmed that in itself a challenge by a generic company of the originator's patent invoked against its entry can lead courts to reject an injunction. This is so because courts may find that the balance of convenience weighs in favour of the generic company. For instance: *"In Germany, [...] If the validity of the patent is questioned, an injunction cannot be obtained (i.e., to the extent there is an ongoing procedure of invalidity before the EPO or any other*

be an actual competitor if it had already started selling. But even in this case it cannot be excluded that the generic undertaking will remain a potential competitor as long as there is no final injunction and possibilities of legal challenge remain.¹¹³⁶

- (625) Patent litigation, which is very common when new generic products become available through expiry of exclusivity on originator medicines, is in fact an expression of the independent efforts of generic undertakings to enter the market and therefore a form of competition in the pharmaceutical sector. Likewise, patent litigation is also an expression of competition from the side of the originator undertaking, which in this way is trying to defend its market position against generic competition.
- (626) In the pharmaceutical sector, patent challenges are an essential part of the competitive process between generic companies seeking market entry for compounds that are no longer patent-protected and originator companies that invoke process patents or other process patents against such market entry.¹¹³⁷ The Commission's 2009 inquiry into the pharmaceutical sector found that *"about half of the medicines subject to in-depth investigation faced generic entry within the first year after loss of patents (including SPC) and data exclusivity...Delays are important as the price at which generic companies enter the market was, on average, 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after entry, prices of generic medicines were on average 40% below the former originator price."*¹¹³⁸ In such a situation, competition – actual or potential – from generic undertakings trying to enter the market by inventing around, seeking declarations of non-infringement or trying to invalidate process patents or formulation 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. Accepting that merely because of the (threatened) invocation of a patent or even a genuine patent dispute, an originator undertaking can pay money to a generic undertaking in exchange for the latter signing a document stating that it is (possibly) infringing a patent and ceasing its efforts to enter the market, would make the necessary application of competition law to market exclusion agreements in this industry *de facto* impossible.
- (627) In the case at hand, potential competition became even more likely as of the moment of the expiry of exclusivity on the compound and the original two production processes because of Lundbeck's own assessment that, at least in the United Kingdom, the crystallisation patent, on which Lundbeck heavily relied to deter generic entry, had a 60% chance of being held invalid by the United Kingdom Patent Court. From the moment the crystallisation patent application became known, in January 2001 through a warning letter Lundbeck sent to many API producers and

judicial or regulatory body, no injunction can be granted)." See ID 5394, page 56. If on these grounds an interim injunction against the generic company is rejected, the generic undertaking is entirely free in deciding whether to continue selling the generic medicine or whether to launch it.

¹¹³⁶ Of course, the generic company exposes itself to damages if its assessment of product proves wrong.

¹¹³⁷ See sections 4.1 and 9.1 above. See also European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, in particular pages 10 to 15 and 195 to 383.

¹¹³⁸ European Commission, -DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 8-9.

generic suppliers, it was analysed by Lundbeck's "enemies" as "high school chemistry"¹¹³⁹ and not novel, meaning that parties realised that this patent could very well be held partially or entirely invalid by a court, a national patent office or the EPO.

- (628) It is, of course, true, as mentioned by several of the parties, that the General Court held in *AstraZeneca*:

*"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."*¹¹⁴⁰

This does not, however, in the view of the Commission mean that the possibility of challenging the validity of a patent should be disregarded for the purpose of assessing the potential for competition, all the more so when the compound patent has expired and the medicine in question can in principle be sold. The assumption of validity of the patent does not bar legal action in court to challenge the validity of the patent. In the Commission's view, while the assessment of potential competition *"has to be based on realistic grounds, the mere theoretical possibility to enter a market is not sufficient"*¹¹⁴¹, nothing prevents the possibility of invalidity of an invoked patent from being included in these "realistic grounds". 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."*¹¹⁴² In the same vein, the General Court in *AstraZeneca* considered that undue patent protection can reduce incentives to engage in innovation: *"It is quite clear that, where established, such behaviour is indeed contrary to the public interest, as weighed up and applied by the legislator. [...] 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."*¹¹⁴³

The Commission points out that, in this case, it has, with respect to the likelihood of invalidity (or of infringement) of Lundbeck's patents, relied on assessments by the parties themselves, in particular as found in contemporaneous documents.¹¹⁴⁴ Finally,

¹¹³⁹ See recital (149) above.

¹¹⁴⁰ Case T-321/05, *AstraZeneca AB and AstraZeneca plc v Commission*, judgment of 1 July 2010, paragraph 362.

¹¹⁴¹ 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 10.

¹¹⁴² Case 193/83, *Windsurfing International v Commission*, [1986] ECR 611, paragraph 92. As Ranbaxy stated in reply to the Statement of Objections: "[Lundbeck employee] does not appear to take into account the possibility that Ranbaxy might have claimed that the relevant patents were invalid if it had been forced to defend itself in an infringement proceeding. Ranbaxy therefore submits that Lundbeck overstates the point when stating that at the end of May 202, it became "certain that Ranbaxy was infringing"....". See ID 6539, page 4.

¹¹⁴³ Case T-321/05, *AstraZeneca v Commission*, [2010] ECR II 02805, paragraph 367.

¹¹⁴⁴ See the specific legal assessments of the existence of potential competition for each agreement in chapter 12. See also recital (157) above.

it may be noted that the General Court refers in this AstraZeneca quote to "competitors", even if they may "normally" be held away by a patent.

- (629) The Commission therefore does not agree with Lundbeck's claim that "*Companies that would be able to enter the market and "compete" with products manufactured on the basis of infringing processes cannot be regarded as "potential competitors"*".¹¹⁴⁵ Again Lundbeck entertains confusion on the word "infringing". The point is precisely that as long as a court has not pronounced itself on whether a patent has been infringed or, in an interim procedure, is likely to have been infringed, the generic undertaking's product can only be considered as potentially infringing and can be sold to the market. In fact, the patent holder first has to bring infringement proceedings, and then prove the infringement to the satisfaction of the judge; there is no legal assumption that a patent is infringed. This is particularly relevant, where exclusivity on the compound has already expired, because with patent expiry the sale of the compound is in principal free; Lundbeck explained that infringement of a process patent is more difficult to establish.¹¹⁴⁶ Moreover, should it transpire in court proceedings that a specific generic product that is subject to litigation may really be infringing a process patent confirmed valid, generic companies may still be free to switch to API produced with an amended, non-infringing process produced by the same API producer or by a different API supplier with a different process altogether. With respect to citalopram, Merck explained at the time: "*In the meantime we had several legal proceedings against Lundbeck concerning patent issues. By clever changing the raw material sources we could successfully keep our product in the market.*"¹¹⁴⁷
- (630) GUK nevertheless submitted that sales at risk (that is to say sales in the market with the risk that the originator undertaking may start infringement action) do not qualify as either actual or potential competition because they might later be found to have been infringing a patent.¹¹⁴⁸ If this definition were used, most generic sales in the industry would not qualify as competition. Rare is the case where a generic product cannot be subject to any patent challenge. In this sense, virtually all such sales after basic patent expiry are "at risk". Indeed, in the case at hand, Lagap's sales were never formally found by the court to be non-infringing, because Lundbeck settled beforehand. Those sales and the widespread generic entry that followed afterwards in the United Kingdom and elsewhere in Europe based on Matrix product and products of other API suppliers would therefore in the view of GUK be "at risk" and not

¹¹⁴⁵ ID 5394, page 276. Other parties made similar arguments.

¹¹⁴⁶ Lundbeck pointed out in its reply to the Statement of Objections that "*Article 34 TRIPS recognizes the difficulty of enforcing process patents. It requires TRIPS contracting parties to provide for a reversal of the burden of proof in litigation concerning the alleged infringement of process patents, meaning that the generic company must, under certain circumstances, demonstrate that it did not infringe a process patent. However, Article 34 of the TRIPS gives contracting parties the option – which most EEA countries have exercised in their national implementing measures – to subordinate the reversal of the burden of proof to the condition that the patented process concerns the production of an entirely new product. Therefore, in practice, this reversal of the burden of proof often does not apply in favour of patent holders, which makes proof of infringement very difficult.*" (ID 5394, page 29). Even under the United Kingdom system of "clearing the way", the generic undertaking has the possibility to ask the originator undertaking to "sue us now", thereby ensuring that the originator undertaking still has the burden of proving that the generic product infringes. See footnote 312 above.

¹¹⁴⁷ See recital (351) above.

¹¹⁴⁸ ID 6661, pages 3 to 5.

qualify as competition, even though they reduced significantly Lundbeck's market share for citalopram.

- (631) It is quite possible for an originator undertaking to decide for commercial reasons not to launch infringement action against sales of generic products, even if it believes such products are likely to be infringing. Again, after Lundbeck had settled in Lagap, it completely gave up any further litigation against generic sales by other generic undertakings in the United Kingdom, including with different products than Lagap had used, whether or not such products would have been infringing. The same may happen after an originator undertaking has successfully switched to a successor product. In that case, it may decide not to challenge generic competition on the old product anymore, whether or not such products would be infringing. To say that in those situations there was no competition because there might be patent infringement would amount to a legal fiction that ignores reality.
- (632) The invocation by several of the parties of the Technology Transfer Regulation¹¹⁴⁹ and accompanying Guidelines¹¹⁵⁰ is of no avail in this respect.¹¹⁵¹ The Technology Transfer Regulation does not apply to the agreements covered by this Decision, because those agreements did not transfer any technology. The situation of, in principle, pro-competitive licensing agreements, whether concluded between competitors or not, and the restrictions that may be acceptable in such a context, is to be clearly distinguished from the horizontal anti-competitive agreements in this case. As the Guidelines state: *"Indeed, licensing as such is pro-competitive as it leads to dissemination of technology and promotes innovation. In addition, even licence agreements that do restrict competition may often give rise to pro-competitive efficiencies, which must be considered under Article 81(3) and balanced against the negative effects on competition. The great majority of licence agreements are therefore compatible with Article 81."*¹¹⁵² Licensing agreements can lead to new sales and new competition that would not have taken place in the absence of the licensing agreement. The reverse is true for the agreements under consideration: They led to the abandonment of potential competition that existed before the agreements were

¹¹⁴⁹ Commission Regulation (EC) No 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, OJ L 123 of 27.4.2004. Article 1 of the Technology Transfer Regulation refers to competing undertakings on the relevant technology market as undertakings that license out competing technologies *"without infringing each others' intellectual property rights (actual competitors on the technology market)"* and to competing undertakings on the relevant product market as undertakings that are active on the relevant product and geographic market *"without infringing each others' intellectual property rights (actual competitors on the product market)"*.

¹¹⁵⁰ 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 29 of the Technology Transfer Guidelines states: *"The parties are considered to be potential competitors on the product market if in the absence of the agreement and without infringing the intellectual property rights of the other party it is likely that they would have undertaken the necessary additional investment to enter the relevant market in response to a small but permanent increase in product prices."* Point 32 of the Technology Transfer Guidelines states: *"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. This is for instance the case where one patent covers an improvement of a technology covered by another patent. In that case the exploitation of the improvement patent pre-supposes that the holder obtains a licence to the basic patent."*

¹¹⁵¹ See also section 11.2 below.

¹¹⁵² Point 9 of the Technology Transfer Guidelines.

concluded. Any claimed efficiencies for the agreements covered by this Decision will be analysed in chapter 14 below, but it can already be stated here that none of the parties has proven, or even submitted the required evidence to argue, that the requirements of Article 101(3) of the Treaty have been met in this case.

- (633) In conclusion on this point, the Commission considers that in the circumstances of the case at hand, in particular given that the compound patent on citalopram had expired, legal challenges to the originator undertaking's remaining process patents, whether in the form of a defence against claims of infringement, actions to clear the way or actions to invalidate such patents, were, along with other routes to the market open to the generic undertaking¹¹⁵³, an expression of potential competition from generic undertakings intending to enter the market with a generic version of the compound in question. 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 any such patent could be invalidated. As will be explained below in section 9.4.5, the agreements in question were designed to replace the uncertainties of the competitive process for the certainty of an agreement between undertakings, in exchange for a payment.

9.4.5. *Lundbeck's remaining process patents were not capable of blocking all possibilities of market entry*

- (634) Even if the argument were accepted that potential competition could be absent if it were – objectively considered¹¹⁵⁴ – impossible to enter the market because of Lundbeck's process patents¹¹⁵⁵, the fact is that Lundbeck itself confirmed to the Commission that its process patents were not capable of blocking all possible routes to the market: *"...generic entrants could have produced citalopram by using the process described in Lundbeck's original compound patent filed in 1977, albeit with a different and potentially less efficient method of purification, or they could have invested to invent an entirely new process."*¹¹⁵⁶ Lundbeck also explained to the Commission that *"In the 2002-2004 timeframe, there were several processes available to produce citalopram. Instead of using one of the several processes*

¹¹⁵³ See recital (635) below.

¹¹⁵⁴ In this respect the Commission draws attention to point 32 of the Technology Transfer Guidelines: *"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 Lundbeck and the generic undertakings covered by this Decision had a common interest in arguing to the Commission that Lundbeck's patents were being infringed or were likely to be infringed, arguing on that basis that no potential competition existed. The Commission relies, in this respect, particularly on contemporaneous documents.

¹¹⁵⁵ See, in this respect, Case T-112/07, *Hitachi v Commission*, judgment of 12 July 2011, not yet reported paragraph 226.: *"[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]".* See also Case T-360/09, *E.ON Ruhrgas AG and E.ON AG v Commission*, judgment of 29 June 2012, paragraph 123: *"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."*

¹¹⁵⁶ See recital (150) above. The Commission recalls that in the Lagap litigation, Lundbeck's counsel declared about the Matrix II process: *"I do accept that it can be run economically. It does depend on how you do the cyanation. They [Matrix] do the cyanation more efficiently than we have believed that they could do it."* See recital (158) above.

available, generics freely chose to use the process described in the Crystallization patent because it was more efficient than the other processes". Lundbeck listed the following non-infringing processes which generic companies could choose to use in the period 2002-2004:

- the original cyanation and alkylation processes;
- the Matrix washing method;
- Sekhsaria's process;
- Sumika's process;
- other processes, including processes of the API producers Max Pharma, Natco and Cipla, which these API producers claimed to be non-infringing.¹¹⁵⁷

Specifically with respect to Lundbeck's crystallisation patent, on 2 March 2002, Lundbeck's patent experts concluded: "*SPE has shown that it is possible to make an active pharmaceutical ingredient (API) that very probably does **not** require crystallisation of the free base*".¹¹⁵⁸

Consistent with these latter explanations is also a contemporaneous statement of 9 November 2002 that Lundbeck's Senior Vice President gave to the press: "*It would be naïve to think that it is not possible for producers of generic copies to produce Cipramil without breaking our patent*".¹¹⁵⁹

These statements show that the production of citalopram that met European regulatory requirements was in principle possible without infringing any of Lundbeck's process patents. They show that several generic API suppliers invested at the time in non-infringing production processes and managed to make those available in the period covered by Lundbeck's agreements. These statements therefore rebut Lundbeck's later claims in reply to the Statement of Objections that "*the only industrially viable process that could reduce the impurities in [the two original processes] to API quality was (and still is) the Crystallization Process*".¹¹⁶⁰ This claim was, in any case, not maintained by Lundbeck in the Lagap trial, where Lundbeck withdrew its argument that Matrix's non-infringing washing process was not industrially viable.¹¹⁶¹

(635) Under these conditions, where:

- the compound was no longer patent-protected;
- the two original production processes were no longer patent-protected;
- Lundbeck still had a number of process patents (including, in particular, the crystallisation patent) that covered several, but not all, possible ways to produce marketable citalopram medicine,

¹¹⁵⁷ ID 2773, pages 14 and 15. Regarding this list, Lundbeck clarified: "*Given the number of potential processes to produce citalopram, it is not possible to provide an exhaustive list*." See further footnote 298 above.

¹¹⁵⁸ See further footnote 299 and recital (281) above.

¹¹⁵⁹ ID 1789, page 6.

¹¹⁶⁰ ID 5394, pages 46, 47, 54.

¹¹⁶¹ See section 6.3 above.

generic undertakings wanting to enter the citalopram market in the near future had several alternatives open to them that could lead to market entry even in the presence of Lundbeck's process patents, each of which represented potential competition if the option was available not just in theory, but as a real concrete possibility, as an economically viable strategy. Those possible routes to the market were:

- Launching at risk the product they had and facing Lundbeck's patent challenge;
- Making efforts to "clear the way" with the originator undertaking first before entering the market, especially in the United Kingdom (Lagap being an example);
- Requesting a declaration of non-infringement from a national court before entering the market, as Niche Generics did in the United Kingdom;
- Claiming patent invalidity before the national courts, in particular as a counter-claim to a claim by the originator undertaking of (imminent) patent infringement;
- Opposing a patent before national patent bodies or the EPO, with the request to revoke or narrow the patent, as a number of generic undertakings in the industry did in the case of Lundbeck's crystallisation patent;
- Working with the current API supplier or middleman (for instance, Tiefenbacher, Schweizerhall/Aceto) to change the API suppliers' process in such a way as to eliminate or reduce the risk of infringement of Lundbeck's process patents (for instance, Cipla, the API supplier of Arrow and Alpharma, developed a new and allegedly non-infringing process in the course of 2002);
- Switching to another API supplier within the current supply contract (for instance, Matrix's original process appeared to be less likely to infringe than Cipla's; Matrix developed a new production process in the course of 2002 which Lundbeck had to admit in the Lagap litigation did not infringe);
- Switching to another API supplier outside of the current supply contract, either because the current supply contract permitted that (for instance, Arrow considered it was free to buy from other API suppliers than Cipla or Matrix; Ranbaxy, for instance, offered Arrow citalopram API and claimed to have no infringement issues) or possibly because an exclusive contract could be invalidated if the supplied API was found to be infringing.

(636) Whether a specific generic undertaking was actually a potential or actual competitor to Lundbeck depended on the precise facts in each particular instance. In this respect the Commission will assess in chapter 12 below whether the generic undertaking concerned had already entered the market or, if not, its ability to enter the market in the near future through any of the options mentioned in recital (635) above. In the circumstances of the present case, the Commission considers that absent the agreements, there would have been real concrete possibilities for the generic undertakings to enter the market. The possibility of entering represented a plausible assumption and not a merely theoretical hypothesis.¹¹⁶²

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Case T-461/07, *Visa Europe Ltd and Visa International Service v European Commission*, judgment of 14 April 2011, not yet reported, paragraphs 186 and 187.

10. RESTRICTION OF COMPETITION

10.1. Introduction

- (637) It follows from section 9.1 above that patent settlements, like any other kind of agreements, infringe Article 101(1) of the Treaty when they have the object or effect of restricting competition within the internal market and affect trade between Member States. Patent settlements do not enjoy a special status that exempts them from the reach of competition law.
- (638) That is not to say, however, that patent settlements that limit the commercial autonomy of at least one of the parties necessarily infringe Article 101(1) of the Treaty. When in a patent dispute a settlement is reached without inducement on the basis of each party's assessment of the probability of a patent being held valid and infringed by a court, such a patent settlement will normally not infringe Article 101(1) of the Treaty if the agreed limitations on the behaviour of the generic undertaking do not go beyond the rights granted by patent law. Provided such an agreement does not come about or is induced by elements extraneous to the issue of the likely validity and infringement of the patent in question, it may therefore contain an obligation on the generic undertaking not to use the invention covered by the patent during (part of) the period of patent protection. Although in such a case a certain limitation of the commercial behaviour of the generic undertaking is agreed between the parties to the patent dispute, this limitation is based on competing interests and directly related to the strength of the patent, as perceived by each party. It is precisely because the originator undertaking and the generic challenger have opposite interests in such a case, the latter wanting to enter the market and the former wanting to prevent such market entry, that it may be assumed, subject to evidence to the contrary, that such a patent settlement is likely not to include stricter limitations on the generic undertaking's future behaviour than the generic undertaking feels bound to accept in the light of the strength of the patent.
- (639) Nor is it necessarily the case that all patent settlements that contain payments of some kind would be problematic under Union competition law. Payments 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 in cases 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 of patent validity and infringement is high, 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 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 the patent is invalid or that it is 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 compensating the damage suffered by the generic company. Another example of an unproblematic settlement including payment is the settlement of Neolab with Lundbeck, mentioned in recital (164) above.

- (640) However, when an agreement is concluded in which the generic undertaking accepts to exit or not to enter the market for a certain period of time (in which case one would expect, if anything, a payment by the generic undertaking to compensate the originator undertaking for any damages it may have suffered) but instead the originator undertaking pays a considerable sum of money to the generic undertaking, then such an agreement, whether referred to as a patent settlement or not, merits the full scrutiny of competition law. The reason is that such a constellation could mean that the originator undertaking has paid the generic undertaking to accept to give up, at least for the term of the agreement, its independent efforts to enter the market. Because of the unexpected direction of the payment, such payments are referred to in literature as "reverse" payments. In principle, the higher the originator undertaking estimates the chance of its patent being found invalid or not infringed, and the higher the damage to the originator undertaking resulting from successful generic entry, the more money it will be willing to pay the generic undertaking to avoid that risk. The danger is that such payments, in the light of the specific circumstances of the case, may actually constitute "exclusion" payments, that is to say payments by the originator undertaking to the generic undertaking in exchange for the latter's acceptance of commercial limitations which it would not, based purely on its assessment of the likelihood of infringing a patent and of invalidating any such patent, have the same incentives to accept in the absence of the payment.
- (641) As already mentioned in section 9.1 above, 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. 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 the right to exclude that any means used to obtain this result of exclusion would necessarily be compatible with competition law. In particular, payments made by patent holders to generic challengers aimed 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 are likely to breach 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.
- (642) However, such restrictions are all the more likely to be illegal when the restrictions agreed do go beyond the substantive scope of the patent, in the sense that the same restrictions could not have been obtained by the patentee's right to oppose possible infringement before the court. If a court ruling found a patent valid and infringed, the generic challenger would be stopped from using the invention covered by the patent. In the case at hand, this would mean that a generic undertaking would not be able to use the protected manufacturing process to produce, import or sell citalopram. But nothing in patent law can prevent a generic undertaking from using a different process (either the original process for which patent protection has expired or a new process the generic undertaking has invented itself, or any other process that is not patent-protected) to produce citalopram once the citalopram compound patent and the original process patent have expired (including SPCs). With the expiry of exclusivity on the compound patent, the market for citalopram was in principle open. Any commitment from a generic undertaking in an agreement not to sell

"citalopram" (here with reference to the compound, whether API or medicine) for a certain period cannot be justified by patent law, simply because a process patent does not give the patent holder rights outside the patent's scope, which for process patents is limited to the particular process covered by that patent and products directly obtained by the patented process.¹¹⁶³ Any such clauses (also referred to as "out of scope" obligations) indicate, like the payment itself from the originator undertaking, that the object of the agreement was to commit the generic undertaking to stay out of the generic citalopram market entirely for the duration of the agreement, irrespective of whether or not the generic products which the generic undertaking might have come to sell would have infringed any process patents.

- (643) In such a situation, the originator undertaking and its generic challenger will be at least potential competitors, if not already actual ones, and should therefore in principle pursue contrary commercial interests. Nevertheless, it may in fact, if one ignores the obligation to comply with competition law, be both in the interest of the originator undertaking to pay the generic undertaking a considerable sum of money 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. For the originator undertaking the risk of its patent being held invalid or not infringed by a court multiplied by the significant amount of money the originator undertaking would lose if generic entry were to take place, could well mean that it is commercially more attractive to simply pay the generic undertaking the money that it could hope to gain by entering the market, or more, on condition that the generic undertaking stays out of the market. Such a deal is normally also attractive to the generic company, as it can now make the same kind of profit, or even more, as when it had tried to enter the market, but without any of the efforts and risks attached to market entry, whether risks of litigation by the originator undertaking or risks of price competition from other generic undertakings or the originator undertaking.
- (644) The reason why both competitors can be better off at the same time is that the profit the generic undertaking could make from entering the market will be lower, probably considerably lower, than the money the originator would be likely to lose if generic entry occurred. Generic entrants will tend to price their product lower, often considerably lower, than the originator's product, as otherwise suppliers, 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 product is therefore on price. This is a major difference from competition between different originator products, which takes place mainly on quality and sales promotion rather than 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 4.3, pricing and reimbursement legislation exists in most countries 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 or price level of the originator product. It may thus make

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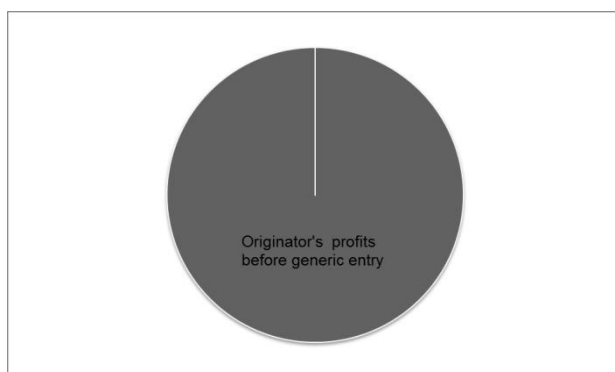
See section 4.1 above.

commercial sense for the originator undertaking to avert generic entry by spending up to the amount of the money it expects to lose if generic entry were to occur. The amount of money the originator undertaking may be willing to spend to avert generic entry may therefore well cover or exceed the profit even several generic undertakings could only have hoped to achieve in the market concerned where not found to be infringing or where they succeeded in invalidating the patent(s) concerned. If such transfers of value succeed in avoiding generic entry, both the originator undertaking and the generic undertaking will be better off than if the generic undertaking had continued trying to enter the market.

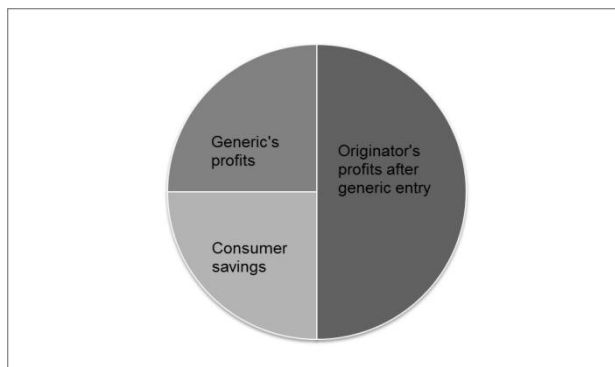
(645) Consumers, however, are likely to be considerably worse off in this situation, as they fail to benefit, whether through their health insurance premium or the public health budget, from the prospect that a generic company might be able to lawfully enter the market (because either the process patents invoked are not valid or not infringed) and the lower prices that would have followed such generic entry.

(646) The following three graphs illustrate this situation:

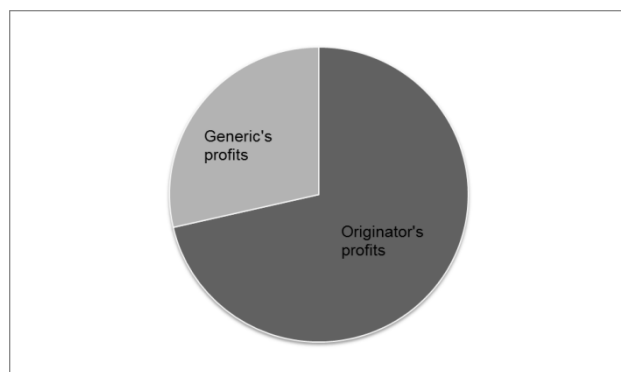
Graph 1: The profits of the originator undertaking before generic entry



Graph 2: Consumer savings after generic entry



Graph 3: Sharing of the consumer savings by the originator undertaking and the generic undertaking through an agreement with an exclusion payment



10.2. Restriction of competition by object

(647) 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 developments, or investment"* or *"share markets or sources of supply"*.

(648) In *Allianz Hungária Biztosító Zrt*, the Court of Justice recently re-affirmed:

"The distinction between 'infringements by object' and 'infringements by effect' arises from the fact that certain forms of collusion between undertakings can be regarded, by their very nature, as being injurious to the proper functioning of normal competition..."

In order to determine whether an agreement involves a restriction of competition 'by object', regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms a part... 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...

In addition, although the parties' intention is not a necessary factor in determining whether an agreement is restrictive, there is nothing prohibiting the competition authorities, the national courts or the Courts of the European Union from taking that factor into account...

*The Court has, moreover, already held that, in order for the 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, that is to say, that it be capable in an individual case of resulting in the prevention, restriction or distortion of competition within the internal market..."*¹¹⁶⁴

(649) According to well-established jurisprudence of the Courts of the European Union, an agreement restricts competition "by object" when the agreement's objective aim, inherent tendency or necessary consequence is to restrict competition. As Advocate

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Case C-32/11, *Allianz Hungária Biztosító Zrt and Others v Gazdasági Versenyhivatal*, reference for a preliminary ruling, judgment of 14 March 2013, paragraphs 35 to 38.

General Trstenjak has stated: *"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."*¹¹⁶⁵

Whether an agreement restricts competition "by object" does not, therefore, depend on whether the parties subjectively intended to restrict competition, but on the objective nature of the agreement. An agreement may restrict competition by object even if the parties had other intentions with their agreement. At the same time, if it can be shown that the parties actually intended to restrict competition with their agreement, this is certainly an element to be taken into account.¹¹⁶⁶

- (650) In *Société Technique Minière (L.T.M.) v Maschinenbau Ulm GmbH (M.B.U.)*, the Court of Justice ruled:

Finally, for the agreement at issue to be caught by the prohibition contained in article 85(1) it must have as its 'object or effect the prevention, restriction or distortion of competition within the common market'.

*The fact that these are not cumulative but alternative requirements, indicated by the conjunction 'or', leads first to the need to consider the precise purpose of the agreement, in the economic context in which it is to be applied. This interference with competition referred to in article 85(1) must result from all or some of the clauses of the agreement itself. Where, however, an analysis of the said clauses does not reveal the effect on competition to be sufficiently deleterious, the consequences of the agreement should then be considered and for it to be caught by the prohibition it is then necessary to find that those factors are present which show that competition has in fact been prevented or restricted or distorted to an appreciable extent."*¹¹⁶⁷

It is clear, therefore, that the clauses of an agreement can be an important indication of a restriction by object, to the extent that they may reveal *"the precise purpose of the agreement."*

- (651) A restriction by object must be serious but it is not necessarily obvious 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.¹¹⁶⁸ As the General Court ruled in *Groupement des cartes bancaires*: *"S'agissant, tout d'abord, de l'argument du requérant selon lequel les mesures en cause ne contiennent aucune restriction patente de concurrence, il y a lieu de*

¹¹⁶⁵ Opinion of Advocate-General Trstenjak delivered on 4 September 2008 in Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd*, paragraph 44.

¹¹⁶⁶ See for instance Case T-491/07 *Groupement des cartes bancaires v Commission*, judgment of 29 November 2012, paragraph 251.

¹¹⁶⁷ Case 56/65, *Société Technique Minière (L.T.M.) v Maschinenbau Ulm GmbH (M.B.U.)*, reference for a preliminary ruling, judgment of 30 June 1966, [1966] ECR 236, at page 249.

¹¹⁶⁸ See footnote 1170 and recital (655) below. The Commission refers in this context to recitals (188) to (191), which show that Lundbeck was or should have been aware that its behaviour was anti-competitive. The Commission also refers to the section "Intention of the parties" in the specific legal assessment of each agreement in chapter 12 below.

rappeler que l'article 81, paragraphe 1, CE ne se réfère pas à la notion de restriction patente."¹¹⁶⁹

Advocate General Trstenjak has stated "...it is clear that the category of restrictions of competition by object cannot be reduced to agreements which obviously restrict competition. If not only the content of an agreement but also its legal and economic context must be taken into account, classification as a restriction of competition by object cannot depend on whether that object is clear at first sight or becomes evident only on closer examination of the circumstances and the intentions of the parties...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 notion of restriction of competition by object cannot be limited to the examples cited in Article 81(1)(a) to (c) EC either."¹¹⁷⁰

- (652) The Commission therefore cannot agree with Lundbeck's argument that the infringement in this case should not be qualified as a restriction by object because "*it took the Commission more than a decade to formulate a legal standard with respect to "reverse" payment settlements*" and because the Danish Competition Authority had said in a press statement in 2004 that the "*Commission considers that this is a gray area and it is unclear how close we are in this case to the black area*"¹¹⁷¹ The decisive criterion for qualifying an infringement as a restriction by object is, as the name indicates, whether the "object", that is to say the objective aim, of the agreement is to restrict competition. The Commission would note, in any case, that the statement of the Danish Competition Authority quoted by Lundbeck shows that the Commission had already at that time clear concerns over agreements that involved reverse payments and limited generic entry. The Commission followed up these concerns by conducting inspections at the premises of several Lundbeck companies in 2005. That investigation led to the current Decision.

¹¹⁶⁹ Case T-491/07 *Groupeement des cartes bancaires v Commission*, judgment of 29 November 2012, paragraph 146, no official English translation available yet. Informal translation: "*With respect, firstly, to the argument of the applicant that the measures in question do not contain any obvious restriction of competition, it needs to be recalled that Article 81, paragraph 1, does not refer to the notion of obvious restriction.*"

¹¹⁷⁰ Opinion of Advocate-General Trstenjak delivered on 4 September 2008 in Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd*, paragraphs 47-48. An example of a restriction by object that was not obvious can be found in Case C-439/09, *Pierre Fabre Dermo-Cosmétique SAS*, 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.*" Case C-439/09, *Pierre Fabre Dermo-Cosmétique SAS*, reference for a preliminary ruling, judgment of 13 October 2011, paragraph 47.

¹¹⁷¹ For both quotes, see ID 5394, page 278.

- (653) 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 *NV IAZ International Belgium*, the Court of Justice ruled:

*"Therefore, the purpose of the agreement, regard being had to its terms, the legal and economic context in which it was concluded and the conduct of the parties, is appreciably to restrict competition within the common market, notwithstanding the fact that it also pursues the objective of protecting public health and reducing the cost of conformity checks."*¹¹⁷²

- (654) In application of this well-established jurisprudence, the Commission explained in its Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements that:

*"Restrictions of competition by object are those that by their very nature have the potential to restrict competition within the meaning of Article 101(1). It is not necessary to examine the actual or potential effects of an agreement on the market once its anti-competitive object has been established."*¹¹⁷³

- (655) The Commission added in the same Guidelines:

*"According to the settled case-law of the Court of Justice of the European Union, in order to assess whether an agreement has an anti-competitive object, regard must be had to the content of the agreement, the objectives it seeks to attain, and the economic and legal context of which it forms part. In addition, although the parties' intention is not a necessary factor in determining whether an agreement has an anti-competitive object, the Commission may nevertheless take this aspect into account in its analysis."*¹¹⁷⁴

- (656) Earlier, the Commission had stated in the Guidelines on the application of Article 81(3) of the Treaty [now Article 101(3) of the Treaty]:

*"In the case of horizontal agreements restrictions of competition by object include price fixing, output limitations and sharing of markets and customers."*¹¹⁷⁵

In those same Guidelines, the Commission highlighted the key importance for Article 101 of the Treaty of *"the protection of rivalry and the competitive process"* as *"essential driver"* of economic progress, summarising:

*"In other words, the ultimate aim of Article 81 [now Article 101 of the Treaty] is to protect the competitive process."*¹¹⁷⁶

¹¹⁷² Joined Cases 96-102, 104, 105, 108 and 110/82, *NV IAZ International Belgium* and others v Commission, judgment of 8 November 1983, paragraph 25.

¹¹⁷³ 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 24.

¹¹⁷⁴ 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 25.

¹¹⁷⁵ Commission Notice: Guidelines on the application of Article 81(3) of the Treaty, OJ C 101, 27.4.2004, page 97, point 23.

¹¹⁷⁶ Commission Notice: Guidelines on the application of Article 81(3) of the Treaty, OJ C 101, 27.4.2004, page 101, point 105.

- (657) The protection of rivalry 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.¹¹⁷⁷ 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 stated, in this respect:

"The BIDS arrangements are intended therefore, essentially, to enable several undertakings to implement a common policy which has as its object the encouragement of some of them to withdraw from the market and the reduction, as a consequence, of the overcapacity which affects their profitability by preventing them from achieving economies of scale.

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...".*¹¹⁷⁸

- (658) The European Court of Justice in *Irish Beef* concluded that the arrangements in question were a restriction by object. Advocate General Trstenjak characterised the arrangement as *"the 'buying off' of competition."*¹¹⁷⁹ At the core of the analysis were, like in the present Decision, exclusion payments. The facts in this Decision show therefore important parallels to the situation in *Irish Beef*, in that in each agreement covered by this Decision two potential or actual competitors agreed on a common

¹¹⁷⁷ Commission Notice: Guidelines on the application of Article 81(3) of the Treaty, OJ C 101, 27.4.2004, page 97, point 14.

¹¹⁷⁸ Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd*, judgment of 20 November 2008, paragraphs 33 to 35. A comparison may also be made with COMP Case 38.543 – *International Removal Services*, 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 Cases T-208/08 and T-209/08, *Gosselin Group NV and Stichting Administratiekantoor Portielje v Commission*, judgment of 16 June 2011, 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.

¹¹⁷⁹ Opinion of Advocate-General Trstenjak delivered on 4 September 2008 in Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd*, paragraph 77.

plan to ensure, through financial compensation the withdrawal from or non-entry into the market of one of them, the generic undertaking, for a certain period of time.¹¹⁸⁰

- (659) The statement in recital (655) above concerning the need to examine the facts and specific circumstances underlying the agreement is particularly appropriate in this case, as settlements which are based purely on each party's assessment of the strength of the patent and which impose limitations on the behaviour of the generic undertaking that fall within the exclusivity rights of the patent holder granted by patent law do not, in principle, constitute an infringement of Article 101 of the Treaty. If, however, the limitations on entry in question are not achieved through the strength of the patent, but through inducements from the originator undertaking to the generic undertaking aligning previously competing interests, then a restriction of competition by object may exist, including, in particular, when the limitations in question exceed the substantive scope of the patent.
- (660) Decisive for the legal assessment in this case is therefore not only whether certain limitations on the generic undertaking's behaviour were part of the agreements in question, but also, and particularly, whether those limitations were paid for by the originator undertaking.¹¹⁸¹ This applies as much to restrictions agreed in exchange for a payment that fall within the scope of the patent as to restrictions exceeding that scope. Payment for the limitations may have taken place either simply in the form of an outright cash payment or through a more covert transfer of value to the generic undertaking which cannot be adequately explained by, or which considerably exceeds, the value to the originator undertaking of any counter-performance of the generic undertaking. The specific facts and circumstances surrounding each agreement are obviously important in this respect.
- (661) In order to identify whether each agreement had the potential to restrict competition by its very nature, the analysis in chapter 12 below will in particular take into account whether:
- the generic undertaking and the originator undertaking were at least potential competitors;
 - the generic undertaking committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter one or more EEA markets with generic product; and
 - the agreement was related to a transfer of value from the originator undertaking which substantially reduced the incentives of the generic undertaking to

¹¹⁸⁰ The two main differences with *Irish Beef* are that:

i) in the case at hand, there is no question of reducing any existing overcapacity from numerous competitors in the market, but rather of *de facto* preserving and sharing the supra-competitive profits of a single incumbent undertaking through the postponement of potential competition; and
ii) the agreements in the case at hand were concluded against the background of patent disputes, with considerable uncertainty as to the possible outcome of potential or actual patent litigation.

¹¹⁸¹ Payments from an originator undertaking to a generic undertaking in exchange for the latter's acceptance of restrictions on its freedom to try to enter the market, in particular in a situation where there is considerable doubt about whether the originator undertaking's patents are valid and infringed, should be clearly distinguished from payments from an originator undertaking to a generic undertaking to compensate for actual damages incurred by the latter in a situation where parties agree that the generic undertaking is not infringing any patents and obtains immediate free access to the market, as described in recital (639).

independently pursue its efforts to enter one or more EEA markets with generic product.

- (662) In the present case other important factors will also be taken into consideration, namely: the fact that the value which Lundbeck transferred took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market; the fact that Lundbeck could not have obtained the limitations on entry through enforcement of its process patents, the obligations on the generic undertaking in the agreement going beyond the rights granted to holders of process patents; and the fact that the agreement contained no commitment from Lundbeck to refrain from infringement proceedings if the generic undertaking entered the market with generic citalopram after expiry of the agreement.
- (663) In this case the Commission also analysed the parties' arguments on the existence of justifications for the agreements under Article 101(3) of the Treaty and found that the conditions of this provision were not met.
- (664) The Commission has concluded that the agreements, containing transfers of value from Lundbeck which induced the generic undertakings in question not to pursue their independent efforts to enter the market, constituted infringements of Article 101 of the Treaty.
- (665) Before entering into the legal assessment of each individual agreement, the Commission will first analyse in chapter 11 below certain general arguments that parties made and that apply to all or most of the agreements.

11. GENERAL ARGUMENTS OF THE PARTIES

- (666) In the course of the investigation leading up to this Decision, both before and following the Statement of Objections, several of the parties made certain arguments of a general nature, applicable in principle to all agreements. This chapter analyses those arguments to the extent they are considered relevant for the question whether parties' conclusion and operation of the agreements covered by this Decision constituted an infringement of Article 101(1) of the Treaty. Specific arguments of the parties with respect to each of the agreements covered by this Decision will be assessed in chapter 12 below.¹¹⁸² Claimed efficiency gains will be analysed in Chapter 14 below within the context of Article 101(3) of the Treaty, after effects on trade have been dealt with in chapter 13.

11.1. The validity of Lundbeck's patents

- (667) With respect to the crystallisation patent, Lundbeck argued to the Commission that "*Lundbeck's agreements relate to a valid patent, which was upheld by the European Patent Office on July 2, 2009.*"¹¹⁸³ It should be noted that only four of the six

¹¹⁸² Many parties raised similar or identical arguments; the relevant sections may refer to just one submission in order to avoid repetition.

¹¹⁸³ ID 823, page 2. It should be noted that only four of the six agreements Lundbeck concluded contained an explicit reference to the crystallisation patent; the agreements with Merck (GUK) for the United Kingdom (which did not mention any patent) and with Ranbaxy for the EEA (which mentioned two other process patents of Lundbeck) did not mention the crystallisation patent. However, Lundbeck and the generic undertakings concerned argued in their replies to the Statement of Objections that concerns about the crystallisation patent also played a role for Merck (GUK) and Ranbaxy in coming to an agreement with Lundbeck.

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- (668) In its reply to the Statement of Objections, Lundbeck claimed more generally that "*Lundbeck's process patents were valid and legitimate*"¹¹⁸⁴, thereby implicitly referring to all of its process patents.¹¹⁸⁵ As a first observation, the Commission notes that the issue of the assumed validity of a patent is hardly relevant in situations where the new market entrant does not infringe the patent. One cannot therefore deduce from the assumed validity of a process patent that the patent holder necessarily has the right to exclude competition with respect to a compound. In the present case, considering that Lundbeck's litigation against generic companies focused on enforcement of the crystallisation patent,¹¹⁸⁶ the following analysis is carried out mainly with reference to that patent.
- (669) The relevant perspective under which the legality of Lundbeck's agreements must be determined is that at the time of conclusion of these agreements (the so-called "*ex ante perspective*"). While patents are assumed to be valid until invalidated by a court, as explained before¹¹⁸⁷, a patent can always be challenged and therefore can always be declared invalid by a court. The evidence in the file shows that at the time of conclusion of the agreements, Lundbeck and the generics believed that there was a distinct possibility¹¹⁸⁸ that if the validity of the crystallisation patent were challenged, a court of law, the EPO or a national patent office would hold the crystallisation patent partially or entirely invalid. Generic companies considered the crystallisation process to be "*high school chemistry*"¹¹⁸⁹ and, moreover, not novel. Lundbeck itself estimated in the course of the Lagap litigation that there was a 60% likelihood that the United Kingdom judge would hold the crystallisation patent invalid.¹¹⁹⁰ Indeed, the preamble of some of the agreements stated that the generic undertaking did not admit the validity of Lundbeck's crystallisation patent.¹¹⁹¹ These contemporaneous assessments show that parties believed at the time of conclusion of the agreements that, there was a realistic prospect, which both generic companies and Lundbeck

¹¹⁸⁴ ID 5394, page 89.

¹¹⁸⁵ At the same time, for the film distillation patent, which Lundbeck invoked in its agreements with Arrow and Alpharma, Lundbeck stated in its reply to the Statement of Objections that Lundbeck "*realized that it was possible for generic companies to design around the Film Distillation Patent*" and "*renounced enforcing that patent because it lent itself to invalidity claims.*" See ID 5394, page 162.

¹¹⁸⁶ See recital (149) above. Regarding the present agreements, Lundbeck claimed that out of the six agreements with four generic undertakings, five were "*designed to enforce one process patent* [that is to say the crystallisation patent] (*while one agreement was designed to enforce two different process patents* (emphasis in original))". See ID 6814, page 6.

¹¹⁸⁷ See recital (78) above.

¹¹⁸⁸ See also footnote 292.

¹¹⁸⁹ See recital (149) above.

¹¹⁹⁰ See recital (157) above.

¹¹⁹¹ See the agreement with Merck (GUK) regarding the EEA (recital (348) above) and the agreement with Arrow regarding the United Kingdom (recital (393) above).

were aware of, that the crystallisation patent would be held invalid if challenged before a national court, the EPO or a national patent office.¹¹⁹²

- (670) As for Lundbeck's claim that the crystallisation patent was "*upheld*" by the EPO, the crystallisation patent was opposed by a number of generic companies immediately after it had been granted. The opposition procedure led to the patent's revocation by the EPO in 2006. The patent was only reinstated in amended form in 2009 after an appeal by Lundbeck. The amendment resulted in the deletion of claims 1, 2 and 5 as granted and in a significant limitation of the scope of claims 3 and 8 as granted.¹¹⁹³ Moreover, the fact that the EPO ultimately reinstated the patent does not mean that a national court could not hold the patent invalid even after the EPO's ruling.
- (671) To the extent that Lundbeck's argument is based on the assumption of validity of patents, the Commission refers to recitals (78) and (628) above and recital (1036) below. In no Contracting Party to the EEA Agreement has any judge ever issued a final ruling in a main proceeding on (counter-) claims of invalidity of the crystallisation patent raised by generic undertakings. The United Kingdom litigation was settled by Lundbeck and Lagap before any such ruling could be given.¹¹⁹⁴

11.2. The infringement of Lundbeck's patents

- (672) Lundbeck argued to the Commission that "*Lundbeck's scientific analysis demonstrated that the generic companies infringed Lundbeck's patents, so Lundbeck had a right to exclude them from the market.*"¹¹⁹⁵
- (673) Lundbeck's claim that its laboratory analyses of the generic products concerned showed beyond doubt that such products were infringing is not reflected in the wording of the agreement. The kind of formulation Lundbeck used in a number of the agreements was that "*the results of these laboratory analyses give Lundbeck substantial reason to believe that the production methods used to produce [company's] products infringe Lundbeck's intellectual property rights.*"¹¹⁹⁶ Usually, the next paragraph would then state that the generic company concerned did not admit any infringement of Lundbeck's patents.¹¹⁹⁷ Only Alpharma accepted as part of the agreement with Lundbeck under which it received EUR 11.7 million that "*the findings by Lundbeck are correct*"¹¹⁹⁸. Also before the courts, Lundbeck used more careful language. For instance, in the United Kingdom litigation against Alpharma, Lundbeck's head of chemistry stated: "*Such material has the fingerprints associated with the 2002-1 [cyanation] process, but at the reduced levels which are consistent to the best of my own knowledge only with purification using the processes disclosed in UK Patents 2 356 199 B and 2 357 762 B (emphasis added).*" It should also be noted

¹¹⁹² See further recital (677) below.

¹¹⁹³ See recital (166) above. Lundbeck claimed that the core of the crystallisation patent was maintained in the final wording of claim 3.

¹¹⁹⁴ See recital (160) above.

¹¹⁹⁵ ID 823, page 2. See also ID 2774.

¹¹⁹⁶ See the preambles of the agreements with Merck (GUK) regarding the EEA (see recital (348) above), Arrow regarding the United Kingdom (see recital (393) above), Arrow regarding Denmark (see recital (456) above), Alpharma regarding the EEA (see recital (522) above) and Ranbaxy regarding the EEA (see recital (567) above).

¹¹⁹⁷ See the preambles of the agreements with Merck (GUK) regarding the EEA (see recital (348) above), Arrow regarding the United Kingdom (see recital (393) above), Arrow regarding Denmark (see recital (456) above) and Ranbaxy regarding the EEA (see recital (567) above).

¹¹⁹⁸ See recital (522) above.

that Lundbeck raised many technical arguments for infringement with the Commission which it had dropped before the court in the United Kingdom Lagap litigation in 2003, claiming at the same time that the Commission lacked jurisdiction to evaluate those arguments.

- (674) As a point of principle, however strongly Lundbeck may at the time of the conclusion of the agreements have believed that its crystallisation patent or any other patents were infringed, Lundbeck could not - and cannot now - claim as an objective fact that an infringement existed and that Lundbeck therefore had the right to exclude its generic challengers from the market. Lundbeck could have used the national court procedure to enforce its patents, or it could have settled purely based on the strength of its patents, if indeed Lundbeck was convinced that its patents were valid and infringed. In the one case in the United Kingdom where Lundbeck did try to enforce its crystallisation patent before the court, in the Lagap litigation, Lundbeck failed.¹¹⁹⁹ The judge stated after an inspection had taken place of Matrix' production process in India:

*"Lundbeck and [an independent expert on whose views Lundbeck had relied] now had to admit, having examined the process in operation in India, that their firm and unshakeable confidence that it was impossible for Lagap and its suppliers to be operating a non-infringing process was unfounded. The process that they had seen was indeed a non-infringing process and did produce a product which appeared to be Lagap's product."*¹²⁰⁰

This situation of uncertainty as to whether an independent judge would hold Lundbeck's process patent valid and infringed, which prevailed at the time of the agreements, meant that there was a realistic possibility that generic companies could enter the market and face up to Lundbeck's patent challenge, to the benefit of consumers. The agreements eliminated that possibility by disallowing any entry in exchange for transfers of value.

- (675) Finally, to the extent that the agreements went beyond what a court could have decided in favour of Lundbeck in a concrete infringement proceeding dealing with a particular product produced in a particular manner, Lundbeck cannot argue that in concluding the agreements Lundbeck was merely enforcing its valid and infringed patents, precisely because the scope of the agreement was broader than the scope of the patent, and the commitments accepted by the generic in the agreement went beyond what a court enforcement of Lundbeck's process patents could have achieved.
- (676) In conclusion on this point, therefore, Lundbeck did not have any right flowing from its process patents to exclude generic competitors from the market by paying them as much as or more than they could possibly earn in profit from a successful market entry, thereby eliminating the incentive for these undertakings to compete with Lundbeck for the terms of the agreements and thereby depriving consumers of the significant price decreases that would have followed from early generic entry.
- (677) It should be noted that all generic undertakings in this case also argued to the Commission that they believed their product was infringing or at least that they had

¹¹⁹⁹ Lundbeck was more successful in its requests for preliminary injunctions in other EEA countries, in particular against Cipla products.

¹²⁰⁰ See recital (155) above.

concerns in this respect. Moreover, several parties argued that in accordance with the Technology Transfer Guidelines, no potential competition existed in this case, because generic undertakings would have been blocked from entry by Lundbeck's process patents.¹²⁰¹ With respect to the question whether Lundbeck's process patents blocked any possible way to produce marketable citalopram, the Commission refers to recital (634) above, in which Lundbeck itself stated to the Commission that it was in principle possible to produce marketable citalopram in a non-infringing way. This was also proven by the Lagap litigation, after which, first in the United Kingdom and later across the EEA, generic companies entered with generic citalopram, without being hindered by Lundbeck's crystallisation patent, which is still in force. As for the Technology Transfer Guidelines, the Commission refers to section 9.4.4 above. These Guidelines are not applicable to this case, as Lundbeck did not transfer any technology to the generic undertakings in any of the agreements subject to this Decision.¹²⁰² The situation of potentially pro-competitive licensing agreements, and the restrictions that may be acceptable in such situations, is to be clearly distinguished from the horizontal anti-competitive agreements in this case. The Commission would note, moreover, that the guidelines state specifically 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..."*¹²⁰³ In order to determine the extent to which generic undertakings had concerns over Lundbeck's process patents, the Commission has therefore relied primarily on contemporaneous documents rather than *ex post facto* statements by the parties to the Commission. Those documents show that at the time of events, each generic undertaking had one or more realistic prospects of entering one or more markets in the EEA within the period covered by the agreements without infringing any process patents of Lundbeck or by proving that such patents should be declared invalid.

11.3. The nature of the agreements

(678) According to Lundbeck, the agreements were:

- *"intended to preserve the parties' rights while litigation was pending";* and
- *"for short durations that correlated with the expected timeframe for existing or pending litigation".*¹²⁰⁴

This argument suggests that the agreements served to preserve for a short time the status quo while the legal issues between the parties were being solved in court. The Commission disagrees with this interpretation of the nature of the agreements.

(679) As a preliminary remark, the Commission notes that the concept that the agreements had a *"short duration"* is a relative notion. The shortest of the six agreements, the agreement with Arrow for Denmark, lasted ten months.¹²⁰⁵ The longest of the

¹²⁰¹ See for instance Lundbeck in ID 5394, page 267. See also recitals (632) and (634) above.

¹²⁰² See point 49 of the Technology Transfer Guidelines: *"The TTBER [Transfer Technology Block Exemption Regulation, Commission Regulation 772/2004, OJ L 123 of 27.4.2004, page 11] only applies to agreements that have as their primary object the transfer of technology as opposed to the purchase of goods and services or the licensing of other types of intellectual property."*

¹²⁰³ See point 32 of the Technology Transfer Guidelines.

¹²⁰⁴ ID 823, pages 2 and 14. See also ID 1259, pages 3 and 7.

¹²⁰⁵ Compare the case T-18/03, *CD-Contact Data GmbH v Commission*, [2009] ECR II-1021, paragraph 24, where the duration of the infringement (agreement to limit parallel trade) was two months.

agreements (including extensions), the two agreements with Merck and Arrow for the United Kingdom, both lasted one year and nine months. The agreement with Ranbaxy for the EEA lasted one year and six months, the agreement with Alpharma for the EEA one year and three months and the agreement with Merck for the EEA one year exactly. On average, the agreements covered by this Decision lasted one year and four months. A year of market exclusion is a long time in the crucial period when a major compound with high sales ceases to be patent-protected and generic entry is, in principle, possible. In the year 2002, Lundbeck's citalopram turnover in the United Kingdom alone amounted to EUR [40-150]* million.¹²⁰⁶ Lundbeck's citalopram turnover in the EEA as a whole in that year was EUR [400-600]* million, which represented [80-90]* percent of Lundbeck's total turnover covering all of its products in the EEA.¹²⁰⁷ A lot was therefore at stake for the undertaking Lundbeck as a whole. The one year and ten months of delay in widespread generic entry in the United Kingdom the agreements provided Lundbeck (between January 2002 and the end of October 2003) was extremely valuable to Lundbeck, not only because of the turnover on citalopram maintained in this period but also because it allowed Lundbeck to introduce escitalopram in the United Kingdom in June 2002, six months after generic entry in the United Kingdom had become possible and a year and four months before widespread generic entry in the United Kingdom actually occurred.¹²⁰⁸ Finally, the United Kingdom agreements were terminated because Lundbeck settled with Lagap. If Lundbeck had won the Lagap litigation, at least some of the agreements in question (in particular those that did not concern Matrix citalopram) might well have been further extended.¹²⁰⁹ It could not, therefore, be foreseen at the time these agreements were initially concluded that they would not last, through different extensions, beyond October 2003.

- (680) If the reference to "*litigation*" is meant to refer to litigation between the parties to the agreements, it should be noted that of the six agreements covered by this Decision, only one was concluded at a point in time when litigation between Lundbeck and the generic company concerned was already pending. This was the agreement with Alpharma regarding the EEA, which was concluded on 22 February 2002, after Lundbeck had initiated legal proceedings against Alpharma in the United Kingdom (but not in any other EEA Contracting Parties) on 31 January 2002. However, in Article 1.1 of their agreement, Lundbeck and Alpharma agreed to dismiss this lawsuit. This United Kingdom litigation was consequently stayed in April 2002, at the request of both parties. Parties therefore knew at the time they concluded their agreement that the litigation would not lead to any clarification of the question whether Alpharma's products infringed any Lundbeck patents.
- (681) The five other agreements were concluded at a time when no litigation between the parties was as yet pending. Moreover, neither Ranbaxy nor Merck (both in respect of the United Kingdom agreement and the agreement regarding other EEA Contracting Parties than the United Kingdom) became involved in any litigation regarding citalopram with Lundbeck after the agreements with them had been concluded. Lundbeck did initiate litigation against Arrow in the United Kingdom one day after

¹²⁰⁶ ID 983, page 20.

¹²⁰⁷ See recital (26) above.

¹²⁰⁸ See recitals (198) to (201) above.

¹²⁰⁹ In particular the agreements with Merck (GUK) and Ranbaxy might have been extended if Lundbeck had won the Lagap litigation. See recital (305) above.

the agreement regarding the United Kingdom had been concluded, allegedly to clarify the legal issues, but neither party pursued this litigation. That same litigation, even if it had been pursued, was also by its very nature not decisive for the agreement with Arrow regarding Denmark, because a Danish court would not be bound by any British ruling.

- (682) When Lundbeck therefore talks of "*pending litigation*", it can hardly mean litigation between the parties. Lundbeck has indeed also argued that "*Lundbeck entered into short-term, interim settlement agreements to preserve the status quo pending the outcome in a key litigation (Lagap)*."¹²¹⁰ If this is the meaning of Lundbeck's argument, several observations need to be made in respect of it.
- (683) Lundbeck started its infringement litigation against Lagap on 14 October 2002, almost nine months after it had concluded agreements with Merck and Arrow regarding the United Kingdom (on 24 January 2002), almost eight months after it had concluded an agreement with Alpharma regarding the EEA (on 22 February 2002), more than four months after it had concluded an agreement with Arrow regarding Denmark (on 3 June 2002) and four months after it had concluded an agreement with Ranbaxy regarding the EEA (on 16 June 2002). There is no indication in the case file that the possibility of future litigation by Lundbeck against Lagap was taken into account by the parties when they negotiated their agreements. Indeed, at those points in time, there was no certainty that there would ever be any Lagap litigation, if only because of the simple fact that Lundbeck might very well also have concluded an agreement with Lagap.¹²¹¹ This shows clearly that these five agreements were not originally concluded while awaiting the resolution by the Lagap court of any legal issues, but simply to ensure the market exclusion of the generic companies concerned for the term of the agreement.
- (684) Of these five agreements, Lundbeck's agreements with Arrow regarding Denmark, with Alpharma regarding the EEA and with Ranbaxy regarding the EEA never became tied at all to the Lagap litigation. These agreements operated independently of what happened in the Lagap litigation. Indeed, Ranbaxy's agreement with Lundbeck continued, also in respect of the United Kingdom, until the normal expiry date foreseen in the agreement, 31 December 2003, even if widespread generic entry became possible in the United Kingdom shortly after Lundbeck had settled with Lagap on 13 October 2003.
- (685) As for Lundbeck's agreements with Merck regarding the United Kingdom and with Arrow regarding the United Kingdom, it was only in their second extension that the expiry of these agreements became linked to the fate of the Lagap litigation.¹²¹² Such a link was logical, as there was no sense for Lundbeck to continue paying these companies to stay out of the United Kingdom market if Lundbeck lost the Lagap

¹²¹⁰ ID 1944, page 22.

¹²¹¹ See recital (197) above, which quotes a Lundbeck document of 21 May 2002 mentioning a possible settlement with Lagap after Lagap would have received a marketing authorisation. Indeed, the Lagap litigation was ultimately settled by Lundbeck on 13 October 2003 shortly before a ruling was issued, after the United Kingdom judge had indicated that the inspected production process of Matrix did not infringe Lundbeck's crystallisation patent. As a result of the settlement, no ruling by a United Kingdom court on the validity of Lundbeck's crystallisation patent was ever made. See recitals (152) to (162) above.

¹²¹² See recitals (301) and (437) above.

litigation and widespread market entry into the United Kingdom became possible. This is precisely the reason why Lundbeck terminated the United Kingdom agreements with Merck and Arrow¹²¹³ immediately after Lundbeck in its settlement with Lagap had given Lagap a royalty-free non-exclusive licence to sell generic citalopram.¹²¹⁴ However, for the case it would have prevailed against Lagap, Lundbeck was already considering to extend the agreements with Merck (GUK) and Ranbaxy.¹²¹⁵

- (686) At the same time, however, Lundbeck had made it very clear to Arrow during the negotiation of the second extension of the United Kingdom agreement that *"If Lagap [sic] trial is withdrawn, you will have to invalidate the [crystallisation] patent yourself – I believe that is fair."*¹²¹⁶ It is thus clear that the main use the Lagap litigation could have had for the generic companies that concluded agreements with Lundbeck, namely the invalidation of Lundbeck's crystallisation patent, could be and was avoided by Lundbeck by settling with Lagap. This meant that the other companies would have to start the legal fight against the crystallisation patent all over again before the United Kingdom court if they wanted to obtain legal clarification of the status of that patent. Even in this respect, therefore, the Lagap litigation did not clarify any legal issues of relevance between Lundbeck and the generic companies that concluded agreements with it.
- (687) Moreover, even if Lundbeck and the generic companies had known at the time they concluded their agreements that there would be a Lagap litigation, whatever the Lagap litigation was likely to clarify about the question whether Matrix's new production process infringed Lundbeck's crystallisation patent, such clarification would in itself not be decisive for the generic companies in question, all of which used API from other producers than Matrix. This applied to Merck, which used API from Natco; to Arrow and Alpharma, which had bought API from Cipla – in the meantime, Cipla had developed a new and allegedly non-infringing process which was different from that of Matrix; and to Ranbaxy, which used its own API. Whether Matrix's API infringed Lundbeck's crystallisation patent was, in fact, only relevant to the extent that Arrow and Alpharma had the option under their contract with Tiefenbacher of switching from Cipla API to Matrix API. The United Kingdom judge stated in the course of the Lagap litigation that Lundbeck had to admit that Matrix's inspected production process did not infringe Lundbeck's crystallisation patent.¹²¹⁷ In this respect the Lagap litigation can, in retrospect, be said to have provided clarification on a legal issue of relevance to Arrow and Alpharma in the United Kingdom. But of course, as already mentioned, neither Lundbeck nor Arrow nor Alpharma could have any idea that this would happen when they concluded their agreement with Lundbeck nine, respectively eight months before the Lagap litigation even started.¹²¹⁸

¹²¹³ See recitals (305) and (444) above.

¹²¹⁴ It is recalled that this licence allowed Sandoz to sell Matrix products in the United Kingdom also via other generic suppliers. Wide-spread generic entry into the United Kingdom was therefore to be expected. In other Contracting Parties of the EEA Agreement than the United Kingdom, however, the licence allowed Sandoz only to sell the product itself. See recital (159) above.

¹²¹⁵ See recital (305) above.

¹²¹⁶ See recital (434) above.

¹²¹⁷ See recital (155) above.

¹²¹⁸ See recital (683) above.

- (688) Finally, a United Kingdom ruling would not have been decisive for the resolution of legal issues in other EEA Contracting Parties. The Lagap litigation was therefore by its very nature not directly relevant for Lundbeck's agreements with Merck, Alpharma, Arrow and Ranbaxy that covered other countries than the United Kingdom. This includes the sixth agreement, the one with Merck regarding other EEA Contracting Parties than the United Kingdom, which is the only agreement that was concluded after the Lagap litigation had started in the United Kingdom (the agreement was concluded on 22 October 2002, whereas the Lagap litigation started on 14 October 2002). This agreement was, moreover, not tied in any way to the fate of the Lagap litigation. It was a straightforward exclusion agreement for a fixed period of a year and expired automatically at the end of this period, irrespectively of what happened in the Lagap litigation.
- (689) In conclusion, the argument that the agreements covered by this Decision served only to preserve the status quo for a short period while the legal issues were being clarified by the court does not correspond with the facts, the most important of which are that the agreements covered a crucial period for Lundbeck and that five of the six agreements were concluded long before the Lagap litigation even started, whereas the sixth agreement had no link with the Lagap litigation at all.

11.4. The scope of the agreements

- (690) Lundbeck argued that "[t]he agreements were narrowly tailored and covered specific infringing products that Lundbeck had tested and confirmed as infringing."¹²¹⁹ According to Lundbeck, the agreements "left the generic companies free to produce and sell non-infringing citalopram products in the EEA."¹²²⁰
- (691) The part of this argument dealing with the claim that Lundbeck had tested and confirmed the products as infringing has already been considered in section 11.2 above.¹²²¹
- (692) As to the claim that the agreements were narrowly tailored and covered only allegedly infringing products, the facts show the opposite: For none of the six agreements covered by this Decision Lundbeck could have obtained the same extensive limitations on entry through enforcement of its process patents in court.
- (693) Four of the six agreements went beyond the scope of patent law in that they covered not just the citalopram product the generic undertaking had in stock, against which Lundbeck could have started infringement litigation, but also other citalopram, including future citalopram products that could have been produced in a non-infringing manner. This was the case for Lundbeck's agreements with:
- Merck regarding other EEA Contracting Parties than the United Kingdom ("*pharmaceutical products containing Citalopram*");¹²²²
 - Arrow regarding the United Kingdom ("*(1) the said Citalopram or (2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights*");¹²²³

¹²¹⁹ ID 823, page 2.

¹²²⁰ ID 823, page 26.

¹²²¹ See section 11.2 above.

¹²²² See recital (348) above.

¹²²³ See recital (394) above.

- Arrow regarding Denmark ("*products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights in the Territory*");¹²²⁴ and
 - Alpharma regarding the EEA ("*pharmaceutical products containing Citalopram*");¹²²⁵
- (694) As for the agreement with Ranbaxy regarding the EEA ("*pharmaceutical products based hereon*", including citalopram products based on "*any production method used by Ranbaxy*")¹²²⁶, this agreement made it impossible for Ranbaxy to sell its own generic product, whether or not the production process used infringed Lundbeck's process patents. Ranbaxy was, however, in principle still free to sell generic product from other producers.
- (695) The out-of-scope product descriptions in these five agreements were not a matter of clumsy drafting. Lundbeck and its lawyers¹²²⁷ knew very well how to draft a correct product description in the case of alleged infringement of process patents. A consent order drafted in April 2002 by Lundbeck's and Alpharma's lawyers and submitted to the United Kingdom court talked about "*pharmaceutical products containing citalopram made utilising any of the processes claimed under GB patents 2 357 762 B and GB 2 356 199 B or any equivalent patent granted or applied for in relation to any of the Relevant Territories...*"¹²²⁸ where the agreement with Alpharma two months earlier, which was now being reinforced through the consent order, had talked about "*products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights in the Territory*".¹²²⁹
- (696) As for the sixth agreement, Lundbeck's agreement with Merck (GUK) for the United Kingdom, this agreement also imposed obligations on Merck (GUK) that could not have been achieved if Lundbeck had successfully enforced its patent rights in court. Through the exclusivity clause in the distribution agreement with Lundbeck, Merck (GUK) gave up all possibilities to sell generic citalopram products in the period covered by the agreement, whether such generic citalopram infringed any Lundbeck patents or not. The agreement did not even specify any patents that Merck (GUK)'s product was supposed to be infringing.
- (697) Lundbeck's claim that "*[t]he agreements were narrowly tailored and covered specific infringing products*" is therefore incorrect.
- (698) Moreover, as already mentioned in section 9.2.2 above, even if the restrictions the generic undertakings had accepted in exchange for Lundbeck's transfers of value had all been, as Lundbeck put, "*within the temporal, territorial, and substantive scope*"¹²³⁰ of the patents invoked, this would not have changed the fundamental legal analysis of the Commission of those restrictions. Several parties have proposed a "*scope of the patent test*" which would mean that, in Lundbeck's words, "*Provided a genuine dispute exists and there is no restriction of competition beyond that*

¹²²⁴ See recital (457) above.

¹²²⁵ See recital (523) above.

¹²²⁶ See recital (568) above.

¹²²⁷ Lundbeck explained that the agreements were concluded "*only after receiving advice from its external competition counsel... who reviewed and/or drafted each of the agreements to ensure they complied with competition and other applicable laws.*" See ID 823, page 2.

¹²²⁸ See recital (536) above.

¹²²⁹ See recital (457) above.

¹²³⁰ ID 5394, page 265.

*legitimately created by the patent itself, a patent settlement agreement should not attract antitrust scrutiny at all, regardless of whether it involves the payment of money. This is the only test that is capable of striking a reasonable balance between the interests protected by patent law and those protected by competition law".*¹²³¹ Significantly, Lundbeck added to this: *"Indeed, to the extent that a patent settlement restricts competition, any such restrictive effects are simply those inherent to the underlying IPR..."*¹²³². Such a test is not appropriate as it would allow originator undertakings in the pharmaceutical sector to induce generic competitors, including producers of APIs, through financial incentives coupled with claims of patent infringement (at least if such claims are not obviously a scam) to abandon any effort to enter markets for medicines whose compound patent had expired, and to do so for the entire 20 year duration of the process patents in question, even if a considerable likelihood existed that generic undertakings could well within that period bring a product to the market that did not infringe any patent. Such a test 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. To balance the interest of patent holders to exclusively exploit their inventions with the interest of consumers in lower prices once compound patents have expired, certain legal procedures exist through which originator undertakings can try to enforce whatever process patents they might still have after expiry of the compound patent. Paying potential competitors not to try to enter the market at all is not based on any rights granted by patent law, nor is it based on the strength of the patent, nor is it one of the legitimate means society has provided for the defence of patent rights. In this sense, one could say that the agreements covered by this Decision fall outside of the "specific subject matter" of the patent, which includes the right to oppose, but not the right to buy off competition.

11.5. The direction of the payment

- (699) Lundbeck argued that the Commission scrutinises settlement agreements which contain a payment from the originator company to the generic company, but that settlements which contain a payment from the generic company to the originator

¹²³¹ In its reply to the Statement of Objections, Lundbeck claimed that the scope of the patent test is the right legal test and that it finds support in United States case law. According to Lundbeck, the "scope of the patent" test is the predominant test under United States case law. See ID 5394, page 268. The Commission considers that this test is not transposable as such under Union law. Under the Hatch Waxman Act (which embodies Congress' intent *"to make available more low cost generic drugs"*, Re Cardizem, 105 F. Supp. 2d 618, 628) a generic undertaking can file an ANDA (Abbreviated New Drug Application) whereby the generic undertaking relies on the FDA's prior determination, made in the course of approving an earlier "pioneer" drug, that the proposed new drug is safe and effective) with a paragraph IV certification (i. e. the generic undertaking certifies that the patent is invalid or would not be infringed by the manufacture, use, or sale of the new generic drug. The patent holder ordinarily brings suit shortly after the paragraph IV ANDA filing). The paragraph IV certification provides strong incentives to the generic undertaking because the generic undertaking can be entitled to a 180-day period during which it would be the exclusive generic drug in the market. This 180-day period is of substantial benefit to the generic undertaking which obtains it because it gives that manufacturer *"a significant head start over other manufacturers"* (see *Geneva farms. Tech Corp. v Barr Labs Inc.* 386 F.3d 485 (2nd Circ. 2004)). The paragraph IV certification therefore offers a strong incentive for generic undertakings to challenge patents of originator undertakings that they consider may not be infringed or may be invalid. Nothing of the kind exists under Union law or under the national laws of the Member States.

¹²³² ID 5394, page 265.

company "*do not appear to be subject to such scrutiny*", whereas both kinds of settlement could prevent the generic company from entering the market. Lundbeck concludes that the direction of the payment in a settlement is "*a poor and inconclusive indicator of anticompetitive objects or effects.*"¹²³³

- (700) The Commission disagrees. First of all, it should be emphasised that an argument that the Commission should also have investigated other possibly anti-competitive behaviour is not a defence against the infringements the Commission has found in this particular investigation.
- (701) Secondly, the Commission's findings that the six agreements covered by this Decision constitute infringements of Article 101(1) of the Treaty are based on the entire set of specific facts and circumstances underlying the agreements in question as well as on the legal considerations described in detail in this Decision.
- (702) That the Commission does not simply base itself on the direction of the payment is amply demonstrated in section 10.1, where the Commission has stated that a payment from an originator company to a generic company in the context of a settlement agreement may be entirely legitimate.¹²³⁴ That same section also points out, however, that the Commission does consider that a payment from an originator company to a generic company in the context of an agreement that prevents the generic company from entering the market is a clear warning signal that merits further examination.¹²³⁵ But in the final analysis, each case must be assessed on its own merits, taking into account the specific facts and circumstances of the case. This is precisely what this Decision does.

11.6. The role of the generic undertakings

- (703) Lundbeck argued to the Commission that "*The generic companies had leverage to extract payments from Lundbeck because it would be impossible for Lundbeck to obtain full compensation for the irreparable harm resulting from patent infringement.*"¹²³⁶ According to Lundbeck:

"...there was a certain risk that some courts might not grant an injunction.

While Lundbeck fully expected to succeed on the merits against those early generic infringers (whose products were based on API from Cipla, Matrix and Natco), the risks were simply too great: entry by any one of these infringing generic companies would have inflicted irreversible and incalculable financial damage on Lundbeck, which was not likely to be recovered by a damages award. For example, entry by a generic company onto the market would, under the national rules of some Member States, result in mandatory price reductions including for the patented product – in such cases it would be very difficult, if not impossible, to restore prices to their previous levels following a successful infringement lawsuit. Even if [it] were possible to estimate the long-term damages resulting from infringing generic entry, Lundbeck's losses would significantly exceed the profits of any of the generic

¹²³³ ID 1259, page 2. See also ID 1683.

¹²³⁴ See recital (639) above.

¹²³⁵ See recital (640) above.

¹²³⁶ ID 823, page 2.

infringers, making it very unlikely that Lundbeck would ever collect any damages."¹²³⁷

- (704) In a later submission¹²³⁸, which Lundbeck acknowledges is "*not intended to describe Lundbeck's specific facts or decision process*", Lundbeck made the same point that the generic company was able to "*extract a significant payment from the innovator as part of a settlement.*"¹²³⁹ In this submission Lundbeck analysed what it calls the "*hold-up*" problem. According to Lundbeck, when an originator company stands to lose much more from even a small chance of successful generic entry than its generic challengers stand to gain from even a large chance of successful entry, there is an "*asymmetry of risk*" which generic companies can exploit to negotiate significant payments in settlement agreements. In this kind of scenario, depending on the precise chances and financial outcomes used for the different options, there are circumstances where the originator company as a rational actor would prefer to pay a considerable sum of money as part of a settlement in which the generic company does not enter – or exits - the market rather than face litigation with a certain risk of market entry which would result in much greater commercial damage, even if the originator company believes it has a good chance of winning litigation.
- (705) The Commission observes first that, as explained in sections 9.2.2 and 9.4, the generic companies' leverage was a direct function of the competitive threat they posed to Lundbeck as potential generic entrants. There was nothing unlawful in this leverage.
- (706) As a second observation, even if Lundbeck could show that the generic companies, in the concrete case at hand rather than in theory, had leverage to extract payments from Lundbeck, according to long-standing jurisprudence of the Courts of the European Union it makes no difference for the assessment of whether an agreement restricts competition by object that such an agreement may have come about as a result of pressure by one of the contracting parties. For instance, in *Cimenteries CBR*, the General Court ruled that "*Undertakings cannot justify infringement of the rules on competition by claiming that they were forced into it by the conduct of other traders.*"¹²⁴⁰
- (707) There is, moreover, no indication from the facts in the file that Lundbeck was reluctantly forced into concluding the agreements covered by this Decision by the generic companies concerned. As explained in chapter 6 and as confirmed by the detailed facts described in chapter 7, it was part of Lundbeck's general strategy against generic entry to conclude in certain instances agreements with generic companies delaying their entry. If anything, it appears from the facts as described in chapter 7 that both sides to the different agreements had their own interests in entering into the negotiation and agreeing a mutually advantageous deal.
- (708) If, however, Lundbeck's argument is that because of the asymmetry of risk it acted rationally in choosing the most lucrative commercial option available to it and that this somehow makes Lundbeck's behaviour in the present case legal, the Commission

¹²³⁷ ID 823, pages 13-14.

¹²³⁸ ID 1259. See also ID 1683.

¹²³⁹ ID 1259, page 2.

¹²⁴⁰ Joined Cases T-25/95 etc, *Cimenteries CBR and Others v Commission*, [2000] ECR II-491, paragraph 21.

does not agree. The Commission see why, if one ignores Lundbeck's obligation to comply with competition law, it was in Lundbeck's commercial interest to offer the generic companies in question money in exchange for stopping, for a certain period of time, their efforts to enter the market. By doing so, Lundbeck avoided the risk that it would not obtain an interim injunction, it avoided the risk that its patents might be held invalid, it avoided the risk that its patents might be held non-infringed, it avoided the risk that a generic company would not be able to pay any damages that might have been awarded to Lundbeck and it avoided the certainty of very significant losses for the undertaking if widespread lawful generic entry actually occurred. In short, by doing so Lundbeck avoided potential or actual competition from the generic companies in question. It achieved this result not by the strength of its patents, but by making payments to these companies that equalled or exceeded the profit those companies could make if they successfully entered the market. As shown in recitals (198) to (201) above, in the United Kingdom alone Lundbeck saved considerably more in sales than it spent on the six agreements covering not only the United Kingdom but also other EEA countries together. Moreover, as mentioned in recital (201), through these agreements, Lundbeck also managed to introduce escitalopram in the United Kingdom six months after generic entry had become possible and sixteen months before widespread generic entry actually came about. Lundbeck considered at the time that obtaining such a head start for escitalopram was of crucial importance for the undertaking Lundbeck.¹²⁴¹

(709) As explained in section 10.1 above, in this kind of agreement between an originator undertaking still holding a quasi-exclusive position on the market and generic challengers it may be possible that both the originator undertaking and the generic undertaking will be better off by the arrangement than if they had continued to compete. That does not imply, however, that such behaviour which is lucrative for both parties to the agreement is also necessarily legal. Competitors that together enter into a cartel may also believe that it is in their better commercial interest to work together with their competitors, for instance by collectively raising prices, than to follow the much harder, much riskier and quite possibly less profitable road of actually competing with each other on quality and price for the consumer's favour. Originator undertakings and generic challengers that together decide that it is in their best commercial interest not to compete with each other and instead share the exclusivity profits of the originator undertaking at the expense of consumers infringe competition law and commit an illegal act.

(710) In reply to the Statement of Objections, Lundbeck submitted to the Commission an "*Economic assessment of the Commission's Statement of Objections in Case COMP 39.226*"¹²⁴² with economic arguments. Lundbeck made in principle two points:

Firstly, in Lundbeck's view, limits on patent settlements may be bad for consumers in the long term. Limits on patent settlements reduced the scope of patent protection

¹²⁴¹ See section 6.2 above, where one can find such contemporaneous Lundbeck statements as "*The S-Citalopram project can lead to the launch of a patent protected product in year 2002. When this happens, Lundbeck's protection against generic competition will be prolonged until 2012 or later...*" (recital (136)); "*The enantiomer of citalopram, S-citalopram, is expected to become Lundbeck's most important defence against generic competition on the citalopram racemate*" (recital (137)); "*Launch and promotion of Cipralex (escitalopram) have the highest priority in Lundbeck in 2002*" (recital (140)); and "*Lundbeck fights generics to create a window of opportunity to switch to escitalopram*" (recital (141)).

¹²⁴² See ID 5395.

and therefore incentives to invest in pharmaceutical R&D by lowering originators' profits. This would come about because there would be fewer settlements and more at-risk entry. The originator company would suffer losses from (i) lost profits on lost sales, (ii) lost profits due to lower prices on remaining sales, (iii) lost profits due to mandatory price reductions and cross-referencing after generic entry in another Member State, (iv) inability to recover potential damages from small or undercapitalized generic companies. As less profit for the originator would result in lower R&D investment, consumers could be negatively affected by a smaller number of new medicines or higher prices.

Secondly, patent settlements would be good for consumers even in the short term. As long as short-term settlements facilitated "final" settlements, they could trigger early generic entry (that is to say before the expected entry under litigation). This is illustrated with a theoretical economic model where a generic company's and an originator company's decision to enter a "final" settlement or to litigate are analysed.

- (711) Regarding the first point, in its analysis of the long-term effects of restricting settlements with reverse value transfers, Lundbeck does not take into account an important effect that such a limitation on reverse payment settlements may have on the incentives of generic companies to enter into litigation with the originator company in the first place. If reverse value transfers cannot be obtained, certain generic companies may decide not to enter into disputes. This, other things being equal, reduces the originator company's exposure to "generic risk" and in turn, must have a positive impact on the originator company's expected profits. This effect contrasts with a potential loss in the originator's expected profits caused by a higher proportion of the cases litigated till their end or by more generic entries at risk. Therefore, the overall effect of the limitation on reverse payments settlements on the originator company's profit (and thus its incentives to innovate) is at most ambiguous.
- (712) As for the second point, it is important to stress that Lundbeck's model presented in Section IIIB of Appendix 1¹²⁴³ does not reflect the facts of the Lundbeck case. The settlements analysed in the model are "final", that is to say settling the relationship once and forever. Lundbeck uses the model with the caveat "as long as short-term settlements facilitate final settlements". However, there is no indication why this would be the case. Lundbeck presented neither a theoretical argument nor empirical evidence explaining any link between its own settlements and "final" settlements. This link is simply assumed.
- (713) Even when assuming that short-term settlements actually facilitate "final" settlements, the conclusions drawn from the model are flawed. Lundbeck concludes that when reverse payments are allowed, the settled date of entry might actually predate the expected entry date under litigation. However, Lundbeck does not mention that such settlements are not in the interest of the parties signing the settlement. Within the framework of the model presented by Lundbeck, the parties will maximize their joint profits by setting the entry date as late as possible. Settlements with an early entry date might be among the feasible ones, but both the generic company and the originator company share an incentive to postpone entry after the expected date under litigation.

¹²⁴³

See ID 5395.

(714) GUK submitted a report by Oxera¹²⁴⁴ which disputed the SO's factual description of Merck (GUK)'s ability to enter using estimated ex ante profits with settlement and under alternative entry scenarios. The report concluded that the settlement's sums were insufficient to dissuade Merck (GUK) from entering the market if such an entry would have been certain or easy absent the settlement. It is also argued that in view of the settlement's sums, Merck (GUK) was actually unlikely to enter even if the settlement had not taken place.¹²⁴⁵ It must be noted that this report does not bring any factual elements in its assessment.

(715) While in general such an economic analysis may complement the assessment of factual elements, unfortunately Oxera's report is flawed in several aspects, including significant methodological issues which disqualify it as a relevant piece of evidence in this case.

First, there is no equilibrium analysis: the report focuses on Merck (GUK)'s incentives but it does not demonstrate that what appears to be acceptable by Merck (GUK) would, in fact, be proposed by Lundbeck. Thus, there is no necessary proof that the situations used to derive the report's conclusions could have occurred at equilibrium.

Second, the computation of expected profits for several alternatives at one given point in time requires taking into account all possible alternatives available at the time as well as assumptions and beliefs experienced by each firm at that point in time. At the relevant time, Merck (GUK) expected a significant migration from citalopram into escitalopram (50%).¹²⁴⁶ Even if such a migration did not eventually materialize, it played a role in Merck (GUK)'s assessment of its available alternatives, and Oxera does not take this into account. When such an ex ante expectation is included in the analysis, the conclusions of the report do not hold any more.

Third, there are a number of computational errors.¹²⁴⁷

¹²⁴⁴ Annex 6 to Merck's reply to SO.

¹²⁴⁵ More specifically, Oxera's report computes GUK's ex ante profits with settlements and under alternative entry scenarios, including the Commission's counterfactual in which (according to the report) GUK was confident it was not infringing and could enter quickly and effectively the United Kingdom market, a large market, in which prices would have remained high if only one generic producer had entered. The report compares these ex ante profits and concludes that the Commission's counterfactual is inconsistent with GUK's economic incentives: (i) GUK would have an incentive to enter in the Commission's counterfactual (high probability of Lundbeck losing litigation), and not to settle; (ii) GUK would not have an incentive to enter under alternative risk profile (low probability that Lundbeck loses litigation) irrespective of Lundbeck's payments, thus the settlement does not delay entry.

¹²⁴⁶ ID1024 page 49.

¹²⁴⁷ Amongst those: (1) Merck (GUK)'s expected profits following widespread generic entry computes in fact Lundbeck's expected profits and forgets to multiply this results by the proportion of Merck (GUK)'s margin compared to Lundbeck's margin (cells C25-C28 in spreadsheet "Profits & damages"); (2) In the computation of profits in case of validity of the patent, annual litigation costs are not weighted by litigation time (line 24 entitled "Profit if valid" in spreadsheets "Table 4.1" and "Tables 4.2 & 4.3"); (3) In the computation of profits in case of validity of the patent, Merck (GUK)'s annual profit earned during litigation is divided by the number of firms entering at risk, while this profit already takes into account the consequences of the presence of competitors (line 24 "Profit if valid" in spreadsheets "Table 4.1" and "Tables 4.2 & 4.3"); (4) In the computation of profits in case of invalidity of the patent, Merck (GUK)'s annual profit earned during litigation is divided by the number of firms entering at risk (line 23 "Profit if invalid" in spreadsheets "Table 4.1" and "Tables 4.2 & 4.3"); (5) The (annual) profit earned

11.7. The role of Lundbeck

(716) GUK argued that "*Lundbeck engaged in a number of actions that frustrated GUK's attempts to be the first to launch generic citalopram.*"¹²⁴⁸ In particular, GUK argues that Lundbeck:

- restricted GUK's access to citalopram API through the acquisition of VIS and the subsequent withdrawal of the VIS Drug Master File;
- attempted to restrict other API suppliers from supplying citalopram to generic suppliers;
- attempted to delay marketing authorisations; and
- used process patents to block generic entry.¹²⁴⁹

GUK argued that Lundbeck's actions, which have been described in chapter 6 of this Decision, "*adversely affected its [GUK's] anticipated profits*" and "*created substantial uncertainty and risks of further delays and costs*".¹²⁵⁰ According to GUK, "*[t]he settlement agreements which GUK entered into with Lundbeck should be understood and interpreted in the context of the impact of the actions taken by Lundbeck during the relevant time-frame.*"¹²⁵¹

(717) In response to this argument, the Commission refers to the reply it has given Lundbeck when arguing that the generic companies had leverage to extract payments from Lundbeck¹²⁵²: According to long-standing jurisprudence of the Courts of the European Union it makes no difference for the assessment of whether an agreement restricts competition by object that such an agreement may have come about as a result of pressure by one of the contracting parties. As the General Court ruled in *Cimenteries CBR*: "*Undertakings cannot justify infringement of the rules on competition by claiming that they were forced into it by the conduct of other traders.*"¹²⁵³

(718) Moreover, the facts described in sections 7.2 and 7.3 above indicate that Merck (GUK) was not forced into any agreement but that both sides were eager to do a deal. With respect to the agreement regarding the United Kingdom, according to an internal Merck (GUK) e-mail of 5 September 2001, Lundbeck was offering "*a potential deal for the UK market.*"¹²⁵⁴ On 19 November 2001, Merck (GUK) called Lundbeck "*and asked if we were interested in a deal.*"¹²⁵⁵ A Merck (GUK) report of a meeting with Lundbeck on 11 December 2001 stated: "*They [Lundbeck] made no reference to our product infringing. They [Lundbeck] are very keen to do some sort of deal. I [Merck (GUK)'s [employee function]*] am keen provided the numbers stack up....Lundbeck do not want a generic on the market. However, they could*

following widespread generic entry is written to be 4.4 (see notes attached to Tables 4.1, 4.2 and 4.3) while computations use 3.4 for all scenarios (see spreadsheets "Table 4.1" and "Tables 4.2 & 4.3").

¹²⁴⁸ ID 1013, page 1.

¹²⁴⁹ ID 1013, pages 2 to 5.

¹²⁵⁰ ID 1013, page 5.

¹²⁵¹ ID 1013, page 1.

¹²⁵² See section 11.6 above.

¹²⁵³ Joined Cases T-25/95 etc, *Cimenteries CBR and Others v Commission*, [2000] ECR II-491, paragraph 21.

¹²⁵⁴ See recital (238) above.

¹²⁵⁵ See recital (245) above.

compensate us for the profit we would have made etc."¹²⁵⁶ With respect to the agreement regarding other EEA Contracting Parties than the United Kingdom, an internal Merck (GUK) e-mail stated on 1 May 2002: *"I understand...you are starting to talk of a pan-Euro deal with Lundbeck."*¹²⁵⁷ Around 28 May 2002, Lundbeck reported that Merck (GUK) was *"interested in a new deal."*¹²⁵⁸ At the same time, Lundbeck asked Merck (GUK) for a *"valuation of a deal"* for:

- *"Sweden 12 months*
- *UK 6 months extension*
- *Remaining EU 12 months."*

On 10 October 2002, Merck (GUK) could report: *"We have an "agreed offer" on the table...The deal is for 12 months which means that, depending on a possible further lucrative extension, we could start manufacture again mid-2003 and use up most of the existin[g raw material]."*¹²⁵⁹ Finally, on 11 October 2002, Lundbeck confirmed to Merck (GUK): *"OK to the 12 mill euro."*¹²⁶⁰ These facts show that both Lundbeck and Merck (GUK) actively co-operated towards concluding the two agreements and that Merck (GUK) considered that entering into those agreements was a *"lucrative"* option for Merck (GUK) for which *"the numbers stack up"*.

- (719) In a submission to the Commission of 11 January 2012 GUK argued that the agreements it concluded with Lundbeck *"ensured a guaranteed launch of citalopram without obstacles after expiry of the Settlement Agreements, years prior to patent expiry."*¹²⁶¹ This claim is not supported by the facts. Neither Merck (GUK)'s agreement regarding the United Kingdom nor Merck (GUK)'s agreement regarding the other EEA Contracting Parties than the United Kingdom gave Merck (GUK) any right to enter any EEA market with generic citalopram after expiry of the agreement. Indeed, the agreement regarding other EEA Contracting Parties than the United Kingdom stated explicitly in Article 4: *"Furthermore, upon the effective date of termination of this Agreement for whatever reason, any party shall be entitled to exercise and prosecute any intellectual property rights owned by or licensed to such party as such party sees fit."*¹²⁶² It is precisely these facts that show that the agreements in question did not resolve any patent dispute and did not ensure generic entry at any point in time but rather postponed the issue of potential generic entry into the market.

11.8. The applicability of the vertical block exemption

- (720) Lundbeck argued in its reply to the Statement of Objections that the vertical block exemption Regulation ¹²⁶³ applied to the parts dealing with distribution in the agreements it concluded with Merck (GUK) for the United Kingdom and with

¹²⁵⁶ See recital (255) above.

¹²⁵⁷ See recital (324) above.

¹²⁵⁸ See recital (326) above.

¹²⁵⁹ See recital (345) above.

¹²⁶⁰ See recital (346) above.

¹²⁶¹ ID 1978, page 13.

¹²⁶² ID 8, page 230.

¹²⁶³ Commission regulation (EU) No 330/2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices, OJ L 102 of 23.4.2010, page 1.

Ranbaxy.¹²⁶⁴ Article 2(1) of the vertical block exemption Regulation provides that *"Pursuant to Article 101(3) and subject to the provisions of this Regulation, it is hereby declared that Article 101 (1) of the Treaty shall not apply to vertical agreements."* Article 2(4) of the same Regulation states:

"The exemption provided for in paragraph 1 shall not apply to vertical agreements entered into between competing undertakings. However, it shall apply where competing undertakings enter into a non-reciprocal vertical agreement and:

(a) the supplier is a manufacturer and a distributor of goods, while the latter is a distributor and not a competing undertaking at the manufacturing level..."

It follows from Article 2(4) that the vertical block exemption does not apply if both parties to a vertical agreement, such as a distribution agreement, are manufacturers of the goods in question. In the case at hand, both Lundbeck and Ranbaxy were manufacturers of citalopram API and of finished citalopram products. As for Lundbeck and Merck, both undertakings were manufacturers of finished citalopram products. Even if in the industry parlance, Merck was sometimes called a 'distributor', because it distributed generic products, in a technical sense it was also a manufacturer of finished citalopram products, in that it manufactured, through its subsidiary Alphapharm, tablets from the bulk citalopram API which it purchased. GUK itself explained to the Commission that *"GUK and its affiliates...sourced the finished dosage form for citalopram in-house through Alphapharm, a Merck entity based in Australia."*¹²⁶⁵ GUK also stated to the Commission: *"Alphapharm produced the final dosage product based on raw material supplied by Natco".*¹²⁶⁶ Finally, Merck (GUK)'s agreement with Lundbeck stated in the preamble that *"GUK has also developed a product containing citalopram"*. The agreement defined the *"Products"* to be delivered up to Lundbeck as *"the citalopram products developed by GUK in raw material, bulk product and finished pack form as set out in the Schedule and manufactured in accordance with the specification for Products as supplied by GUK at the date of signature. Attached to Schedule 2."* Schedule 2 contained a *"Finished Product Specification"* for the tablets in question, including *"5.5 mm, normal convex, white film coated tablet debossed "CM" on one side and "G" on the other."* These documents therefore clearly show that Merck was the producer of the citalopram tablets in question. The vertical block exemption therefore does not apply to the distribution parts of the agreements Lundbeck concluded with Ranbaxy and with Merck for the United Kingdom.

11.9. The lack of appreciability of the restriction of competition

- (721) Several parties have questioned whether the agreements restricted competition in the markets concerned to an appreciable degree.¹²⁶⁷
- (722) This claim must be understood to mean that it is the continuous course of conduct as a whole that must be capable of affecting competition to an appreciable degree. It is not required that each individual practice, each provision of an agreement or each agreement that forms part of a single and continuous infringement is capable of doing so. In the case at hand, therefore, the claim of lack of appreciability of the

¹²⁶⁴ ID 5394, page 279.

¹²⁶⁵ ID 1267, page 15.

¹²⁶⁶ ID 660, page 17. See also footnote 564 above.

¹²⁶⁷ See for instance Alpharma in ID 6056, page 47; GUK in ID 6026, pages 87 to 89 and 92 to 99.

restriction of competition concerns the set of agreements between Lundbeck and Merck, the set of agreements between Lundbeck and Arrow, the agreement between Lundbeck and Alpharma and the agreement between Lundbeck and Ranbaxy.¹²⁶⁸

(723) The Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) of the Treaty establishing the European Community (hereafter referred to as the *de minimis* Notice) acknowledges that *"The Court of Justice of the European Communities has clarified that this provision [Article 81(1) EC, now Article 101(1) of the Treaty] is not applicable where the impact of the agreement on intra-Community trade or on competition is not appreciable."*¹²⁶⁹

(724) In this Notice the Commission quantifies, with the help of market share thresholds, what is not an appreciable restriction of competition under Article 101 of the Treaty. However, point 11 of the Notice explains that these *de minimis* thresholds *"do not apply to agreements containing any of the following restrictions:*

(1) as regards agreements between competitors as defined in point 7, restrictions which, directly or indirectly, in isolation or in combination with other factors under the control of parties, have as their object:

...

(b) the limitation of output or sales;

(c) the allocation of markets or customers;

..."

As each of the agreements covered by this Decision had the object of preventing or stopping the generic undertaking concerned from entering one or more markets in the EEA with generic citalopram, these agreements limited the potential output and sales of generic citalopram in EEA markets. They also de facto allocated the citalopram markets in question to Lundbeck, in the sense that the generic companies concerned agreed to refrain from competing with generic citalopram with Lundbeck in those markets. Such agreements cannot benefit from the *de minimis* thresholds in this Notice. The Commission refers, in this respect, also to *Expedia*, in which the Court of Justice stated in a preliminary ruling:

*"It must therefore be held that 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."*¹²⁷⁰

(725) Even if the *de minimis* market share thresholds did apply to the agreements in question, those thresholds were clearly exceeded in the years concerned by the agreements, 2002 and 2003. According to point 7 of the *de minimis* Notice, *"The Commission holds the view that agreements between undertakings which affect trade*

¹²⁶⁸ See section 12.8 above.

¹²⁶⁹ Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) of the Treaty establishing the European Community, OJ C 368 of 22.12.2001, page 13.

¹²⁷⁰ Case C-226/11, *Expedia Inc. v Autorité de la concurrence and Others*, reference for a preliminary ruling, judgment of 13 December 2012, paragraph 37.

between Member States do not appreciably restrict competition within the meaning of Article 81(1):

(a) if the aggregate market share held by the parties to the agreement does not exceed 10% on any of the relevant markets affected by the agreement, where the agreement is made between undertakings which are actual or potential competitors on any of these markets (agreements between competitors);

...¹²⁷¹

For the purpose of assessing whether the *de minimis* thresholds are exceeded in this case, it is not necessary to adopt a definition of the product market concerned. Even if, as parties propose, the market for all anti-depressants at ATC 3 level were to be taken,¹²⁷² the market share of Lundbeck alone in that market, limited to its sales of citalopram and escitalopram, considerably exceeds 10% both in 2002 and 2003 in the United Kingdom, Denmark and most of the other EEA Contracting Parties.¹²⁷³ See the table in recital (215) above.

- (726) Also from a qualitative perspective, there can be no doubt that the agreements appreciably restricted competition. As mentioned in recital (96), the Commission's inquiry into the pharmaceutical sector has established that on average, the price at which generic companies entered the market was 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after entry, prices of generic medicines were on average 40% below the former originator price. As mentioned in recital (124), as early as 1997 Lundbeck expected in most of the analysed EEA markets to lose between [15-25]*% and [20-30]*% of market share on citalopram after one year of generic competition, increasing to between [35-45]*% and [40-50]*% of market share loss at the end of year two.¹²⁷⁴ For the United Kingdom, by December 2001, Lundbeck stated that *"Immediately following patent expiry in January 2002, generic sales are expected to take [55-65]*% of the citalopram business."*¹²⁷⁵ In the same month, Lundbeck stated: *"[Lundbeck's] generic strategy in the United Kingdom is complex, but is very important because of the significant impact that generic products have been shown to have on sales of*

¹²⁷¹ The Commission draws attention to the words *"on any of the relevant markets"*. This means that if the 10% threshold is surpassed in just one of the relevant markets, the agreement is no longer *de minimis*.

¹²⁷² The European Commission has investigated antidepressants' markets in a number of merger decisions (at the ATC3 level or at a narrower level; see in particular Cases M.631 Upjohn/Pharmacia; M.1229 American Home Products/Monsanto; M.1878 Pfizer/Warner-Lambert; M.3751 Novartis/Hexal; M.5253 Sanofi-Aventis/Zentiva; M.5295 Teva/Barr; M.5476 Pfizer/Wyeth; M.5502 Merck/Schering-Plough; M.5865 Teva/Ratiopharm; M.6613 Watson/Actavis), but has so far left the definition of the relevant product market open. However, with respect to citalopram (in Norway), in case M.5865 *Teva/Ratiopharm* (Decision of 3 August 2010), recital 317, the Commission found that *"the appropriate market definition [for citalopram] was likely to be at the molecule level (...) [T]he exact market definition can nonetheless be left open for the purposes of the present decision."*

¹²⁷³ For a precise calculation of the market share held by the parties to the agreement, not only Lundbeck's sales of citalopram and escitalopram should be included, but also Lundbeck's sales of other products within the ATC3 group of anti-depressants, plus all sales of such anti-depressants by the generic undertaking with which Lundbeck concluded the agreement(s). Such a calculation is not necessary, however, as Lundbeck's sales of citalopram and escitalopram already clearly exceed the 10% level in the United Kingdom, Denmark and most of the other Contracting Parties of the EEA Agreement.

¹²⁷⁴ See the "realistic" estimates for years 1 and 2 for France, Sweden, Finland, Norway, Germany, Belgium, Austria, Greece, Denmark, the United Kingdom, Ireland and the Netherlands.

¹²⁷⁵ See recital (196) above.

branded products (sales of Prozac [branded fluoxetine] fell by 70% within a few months)."¹²⁷⁶ After Lundbeck had settled with Lagap in October 2003 and allowed widespread generic entry into the United Kingdom to take place, prices of generic citalopram there dropped 31% in just three months' time. After seven months, prices of generic citalopram had dropped 69% and after 13 months they had dropped 90%.¹²⁷⁷ By preventing potential entry of generic citalopram, initially in January 2002 by Merck (GUK) and Arrow, in February 2002 by Alpharma and as of June 2002 by Ranbaxy, Lundbeck succeeded in postponing generic price competition in the United Kingdom market which would have been likely to result in considerable price decreases and market share losses for Lundbeck.

- (727) The qualitative impact of the agreements in question on competition was most pronounced in the United Kingdom. In other Contracting Parties of the EEA Agreement, Lundbeck usually did not succeed in keeping a factual monopoly on the citalopram market for such a long period, because other generic undertakings entered the market. Those undertakings were, however, often successfully enjoined by Lundbeck, at least initially. If Merck (GUK) (including via NM Pharma), Alpharma and Ranbaxy (and Arrow in Denmark) had been allowed to sell generic citalopram in EEA markets, their presence on the market would have stimulated price competition between generic companies and with Lundbeck, the more so as the number of API suppliers, with possibly lower production costs, would have increased with Natco and Ranbaxy. Their presence could also have led to additional legal challenges against the patents Lundbeck might have invoked, including possibly, as in the case of Ranbaxy, legal challenges against different Lundbeck patents. In any case, as each infringement covered the United Kingdom, it has been shown that each infringement appreciably restricted competition.

11.10. The principle of legitimate expectations

- (728) In its reply to the Statement of Objections, Merck KGaA argued that the principle of legitimate expectations had been violated by the Commission. Merck KGaA recalled that the Danish Competition Authority stated in a 2004 press release that *"the Commission does not wish to initiate proceedings against Lundbeck."*¹²⁷⁸ According to Merck KGaA, *"Lundbeck, and even more so Merck KGaA, could rely on the fact that the Commission would not open proceedings against them unless the factual circumstances changed, or if information on which the Commission's primary assessment was based proved to be incorrect."*¹²⁷⁹
- (729) The right to rely on the principle of the protection of legitimate expectations, which is a general principle of European Union law, extends to any individual who is in a

¹²⁷⁶ See recital (197) above.

¹²⁷⁷ See recitals (209) to (213) above. It is to be noted that these considerable price and market share effects of generic entry occur even though the molecule in question may previously already have been constrained to a greater or lesser extent by competitive pressures from other molecules. This was also the case for citalopram, as developments following widespread generic entry show, resulting in a 90% price drop after 13 months. It is not necessary to analyse the degree to what other molecules may or may not have constrained the price level and market share of Lundbeck's citalopram, as for instance Alpharma has argued (ID 6056, page 47), as that price level and market share of Lundbeck is taken as the basis from which generic entry on citalopram was likely to cause further price decreases and market share losses for Lundbeck.

¹²⁷⁸ ID 5960, page 406. See also ID 6057, page 6.

¹²⁷⁹ ID 5960, page 407. See also ID 6057, page 6.

situation in which the European Union authorities, by giving him precise assurances, have caused him to entertain legitimate expectations.¹²⁸⁰

- (730) Moreover, the General Court recalled in *Visa* that *"In accordance with settled case-law, that principle extends to any individual in a situation where the authorities have caused him to entertain legitimate expectations, it being understood that no one may plead infringement of that principle unless precise, unconditional and consistent assurances, from authorised, reliable sources, have been given to him by the authorities."*¹²⁸¹
- (731) In the present case, it must be stated that the Commission did not at any point give precise assurances as to the consistency with Union competition law of the initiatives taken by Lundbeck. The Commission did not confirm the Danish press statements and nothing suggests that the Danish Competition Authority was entitled to speak on the Commission's behalf. Moreover, it is not established that the Danish Competition Authority stated that reverse patent settlement agreements are compatible with Article 101 of the Treaty.¹²⁸²
- (732) The Commission observes that it is not bound by press statements released by another competition authority. In any case, the Commission took no decision at that time to refrain from further investigating the practices in question or, eventually, initiating proceedings. As described in section 2.1 above, following the information from the Danish Competition Authority, the Commission received further information regarding Lundbeck's practices with respect to citalopram from the Hungarian Competition Authority. In 2005, the Commission inspected H. Lundbeck A/S, two Lundbeck subsidiaries in Italy and Hungary respectively, and a Hungarian company. Requests for information were sent out in 2006. The replies to these requests for information were examined in 2007. In 2008 the Commission decided to launch a sector inquiry into the pharmaceutical sector. One of the key topics examined was the kind of reverse payment agreement covered by this Decision. Following the adoption of the final sector enquiry report in July 2009, the Commission conducted additional inspections on citalopram in Italy in December 2009. Proceedings were opened against Lundbeck in 2010 and against the generic undertakings involved, including Merck, in 2012. Merck KGaA can hardly criticise the Commission for first wanting to undertake a thorough investigation of the practices in question before opening proceedings. Merck KGaA can have had no

¹²⁸⁰ Case 265/85 *Van den Bergh en Jurgens v Commission* [1987] ECR 1155, paragraph 44, and Case T-220/00 *Cheil Jedang v Commission* [2003] ECR II-2473, paragraph 33.

¹²⁸¹ Case T-461/07, *Visa Europe Ltd and Visa International Service v European Commission*, [2011] ECR II-1709, paragraph 38. See also Joined Cases T-236/01, T-239/01, T-244/01 to T-246/01, T-251/01 and T-252/01 *Tokai Carbon and Others v Commission* [2004] ECR II-1181, paragraph 152 and case-law cited.

¹²⁸² In any case, the Commission recalls that national competition authorities are not empowered to take decisions stating that there has been no breach of Articles 101 or 102 of the Treaty. The Court stated in Cases C-375/09 *Prezes Urzedu Ochrony Konkurencji v Tele 2 Polska*, judgment of 3 May 2011, [2011] ECR I-3055, paragraph 28, that such an empowerment "would call into question the system of cooperation established by the Regulation and would undermine the power of the Commission". In fact, "[s]uch a 'negative' decision on the merits would risk undermining the uniform application of Articles 101 TFEU and 102 TFEU, which is one of the objectives of the Regulation highlighted by recital 1 in its preamble, since such a decision might prevent the Commission from finding subsequently that the practice in question amounts to a breach of those provisions of the European Union law".

legitimate expectation that by not immediately opening proceedings in 2004, the Commission would not initiate such proceedings in the future.

- (733) Moreover, the fact that the Commission first opened proceedings against Lundbeck cannot create legitimate expectations that the Commission would not later open proceedings against Merck KGaA as well.

12. LEGAL ASSESSMENT OF LUNDBECK'S AGREEMENTS

12.1. Introduction

- (734) Taking into account the criteria identified in recital (661) and the other factors mentioned in recital (662) above, this chapter examines each agreement (including any extensions) concluded between a particular generic undertaking and Lundbeck in turn for its compatibility with Article 101(1) of the Treaty. Also for Merck and Arrow, each of which concluded two agreements with Lundbeck which together form a single and continuous infringement¹²⁸³, the legality of each agreement will be separately assessed. The agreements will be examined in the order in which they have been presented in chapter 7.
- (735) The legal assessment in this chapter will, in accordance with well-established jurisprudence of the Court of Justice¹²⁸⁴, 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, allow a conclusion on whether Lundbeck and the generic undertaking in question were at least potential competitors at the time when they concluded the agreement. In a second step, the actual content and objectives of the agreement will be examined. This analysis will in particular identify the commitments the generic undertaking accepted and whether the agreement was related to a transfer of value from the originator undertaking to the generic undertaking. To the extent that the implementation of the agreement throws any further light on these questions, this will also be mentioned. Finally, in a third step, 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. On this basis, the analysis will permit the conclusion for each agreement that it constituted a restriction by object. Specific arguments of the parties relating to this analysis will be taken up in the assessment of each agreement.

12.2. The agreement between Lundbeck and Merck (GUK) regarding the United Kingdom restricted competition by object under Article 101(1) of the Treaty

12.2.1. Introduction

- (736) The general factual context for the legal assessment of the agreements dealt with in this Decision has been set out in chapters 4 to 6 above. The specific factual context for the legal assessment of the Merck (GUK) agreement related to the United Kingdom has been set out in sections 3.2, 3.3 and 7.2 above. The general legal context for the assessment of the agreements dealt with in this Decision has been set

¹²⁸³ See section 12.8 below.

¹²⁸⁴ See Case C-501/06P, C-241/06P, C-515/06P and C-519/06P, *GlaxoSmithKline*, [2009] ECR I-9291, paragraph 58 and the jurisprudence cited therein. See also Cases C-403/08 a.o., *Football Association Premier League*, judgment of 4 October 2011, paragraph 136 and Case C-8/08, *T-Mobile Netherlands BV* a.o., judgment of 4 June 2009, paragraph 27.

out in chapters 8 to 11 above. The current section will make a specific legal assessment of the Merck (GUK) agreement related to the United Kingdom, examining its compliance with Article 101(1) of the Treaty, based in particular on the criteria identified in recital (661) and the other factors mentioned in recital (662) above. This assessment will be made in the manner indicated in recital (735) above, taking into account the actual content and objectives of the agreement, the legal and economic context of the agreement, the implementation of the agreement and the intentions of the parties.

12.2.2. The agreement between Lundbeck and Merck (GUK) was an agreement between undertakings within the meaning of Article 101(1) of the Treaty

- (737) Article 101(1) of the Treaty prohibits "*agreements between undertakings*" that restrict competition. For the general legal assessment of these quoted terms, the Commission refers to section 9.3 above. An agreement within the meaning of Article 101(1) of the Treaty can be said to exist when there is a concurrence of wills between two parties regarding the future behaviour of one or both of them. An undertaking is any entity engaged in an economic activity, such as offering goods or services on a given market, regardless of its legal status and the way in which it is financed. In the present case, Lundbeck and Merck (GUK) were at the time of events economic entities that offered goods on given markets. They were therefore undertakings. As for the "*Settlement and Supply Agreement*" these two undertakings concluded on 24 January 2002, this document, as signed by Lundbeck Limited and Generics [UK] Limited (Merck (GUK)), reflected a concurrence of wills between these two undertakings with respect to the commitments embodied in that document. It therefore qualifies as an agreement between undertakings within the meaning of Article 101(1) of the Treaty.

12.2.3. Lundbeck and Merck (GUK) were at least potential competitors in the United Kingdom at the time they concluded their agreement

- (738) For its general legal assessment of potential generic competition for citalopram in the relevant period, the Commission refers to section 9.4 above. In the period leading up to January 24, 2002, when Lundbeck and Merck (GUK) concluded their agreement regarding the United Kingdom, Lundbeck's citalopram was the only citalopram being sold on the United Kingdom market (partly in the form of parallel imports of Lundbeck product from other Contracting Parties of the EEA Agreement). In 2001, Lundbeck's own brand sales in the United Kingdom market had been worth [50-130]* million to Lundbeck.¹²⁸⁵ On 5 January 2002, Lundbeck's patent covering the citalopram compound and the original alkylation and cyanation production processes had expired in the United Kingdom¹²⁸⁶. As of that date the market in the United Kingdom was in principle open for generic citalopram products, as generic citalopram medicine could henceforth be freely sold provided it met regulatory requirements as to quality, safety and efficacy, as confirmed by a marketing authorisation. Generic undertakings with a business plan to sell generic citalopram in the United Kingdom and a realistic prospect to obtain supplies of generic citalopram medicines and an accompanying marketing authorisation in the near future were

¹²⁸⁵

ID 983, page 11.

¹²⁸⁶

See recitals (227) and (258) above.

potential competitors to Lundbeck and to each other.¹²⁸⁷ Generic market entry at that time, in particular by several generic companies simultaneously, would, based on existing experience, in all probability have set off an intense process of price competition that would have reduced prices for citalopram (in any case generic citalopram and possibly also Lundbeck branded citalopram) quickly and steeply.¹²⁸⁸

- (739) At the time of the conclusion of the agreement, Merck (GUK) had a (development and) supply agreement dated 15 May 2001 with Schweizerhall Pharma International GmbH for generic citalopram API produced by Natco. This agreement made Schweizerhall for a period of eight years the preferred API supplier, and Merck (GUK) the "preferred customer" for the United Kingdom (and other Contracting Parties of the EEA Agreement, see recital (828) below).¹²⁸⁹ Merck (GUK) committed to use this API to produce finished dosage forms of citalopram and agreed with Schweizerhall to apply for marketing authorisation in the United Kingdom.¹²⁹⁰
- (740) On 13 December 2001, Merck (GUK) informed Lundbeck about its plan that it "...intend[s] to import citalopram into the UK shortly after 5 January 2002 which is the expiry date of the Supplementary Protection Certificate [...] of Lundbeck's UK patent [...] The citalopram is made using a process disclosed in the aforementioned GB patent."¹²⁹¹
- (741) On 9 January 2002, Merck (GUK) became the first generic supplier to obtain a marketing authorisation for generic citalopram in the United Kingdom.¹²⁹² In the meantime, it had assembled a stock of 8 million citalopram tablets made from Natco API ready for sale in the United Kingdom, with additional bulk material on order,¹²⁹³ and announced prices for Merck (GUK) citalopram tablets to the United Kingdom market.¹²⁹⁴ The announcement of prices in particular suggests that Merck (GUK) was about to enter the United Kingdom market.¹²⁹⁵ Preamble B summarised: "*GUK has also developed a product also containing citalopram...*"¹²⁹⁶ As of July 2002, Merck

¹²⁸⁷ See section 9.4 above.

¹²⁸⁸ See recitals (92), (96), (124), (198) to (199), (211) to (213) and (239) above.

¹²⁸⁹ For other EEA Contracting Parties see recital (828) below.

¹²⁹⁰ See recital (235) above.

¹²⁹¹ See recital (256) above.

¹²⁹² See recital (258) above.

¹²⁹³ See recitals (261) and (267) above. In September 2001, Merck (GUK) had concluded that "*constant supply should not be a problem*" and saw no need to qualify a second source of generic citalopram. See recital (241) above.

¹²⁹⁴ See recital (261) above.

¹²⁹⁵ In reply to the Statement of Objections, Merck KGaA claimed that publishing prices may "rather" be evidence of GUK's intention to build up negotiating power to achieve favourable terms for the envisaged agreement. (ID 5960, page 262) However, the announcement of prices was no isolated event. Instead, it coincided with all other preparatory steps required for entry including in particular the obtaining of a marketing authorisation and the purchase of stocks. These steps combined prepared Merck (GUK)'s entry. Merck (GUK)'s contemporaneous strategy documents (see recital (748) above) suggest that Merck (GUK) may also have wanted to build up negotiating power. However, that evidence certainly does not allow the conclusion that this would have been Merck (GUK)'s only or primary goal (for Merck (GUK)'s entry plans see recitals (243) and (244) above). Moreover, Merck (GUK) did not know whether it would be able to conclude an agreement with Lundbeck, which explained Merck (GUK)'s "*dual strategy*" of preparing for entry while negotiating a deal. It appears that Merck (GUK) was getting ready to enter, unless it could conclude a more favourable deal with Lundbeck (see recital (748) below). For Merck KGaA's argument see further ID 5960, pages 61-62, 64-75 and 80-82.

¹²⁹⁶ See ID 8, page 208.

(GUK) would also have been in a position to license out any of the six marketing authorisations to other generic suppliers in the United Kingdom, which it had obtained for this purpose.¹²⁹⁷

- (742) Following the conclusion of its agreement with Lundbeck on 24 January 2002, Merck (GUK) abstained from the envisaged launch of generic citalopram until the expiry of the first extension of their agreement end of July 2003. However, when at the beginning of August 2003 Merck (GUK) and Lundbeck could (initially) not agree on a higher amount of financial compensation to be paid to Merck (GUK) for the second extension of their market exclusion agreement, Merck (GUK) simply launched its generic citalopram: *"Between August 1st and 4th, MGUK sold generic citalopram corresponding to £3.3M sales into the market"*.¹²⁹⁸ On 6 August 2003, the moment Merck (GUK) agreed with Lundbeck on the second extension of their United Kingdom agreement,¹²⁹⁹ Merck (GUK) again withdrew from the market.
- (743) The Commission concludes that these facts evidence that Merck (GUK) had concrete realistic possibilities of market entry in the United Kingdom (and of licensing out six marketing authorisations as of July 2002 to further generic entrants). In fact, Merck (GUK) actually entered the market in August 2003 during five days. Merck (GUK) and Lundbeck were therefore at least potential competitors at the time they concluded their agreement in January 2002, and actual competitors in August 2003 before agreeing on the second extension of their United Kingdom agreement. Indeed, the very fact that Lundbeck agreed to transfer considerable value to Merck (GUK) if it accepted not to enter the United Kingdom market with generic citalopram for the term of the agreement shows that Lundbeck considered that Merck (GUK)'s market entry in the United Kingdom was plausible and that Lundbeck perceived Merck (GUK) as a competitive threat to its position in that market.

12.2.4. The possibility of infringement of Lundbeck's process patents did not prevent Merck (GUK) from being at least a potential competitor to Lundbeck

Introduction

- (744) This section responds to the arguments raised by Lundbeck¹³⁰⁰, Merck KGaA¹³⁰¹ and GUK¹³⁰² claiming that there could be no potential competition between Lundbeck and Merck (GUK) when they concluded their agreement because both parties considered at that time that Natco citalopram, on which Merck (GUK)'s generic citalopram tablets were based, may have infringed Lundbeck's crystallisation patent.¹³⁰³ This section will show that at the time of the conclusion of the agreement in January 2002 and the two extensions in January 2003 and August 2003, despite

¹²⁹⁷ See recital (279) above. In February 2003, Merck (GUK) postponed concluding a supply contract with Ivax for the United Kingdom, which shows that other generic companies envisaged selling Natco citalopram in the United Kingdom as well. See recitals (291) and (306).

¹²⁹⁸ See recital (300), and also recital (299) above.

¹²⁹⁹ See recital (301) above.

¹³⁰⁰ ID 5394, pages 13, 117-139; see also pages 148-156. In its reply to the Statement of Objections, Lundbeck went so far to claim that *"GUK's products were based on API supplied by Natco, whose process violated the Crystallization Patent"*. See in this respect also section 11.2 above.

¹³⁰¹ In particular ID 5960, pages 112-159, 193-246, and 247-265. See also pages 282-307.

¹³⁰² ID 6026, pages 9-70. Regarding the legal standard of potential competition, see also recital (630) above, and more generally section 9.4.

¹³⁰³ Merck (GUK) considered also another of Lundbeck's patents problematic, see recital (248) above.

Merck (GUK)'s concerns over Lundbeck's process patents, Merck (GUK) had real concrete possibilities of entering the United Kingdom market immediately or in the near future. In particular, evidence shows that the parties thought that a court might not have found Lundbeck's patents valid and infringed.

- (745) It was already explained in recital (738) above that Lundbeck's citalopram compound patent including its two original production processes had expired resulting in Lundbeck's loss of the complete blocking power. However, Lundbeck did, of course, still have a number of more recent process patents, which gave Lundbeck exclusivity rights on certain (but not all) new ways of producing citalopram that met regulatory requirements in the EEA, including, after 30 January 2002, the patent on purification of citalopram through crystallisation of the free base. Lundbeck could therefore always argue before the United Kingdom courts that one or more of its more recent process patents had been infringed. However, Lundbeck itself stated to the Commission that production of citalopram was in principle possible without infringing any of Lundbeck's remaining process patents, including the crystallisation patent: *"...generic entrants could have produced citalopram by using the process described in Lundbeck's original compound patent filed in 1977, albeit with a different and potentially less efficient method of purification, or they could have invested to invent an entirely new process."*¹³⁰⁴ Moreover, the burden of proving infringement rested in principle on Lundbeck.¹³⁰⁵ According to Lundbeck, in practice, proof of infringement of a process patent is *"very difficult"*.¹³⁰⁶ The risks of patent litigation for Lundbeck are illustrated by the Lagap litigation, where Lundbeck had to admit on 14 February 2003 that the inspected process was non-infringing, even though Lundbeck had previously demonstrated a *"firm and unshakeable confidence that it was impossible [...] to be operating a non-infringing process..."*¹³⁰⁷ In the same proceedings, Lundbeck considered that it was also (before it settled) likely to be unsuccessful in proving to the satisfaction of the United Kingdom judge that Matrix had in reality used an infringing crystallisation process for its exports to the EEA.¹³⁰⁸ In addition, Lundbeck believed at the time of concluding the agreements that it was difficult to obtain an interim injunction in the United Kingdom and that United Kingdom courts were *"not in general pro-patentee"*.¹³⁰⁹ Finally, generic defendants could always argue that the process patent Lundbeck invoked was invalid, for instance because the claimed invention was obvious to a person skilled in the art or because it was covered by prior art.¹³¹⁰ In the Lagap litigation, for instance, Lagap counter-claimed invalidity of Lundbeck's crystallisation patent. Faced with this claim, Lundbeck itself considered that there was a 60% chance that the United Kingdom judge would hold Lundbeck's crystallisation patent invalid.¹³¹¹
- (746) These factors together meant that any generic undertaking with a contract for the supply of generic citalopram and the prospect of receiving soon a marketing

¹³⁰⁴ See recital (150) above.

¹³⁰⁵ See recital (78) above.

¹³⁰⁶ See recital (79) above.

¹³⁰⁷ See recital (155) above.

¹³⁰⁸ See recitals (152) to (162) above.

¹³⁰⁹ See recital (195) above.

¹³¹⁰ See recital (76) above.

¹³¹¹ See recital (157) and more generally section 6.3 above.

authorisation to sell generic citalopram in the United Kingdom was now free to seek entry into the United Kingdom market with generic citalopram.¹³¹² If the API producer of this generic supplier used one of the two original Lundbeck processes to produce citalopram, this could no longer be attacked by Lundbeck because this patent had lapsed. Lundbeck could still claim before the court that the API producer in question had used Lundbeck's patented crystallisation purification process to reduce impurities below regulatory limits, or any other process patent, but whether this would in fact turn out to be the case upon inspection and whether Lundbeck would be able to prove this to the satisfaction of the judge remained uncertain.¹³¹³ There was also a serious risk for Lundbeck that if the generic defender counter-claimed invalidity of the crystallisation patent (or any other process patent Lundbeck invoked), the judge might find such patent invalid. There was therefore no certainty at all for Lundbeck that infringement litigation would be able to prevent generic citalopram from being sold in the United Kingdom and generic suppliers using API based on the original, expired processes had a realistic prospect of being able to enter the United Kingdom market without infringing any patents or by invalidating any such patents. In addition, generic competition for entry could have opened other paths of non-infringing entry: where it transpired from litigation that the specific API subject to litigation may be infringing,¹³¹⁴ any API producer could at any time amend its citalopram production process to a different one that was potentially non-infringing and file for a variation in the marketing authorisation. Also, generic suppliers could potentially switch API producer and license in a marketing authorisation.¹³¹⁵ This could have arguably been possible even where a generic company had an exclusive supply contract with a given API producer, if that API was considered infringing, because of the possibility to terminate contracts in case a product does not have required qualities. It was perhaps for these reasons that in December 2000, Lundbeck had stated in its "Goal, Activity and Budget Plan 2002":

*"The UK is the market that Lundbeck expects to be hit most severely by generic competition. Immediately following patent expiry in January 2002, generic sales are expected to take 60% of the citalopram business."*¹³¹⁶

Contemporaneous evidence on the patent situation and Merck (GUK)'s market entry

- (747) With respect to Merck (GUK) specifically, the production process of its API producer, the Indian generic manufacturer Natco, was based in Merck (GUK)'s assessment on the original process of Lundbeck for which patent protection had expired.¹³¹⁷ Lundbeck's offer to Natco in February 2001 to purchase Natco's citalopram API or intermediates had been rejected; supply by Natco was "*not a problem*".¹³¹⁸

¹³¹² Regarding "clearing the way" see recitals (757) to (760) below.

¹³¹³ See recital (745) above.

¹³¹⁴ See also recital (627) above.

¹³¹⁵ For a different Member State with respect to citalopram, Merck dura internally explained to Merck (GUK): "*In the meantime we had several legal proceedings against Lundbeck concerning patent issues. By clever changing the raw material sources we could successfully keep our product in the market.*" See recital (351) above. This shows that Lundbeck may well have failed with attempts to exclude generic citalopram from EEA markets.

¹³¹⁶ See recital (195) above.

¹³¹⁷ See recitals (227) and (256) above.

¹³¹⁸ See recitals (230) to (233) above and footnote 1295.

- (748) The facts as described in section 7.2 show that on 11 January 2001, Lundbeck sent Merck (GUK), just like many other generic suppliers and API producers, a letter warning of potential patent infringement, annexing a long list of process patents, including the crystallisation utility model as already granted in the Netherlands, as well as a number of pending process patent applications.¹³¹⁹ In fact, in a meeting on 13 September 2001, more than two months after the crystallisation patent application had been published in the United Kingdom¹³²⁰, Lundbeck threatened Merck (GUK) not to enter: "...you must be patent infringing, we will sue you to hell..." to which Merck (GUK) replied "good luck [...] ...this does not affect us launching".¹³²¹ At that time, despite publication of Lundbeck's crystallisation patent in the United Kingdom, Merck (GUK) concluded: "Raw material Natco (Indian). This is non-infringing."¹³²² Two weeks after the meeting with Lundbeck, on 28 September 2001, Merck (GUK) considered that it had two options: In the first scenario, "current plans", meaning launch in the United Kingdom of Natco's citalopram products, Merck (GUK) would earn profits of "...£9m[illion]" in year 1 from its own generic citalopram sales of "1m packs at profit £9/pack". In the second scenario, "Plan 2", Merck (GUK) would be supplied by Lundbeck¹³²³ with the goal "...to achieve the same profit figure" (or, in other words, conclude a deal "provided the numbers stack up").¹³²⁴ However, considering both its doubts and its confidence regarding potential patent issues, Merck (GUK) did not even contemplate staying out of the market in view of possible patent infringement absent a deal with Lundbeck.
- (749) Merck's intentions to enter in the absence of an agreement with Lundbeck were confirmed by the fact that at least since 12 October 2001 Merck (GUK) had been preparing for infringement action by Lundbeck: "...it is now time to move forward in readiness for the legal action from Lundbeck. This will vary in some markets from having documentation ready for when they try to injunct us, through the use of protective writs. There is the potential to prepare for UK, Sweden, France and Germany. In order to do this we need to provide certain documentation to our lawyers which they will ask us from time to time."¹³²⁵ On 23 October 2001, the United Kingdom High Court of Justice rendered its judgment in the Paroxetine case, which Merck (GUK) lost.¹³²⁶ In reply to the Statement of Objections, Merck KGaA argued that "launch at risk suddenly turned out to be an insurmountable issue".¹³²⁷

¹³¹⁹ See recital (225) above. See also recital (267) and footnotes 545 and 546 above.

¹³²⁰ See recital (113) above.

¹³²¹ See recital (240) above.

¹³²² See recital (237) above.

¹³²³ "Met twice with Lundbeck in the UK to achieve a deal", see recital (244) above.

¹³²⁴ See recitals (243) and (255) above. This evidence combined with Merck (GUK)'s refusal of Lundbeck's offer for an extension of their agreement in August 2003 directly followed by generic launch (see recital (755) below) shows that Merck (GUK)'s decision not to seek entry was directly related to the payments agreed in the agreement with Lundbeck, contrary to what Merck KGaA argued in reply to the Statement of Objections. See ID 5960, page 281, and ID 6633, page 41 (slide 81). The causal link further followed from the agreement itself, see recital (787) below.

¹³²⁵ See recital (245) above.

¹³²⁶ See footnote 312 above.

¹³²⁷ ID 5960, page 74. Similarly, in its reply, GUK argued that that judgment "... fundamentally altered the legal framework against which GUK made its risk assessment..." In particular, "GUK was required to provide sufficient evidence that it did not infringe any of Lundbeck's process patents." See ID 6026, pages 20-21 and 57-58. Note, however, that with respect to the burden of proof in United Kingdom

However, only a day after that ruling, on 24 October 2001 Merck (GUK) stated: "*we intend to attack [Lundbeck] by all possible means*".¹³²⁸ On 12 November 2001, Merck (GUK) further observed: "*the process we are using expires in Jan*" and "*actions to pre-empt any injunction were agreed to be worthwhile*".¹³²⁹ As an injunction is only possible when infringement is "*imminent*"¹³³⁰, Merck (GUK)'s preparation for possible injunctions necessarily anticipated the possibility of actual market entry and shows its intention to defend its product against patent claims by Lundbeck.

- (750) On 15 November 2001, Lundbeck had Natco's citalopram seized in Hamburg claiming potential infringement of two patents and analysed it.¹³³¹ On the same day, a Merck (GUK) patent expert commented: "*In relation to these patents, Tiefenbacher's conclusions are the same as mine in that none of the published patent applications disclosed in the letter constitute a problem*".¹³³² These were the patents and patent applications annexed to Lundbeck's letter of 11 January 2001, including the crystallisation patent, which Lundbeck alleged Natco infringed.¹³³³ The above facts demonstrate that Lundbeck perceived Merck (GUK) as a competitive threat.¹³³⁴ On 16 November 2001, Merck (GUK) observed "*...we now know what patents they may come at us with initially. Therefore we should discuss how to best avoid an injunction in the UK*".¹³³⁵ On 29 November 2001, that is to say after just two weeks, Merck (GUK) obtained release of the seized citalopram, thus well in advance of GUK's planned launch in the United Kingdom.¹³³⁶ The seizure could therefore not block Merck (GUK)'s generic market entry.
- (751) By January 2002, as already explained in recital (741) above, despite Lundbeck's threats of legal action for patent infringement, Merck (GUK) had assembled a stock of 8 million citalopram tablets made from Natco API ready for sale in the United Kingdom and announced prices for its citalopram tablets to the United Kingdom market. On 9 January 2002, Merck (GUK) obtained the marketing authorisation for generic citalopram in the United Kingdom. The announcement of prices in particular suggests that Merck (GUK) was about to enter the United Kingdom market. One day later, Lundbeck and Merck (GUK) met at Lundbeck's headquarters for intense negotiations.¹³³⁷

patent litigation, the judgment in the Paroxetine case instructed generic companies how to avoid a shift in the burden of proof. See also footnote 593.

1328

See recital (246) above.

1329

See recital (246) above. See also recitals (152)-(159), (249) and (323) above.

1330

See recital (75) above.

1331

See recitals (247) and (249) above.

1332

See recital (248) above.

1333

On 19 November 2001, Merck (GUK) identified a new patent application, WO 01/68632A1, that in its view Natco was *prima facie* infringing, which, however, it considered clearly lacked novelty. See recital (248) above.

1334

See recitals (748) to (750), and recital (613) above.

1335

See recital (249) above.

1336

See recital (252) above. Although also future shipment would be under the risk of being seized, the watch notice was therefore not able to undermine "*the whole generic launch strategy of GUK*", as argued by Merck KGaA in its reply. (emphasis added) See ID 5960, pages 27, 75-79 and 241-246. Similar, GUK's reply to the Statement of Objections, ID 6026, pages 63-64.

1337

See recital (262) above.

- (752) As concerns the question of whether a judge would have found that Lundbeck's patents were valid and infringed,¹³³⁸ in reply to the Statement of Objections, GUK claimed that the Commission "ignored" or "disregarded" evidence that Merck (GUK) was worried about possible patent infringement and that evidence, on which the Commission had relied, dated from before Lundbeck's crystallisation patent.¹³³⁹ In its reply, Merck KGaA alleged, without submitting further evidence, that "*there was a particularly high likelihood that the Natco process infringed the crystallisation patent*" given that prior art resulted in a citalopram base in the form of an oil, which needed to be processed.¹³⁴⁰
- (753) With respect to the issue of potential patent infringement, the Commission notes firstly that on 27 November 2001 Merck (GUK)'s lawyer requested from Lundbeck to clarify "*which [patent(s)], if any, you consider our clients may infringe.*"¹³⁴¹ After a meeting on 11 December 2001, Merck (GUK) observed: "*Lundbeck have sampled our active and their only comment was that it is of poor quality and they may have to take this 'up with the MCA' [the United Kingdom Medicines Control Agency] when we launch.*"¹³⁴² Two days later, while communicating the intended launch date to Lundbeck, Merck (GUK)'s lawyer reminded: "*we assume that you do not consider it infringes any patents. However, if this is not correct, please let us know which patents you say are relevant as we asked you on 27 November.*"¹³⁴³ Lundbeck never replied to Merck (GUK) by specifying which patent(s), if any, it considered infringed; internally, Lundbeck stated: "*...we are not sure that they purify by crystallisation of the free base.*"¹³⁴⁴ The United Kingdom agreement itself did not specify any specific patent(s) Lundbeck believed Merck (GUK) would infringe.¹³⁴⁵
- (754) Secondly, the Commission considers that the body of evidence shows that Merck (GUK) assessed its patent and supply situation at various points in time both before and after publication (and grant) of Lundbeck's crystallisation patent (the United Kingdom version of which was published on 4 July 2001¹³⁴⁶) as well as in the periods when it concluded with Lundbeck the agreement related to the United Kingdom in January 2002, and its two extensions in January and August 2003 (and the agreement related to the rest of the EEA in October 2002). It is clear that the full context of the evidence summarised below in this recital as well as certain other documents show that Merck (GUK) expressed certain doubts with respect to whether Natco may be patent infringing.¹³⁴⁷ However, in balance the Commission concludes

¹³³⁸ See recital (744) above.

¹³³⁹ See, for example, ID 6026, pages 5, 7, 33, 38-39, 45, 50, 64-70 and ID 6639.

¹³⁴⁰ See ID 6639, pages 13, 14, 20 and 21; and ID 5960, page 213. For this latter point, see the evidence quoted in recital (754) below (in particular related to recitals (248), (304) and (357)).

¹³⁴¹ ID 8, page 363. See recitals (249), (256) and footnote 593.

¹³⁴² See recital (255) above.

¹³⁴³ See recitals (251), (256) and (740) above.

¹³⁴⁴ See recital (260) above.

¹³⁴⁵ See recital (267) above.

¹³⁴⁶ See recital (113) above.

¹³⁴⁷ All parties argued at least uncertainty in this respect (see, for instance, GUK's arguments in its reply to the Statement of Objections, ID 6026, pages 31-50) pointing namely to the following evidence: Lundbeck's warning letter of 11 January 2001 (see recital (225) above); however, having studied that letter Merck (GUK) concluded that Natco's process "*does not infringe any of Lundbeck's later process patents that we are aware of*". See recital (228) above. Regarding Lundbeck's threats towards Natco on 22 February 2001 to have patented many citalopram processes (see recital (231) above), see Merck (GUK)'s observation on this meeting: "*Lundbeck left [Natco] after 45 minutes not knowing anything*

that Merck (GUK)'s assessments show considerable confidence in its patent position and confirm that Merck (GUK) believed that it was far from certain whether a judge would have found Lundbeck's patents to be valid and infringed (highlighting added):¹³⁴⁸ *"Raw material Natco (Indian). This is non-infringing."* (5 September 2001¹³⁴⁹); (responding to Lundbeck's threat *"to sue you [Merck (GUK)] to hell"*) *"good luck we said...this does not affect us launching"* (13 September 2001¹³⁵⁰); *"the patent on the compound and the process we are using expires in Jan"* (12 November 2001¹³⁵¹); *"none of the published patent applications disclosed in the letter constitute a problem"* (15 November 2001¹³⁵²; this was Merck (GUK)'s reaction to the seizure, see further recital (750) above); regarding patent WO 01/68632A1, Merck (GUK) concluded at the time that this patent application clearly lacked novelty and should therefore normally not be granted: *"The published search report in fact cites the basic compound patent [...] as a novelty destroying document."* (15 November 2001¹³⁵³); Lundbeck's *"patent is considered to be weak"* (25 February 2002¹³⁵⁴); *"Our patent position is strong"* (6 June 2002¹³⁵⁵); *"we do not have a patent problem at all"* as witnessed *"by expert statements"* (19 June 2002¹³⁵⁶); *"It is there [sic] contention that this material shows evidence through the impurity profile that it infringes one of their process patents. This is not the case as*

about Natco where they are and the quality of their material" (see recital (233) above) and the evidence quoted in recital (754) (in particular related to recital (248) above). Lundbeck's threats of litigation (see recitals (240) and (326) above) do not appear to have impressed Merck (GUK), as explained in recitals (748), (751), (755), (761), (837), (838) and (840). As concerns Merck (GUK)'s analysis regarding Sweden that "[t]here is [...] a high risk (75%) that they will sue us on the grounds of process or quality or both.", Merck (GUK)'s conclusion is telling: *"If we are sued we perceive there will be a low risk (15%) of being enjoined based on the fact that we clearly follow the synthetic process as disclosed in the basic patent. If we are enjoined we believe we have a high potential of winning (90%)."* See recital (316) above. See further the analysis in recitals (748)-(749) above. The fact that Natco's production process was not entirely identical to the one disclosed in Lundbeck's expiring patents (see recital (228) above) does not mean that Merck (GUK) was infringing, see footnote 458 above; see further the evidence quoted below, in particular related to recitals (248) and (304). As concerns Merck (GUK)'s concerns of March 2002 of *"additional recrystallization"* (see recitals (282)-(283) above), see the evidence quoted below after March 2002, and in particular the one related to recitals (304) and (357). Regarding the statement *"we are fearful that we may not prevail in the courts"* (see recital (331) above), it has to be read in the context of the entire document, because that document mainly discussed options how to explain a deal with Lundbeck to Natco and whether to look after Natco: *"...bear in mind that there are two ways to look at this..."* For the same reasons, the soothing letters that Merck (GUK) exchanged with Natco and NM Pharma have a more limited evidentiary value, when compared to internal patent assessments (not made in such a context). In fact, these letters were carefully drafted to explain Merck (GUK)'s market withdrawal without mentioning any of the payments it was receiving from Lundbeck (the letters and related correspondence is summarised in section 7.3.3 above). Regarding the email exchange of September/October 2003 (see recital (304) above), it is the conclusion that matters (if at all, considering that the exchange took place shortly before the expiry of the agreements); the conclusion is summarised below.

¹³⁴⁸ For the full context see the relevant sections 7.2 and 7.3 above.

¹³⁴⁹ See recital (237) above.

¹³⁵⁰ See recital (240) above. Already on 2 March 2001, Merck (GUK) observed: "... [Natco's] **material** [...] **is excellent** and good enough to get us through registration. If Lundbeck really knew we could be facing a Lundbeck buy-out of Natco." See recital (233) above.

¹³⁵¹ See recital (246) above.

¹³⁵² See recital (248) above.

¹³⁵³ See recital (248) above. See also footnote 508 above.

¹³⁵⁴ See recital (280) above.

¹³⁵⁵ See recital (329) above.

¹³⁵⁶ See recital (334) above.

we know, but they don't, that the material is in fact produced by a route contained in patent that has now expired [...] We are 100% confident that our evidence will show that we do not infringe any of their IP [intellectual property] on this product." (23 October 2002¹³⁵⁷); *"we still don't infringe...including the crystalline base patent."* (24 October 2002¹³⁵⁸); *"we had an excellent case and [...] we shouldn't get enjoined if Lundbeck sued if we launched in Jan"* (20 December 2002¹³⁵⁹); *"we were confident that the patents [of Lundbeck] would be overturned"* (9 February 2003¹³⁶⁰); *"From the samples received by Lundbeck and the data they have on our process, they have not questioned our ability to produce the product by a lapsed basic process and they have not questioned the quality of the product they have tested."* (18 July 2003¹³⁶¹). Shortly after the second extension of the United Kingdom agreement, Merck (GUK) observed: *"We launched in UK recently at expiry of the UK agreement, we were not sued. (Others have been though)."* (29 September 2003¹³⁶²); *"All the claims in this patent require the precipitation [sic] of crystalline citalopram free base. As the Natco process [process description]*, there can be no infringement of the claims regardless of what impurities are removed."* (29 September 2003¹³⁶³). It should be noted that some statements relate to the United Kingdom, while others relate to other EEA countries. However, all statements are relevant, because Lundbeck held identical or similar patents and patent applications in all, or most, EEA jurisdictions, and all quotes relate to Natco citalopram. Because GUK believed, and other evidence confirms,¹³⁶⁴ that there was a realistic chance that a court may have confirmed Merck (GUK)'s contemporaneous view, these assessments evidence real concrete possibilities that Lundbeck could have not prevented Merck (GUK)'s generic entry. Overall, in the Commission's view, the views of Merck (GUK) at the time of conclusion of the agreement with Lundbeck on 24 January 2002 regarding the risk of patent infringement may have been best summarised by the preamble to the agreement itself: *"GUK does not accept that its product is infringing but recognises that there is an inevitable degree of risk in patent litigation plus delays and inconvenience and has agreed not to launch the Products subject to payment in accordance with the terms of this Agreement."*¹³⁶⁵ Importantly, the agreement did not specify any specific patents Lundbeck believed to be infringed.¹³⁶⁶ Later, on 6 June 2002, Merck (GUK) internally wrote: *"Our patent position is strong and Lundbeck have so far not responded in the UK to our letters etc. This must bode well and make it extremely difficult for any future attempts by Lundbeck to get an injunction in UK."*¹³⁶⁷ The Commission notes that Lundbeck, in

¹³⁵⁷ See recital (355) above.

¹³⁵⁸ See recital (357) above.

¹³⁵⁹ See recital (288) above.

¹³⁶⁰ See recital (292) above.

¹³⁶¹ See recital (364) above.

¹³⁶² See recitals (303) and (304) above.

¹³⁶³ See recital (304) above.

¹³⁶⁴ See in particular recitals (745) and (746) above.

¹³⁶⁵ See also footnote 1317 above.

¹³⁶⁶ See recital (267) above.

¹³⁶⁷ See recital (330) above. In its reply, Merck KGaA claimed that this quote is out of context. It argued that the language reflected only Merck (GUK)'s strategy to use *"time out"* under the United Kingdom agreement and of *"clear[ing] the way"* instead of reflecting any belief regarding a possible infringement. See ID 5960, pages 263-264. However, the word *"and"* suggests that on the one hand the e-mail expressed a view about the strength of the *"patent position"* and on the other hand about the fact

turn, at the time of the conclusion of the agreement with Merck (GUK) had carried out several analyses of Natco's citalopram, which showed that Natco may be infringing, but was not really sure which precise process Natco was using.¹³⁶⁸ Furthermore, regarding any potential infringement of its crystallisation patent, the Commission refers to recitals (745) and (746) above.

- (755) Beginning of August 2003, when Merck (GUK) became an actual competitor through the launch of generic citalopram, it became clear that alleged patent issues may not have been able to block Merck (GUK)'s market entry with Natco citalopram. As already explained in recital (748), Merck (GUK) had considered in its September 2001 analysis of options either to earn "*in year 1*" "*...£9m*" through its own generic entry (option 1) or through a deal with Lundbeck (option 2). In August 2003, Merck (GUK) was no longer able "*...to achieve the same profit figure*" it planned to achieve through generic entry. Merck (GUK) considered Lundbeck's "*final offer* [for an extension] *wasn't good enough!!*"¹³⁶⁹, and, in fact, "*...the numbers*" no longer "*stack[ed] up*".¹³⁷⁰ By consequence, in August 2003, irrespective of any alleged patent issues and without being sued¹³⁷¹, Merck (GUK) switched to option 1 by launching generic citalopram: "*Between August 1st and 4th, MGUK sold generic citalopram corresponding to £3.3M sales into the market*".¹³⁷² When Lundbeck on 5 August 2003 tripled its initial offer of 16 July 2003 for an extension of their agreement, Merck (GUK) returned to option 2 prolonging the agreement with Lundbeck and exiting the market.
- (756) Lundbeck terminated the agreement as of 1 November 2003. Immediately, as already explained, Merck (GUK) started offering other companies active in the United Kingdom, including Ivax Pharmaceuticals United Kingdom, supply contracts for Natco citalopram for delivery as of 1 November 2003.¹³⁷³ Moreover, on 1 November 2003 Merck (GUK) re-started selling Natco citalopram in the United Kingdom.¹³⁷⁴ At this time, the crystallisation process patent and other process patents were still in force. In view of the fact that Lundbeck never started any infringement proceedings against Merck (GUK), the Commission considers that it is far from clear whether any of Lundbeck's patents could have blocked Merck (GUK)'s entry before, as already explained, because the patent on the citalopram compound and the two original processes had already expired.

Arguments of the parties

- (757) In reply to the Statement of Objections, Lundbeck, Merck KGaA and GUK argued that Merck (GUK) viewed the agreement related to the United Kingdom (and to the

that "*Lundbeck [...] have not responded*", which combined would make it "*extremely difficult*" for Lundbeck to obtain an injunction in the future. This shows that the e-mail did express an opinion about Merck (GUK)'s patent position as such. Moreover, this quote should be read in the context summarised in footnote 1317.

¹³⁶⁸ An overview of Lundbeck's product analyses is contained in ID 5394, pages 13, 117-139; see also pages 148-156. Regarding Lundbeck's limited understanding of Natco's process see footnote 467 and the references there.

¹³⁶⁹ See recital (299) above.

¹³⁷⁰ See recital (255) above.

¹³⁷¹ See recital (754), and in particular the evidence related to 29 September 2003.

¹³⁷² See recital (300), and also recital (299) above.

¹³⁷³ See recital (306) above.

¹³⁷⁴ See recital (309) above. Entry in August 2003 is explained in recital (755) above.

rest of the EEA) as a means to 'clear the way', for which Merck (GUK) needed time.¹³⁷⁵ Merck KGaA claimed that it could not have successfully entered the United Kingdom market with Natco API without having "cleared the way". It would have been "*excluded from the market for even more than 12 months as a result of an interim injunction*"; furthermore, it would have certainly faced litigation.¹³⁷⁶ The correct counterfactual would have therefore shown that Merck (GUK) was not a potential competitor.¹³⁷⁷ Similarly, in GUK's view "[p]roceedings concerning a declaration of non-infringement" would have delayed generic entry possibly longer than the agreement. Thus, there was only a "*mere theoretical possibility for GUK to enter*".¹³⁷⁸

- (758) The Commission considers firstly, as concerns Merck (GUK)'s alleged objective of "clearing the way", if Merck (GUK) had really intended to 'clear the way' before launching Natco citalopram on the United Kingdom market, nothing would have prevented it from doing so immediately in January 2002, or in fact already before, without concluding an agreement with Lundbeck causing it a delay of 20 months. In fact, to start immediately with one or another form of clearing the way proceeding is precisely, what the United Kingdom High Court of Justice Chancery Division asked generic companies to do in the Paroxetine case: "*The defendants could, so soon as they settled upon the product they were intending to sell, have caused the litigation to start*" by saying to the patentee: "*If you intend to sue us, sue us now.*"¹³⁷⁹ Secondly, Merck KGaA's and GUK's allegation that simply because of an obligation to clear the way Merck (GUK) could not have entered the United Kingdom market anyway for the duration of the agreement cannot be accepted.¹³⁸⁰ The Commission recalls that Lagap inspected in September 2002 in merely four days the production process of its API supplier (Matrix), notified Lundbeck of the results on 9 October 2002 and entered the United Kingdom market on 11 October 2002.¹³⁸¹ The judge therefore did not accept Lundbeck's request for an interim injunction, and Lagap continued selling generic citalopram during the litigation and thereafter.¹³⁸² The fact of almost immediate entry by Lagap shows that a delay of "*possibly longer than two years in case of appeal*", as GUK argued¹³⁸³, cannot be assumed. Moreover, Niche successfully cleared the way on 28 July 2003, requiring just three and a half months.¹³⁸⁴ If Merck (GUK) had started clearing the way in January 2002 with Natco, it could have possibly entered the United Kingdom market in February 2002 at the latest and have raised the issue of non-infringement and invalidity of

¹³⁷⁵ See ID 5394, pages 19, 134-139 and 150-153; ID 5960, pages 100-111, 290-291 and 307-311. ID 6026, pages 26-28 and 45-46 (see also page 96, where GUK fails to consider delay). The parties referred in this respect mainly to the documents quoted in recitals (284), (290) and (293). The parties further argued that the United Kingdom agreement in particular was linked to the Lagap litigation, after which widespread generic entry became possible; that argument is rebutted in recitals (682)-(689). See further footnote 1496.

¹³⁷⁶ See ID 5960, pages 257-260, 264, 268 and 270-271. In its reply, Merck KGaA pointed further in particular to Lundbeck's threat, which was discussed in recital (748) above.

¹³⁷⁷ ID 5960, pages 29 and 254-260.

¹³⁷⁸ See ID 6026, pages 24-25, 89, 94 and 95.

¹³⁷⁹ Highlighting added; see footnote 312 above.

¹³⁸⁰ See recitals (152) and (163) above.

¹³⁸¹ See recital (152) above.

¹³⁸² See recitals (152) to (154) above and footnote 312.

¹³⁸³ See ID 6026, page 24.

¹³⁸⁴ See recital (163) above.

Lundbeck's crystallisation patent before the United Kingdom court eight months before Lagap did. Also, it was only on 27 November 2001 that Merck (GUK)'s lawyers after ten months first reacted to Lundbeck's patent infringement warning letter of 11 January 2001, asking Lundbeck to indicate which specific patents Lundbeck considered Merck (GUK) infringed.¹³⁸⁵ This correspondence with Lundbeck never led to any 'clearing of the undergrowth'.¹³⁸⁶ Moreover, Merck (GUK) was aware at the time of concluding the agreement that the agreement was not suitable to resolve a dispute or potential litigation; it considered that in case Lundbeck's crystallisation patent would not get overturned in the Lagap trial, it might be forced to litigate later.¹³⁸⁷

- (759) Thirdly, Merck KGaA's argument that "[t]he legal and economic context indicates [...] *certainty of being injuncted*" cannot be accepted, because the possibility of being injuncted is clearly not the same as "*certainty of being injuncted*". For instance, Lagap entered the United Kingdom market without being injuncted, which shows that also Merck (GUK) had a realistic chance of avoiding an injunction.¹³⁸⁸ In any case, as early as April 2002 Merck (GUK) held in its hands "*a signed expert report [...] about our process. The conclusion is that it is not infringing.*"¹³⁸⁹ In June 2002, GUK again concluded "*we do not have a patent problem at all... We even have expert statements available about our process.*"¹³⁹⁰ These or additional "expert statements", which Merck (GUK) could have commissioned, could have allowed also Merck (GUK) to enter without delay. Merck (GUK)'s conviction of not infringing or of invalidity of Lundbeck's patents ("weakness") may have convinced a judge and represented a realistic prospect that Merck (GUK) could avoid an injunction and would prevail in a possible litigation.
- (760) Finally, when claiming that there was a "*mere theoretical possibility for GUK to enter*", GUK entirely failed to consider that Merck (GUK) actually launched successfully in August 2003 in the United Kingdom.¹³⁹¹ It is therefore simply incorrect, as GUK did, to claim that "[t]he SO simply assumes that absent the Settlement Agreements GUK would have made the decision to launch at risk..." and that "[t]he SO does not present any evidence for this assumption."¹³⁹² In any case, the Commission considers that with respect to the potential competition which the commitment by Merck (GUK) not to launch citalopram products with Natco API eliminated, the Commission is not required to demonstrate that absent the agreement entry would have certainly happened at a specific point in time. Instead it is sufficient to demonstrate that the limitations on Merck (GUK)'s commercial autonomy eliminated competition in form of the realistic prospect of entry in the United Kingdom market with citalopram products based on Natco API, which could

¹³⁸⁵ See recitals (251) and (256) above.

¹³⁸⁶ See also recital (367) above.

¹³⁸⁷ See recital (288) above and, for the Agreement related to the rest of the EEA, recital (354) above. Closely linked is Merck KGaA's argument about interim injunctions, see footnote 1410. The issue of delay and lack of resolution of the dispute applies also to the agreement related to the rest of the EEA, see footnote 680 above.

¹³⁸⁸ See recital (154) above.

¹³⁸⁹ See recital (323) and footnote 636 above.

¹³⁹⁰ See recital (334) above.

¹³⁹¹ See recitals (755) to (756) above. Through NM Pharma, it also launched in Sweden, see recital (837) below.

¹³⁹² For the rest of the EEA see recitals (837) and (838).

have also involved competition against Lundbeck's patent position. As already explained, in the present case this question appears to be of a rather theoretical nature, because Merck (GUK) did actually enter in August 2003 before the second prolongation of the agreement.¹³⁹³

Conclusion

- (761) In sum, the facts analysed in this section indicate that had it not been for Lundbeck's agreement with Merck (GUK) on 24 January 2002, there would have been a real concrete and realistic possibility that Merck (GUK) would have tried to enter the United Kingdom market with Natco citalopram in the near future, possibly still within the same month of January 2002 and, if necessary, successfully "cleared the way". Evidence shows that Merck (GUK) also believed to have at the time a real concrete and realistic chance to successfully defend itself against a claim of patent infringement, if any, including by challenging the validity of Lundbeck's crystallisation patent. If successful, this would have broken Lundbeck's factual monopoly on sales of citalopram in that market. Had Merck (GUK) really considered that Natco would have been infringing any of Lundbeck's remaining process patents, it could have "...clever[ly] change[d] the raw material sources"¹³⁹⁴ either by working together with Natco to amend the citalopram production process to a non-infringing one or by purchasing API (and the license) from other API manufacturers¹³⁹⁵. Merck (GUK)'s profit estimate of "£9m" for "year 1" in case of entry with generic citalopram shows that Merck (GUK) considered entry at the time an economically viable strategy. As of July 2002, as explained in recital (741), Merck (GUK) would also have been in a position to license out any of its six United Kingdom marketing authorisations to other generic suppliers including to Ivax in February 2003. "*Between August 1st and 4th, MGUK sold generic citalopram corresponding to £3.3M sales into the market*"¹³⁹⁶. All these factors were conducive to the success of Merck (GUK)'s market entry.
- (762) This successful launch, not hindered by any legal action of Lundbeck,¹³⁹⁷ vividly demonstrates that the possibility of launch was not purely theoretical but a plausible assumption; Merck (GUK) was a serious potential competitor also before that entry, irrespective of potential patent issues, which did not block Merck (GUK)'s market entry in August 2003. The Commission therefore concludes that Lundbeck's process patents did not prevent Merck (GUK) from being a potential competitor to Lundbeck at the time they concluded their agreement. Right before the second extension of that agreement on 6 August 2003, Merck (GUK) was an actual competitor.

12.2.5. Commitments accepted by Merck (GUK) in the agreement related to the United Kingdom with Lundbeck

- (763) In the agreement related to the United Kingdom of 24 January 2002, Merck (GUK) accepted four sets of commitments: (i) the commitment not to launch citalopram based on Natco's API (preamble), (ii) the commitment to "*deliver up*" its Natco

¹³⁹³ Because Lundbeck's "*final offer* [for the extension] *wasn't good enough!!*" See recital (755) above.

¹³⁹⁴ See recital (350) above.

¹³⁹⁵ It appears that the latter option would have required a termination or amendment of Merck (GUK)'s contract with Aceto/Schweizerhall. See recitals (235) and (746) above.

¹³⁹⁶ See recital (300), and further recital (299) above.

¹³⁹⁷ As Merck (GUK) internally noticed and emphasized: "*We launched in UK recently at expiry of the UK agreement, we were not sued. (Others have been though).*" See recital (303) above.

citalopram products in stock and on order to Lundbeck (Articles 2.2 and 2.3); (iii) the commitment not to license its United Kingdom marketing authorizations for Natco citalopram products to any other generic supplier (Article 2.7) and, (iv) the commitment to "exclusively purchase" finished citalopram products from Lundbeck (Article 3.2). The Commission establishes in the remainder of this section 12.2 that these commitments limited Merck (GUK)'s freedom of action on the market and constitute restrictions of competition in breach of Article 101 of the Treaty. These commitments are examined in this section in turn.

12.2.5.1. Merck (GUK)'s commitment not to launch citalopram products based on Natco's API

- (764) According to the preamble of the *"Settlement and Supply Agreement"* concluded between Lundbeck and Merck (GUK) on 24 January 2002 in relation to the United Kingdom, Merck (GUK) *"...has **agreed not to launch the Products** subject to payment in accordance with the terms of the Agreement."*¹³⁹⁸ Article 1.1 defined *"Products"* as *"the **citalopram products developed by GUK in raw material, bulk product and finished pack form** as set out in the Schedule and manufactured in accordance with the specification for Products as supplied by GUK at the date of signature. Attached to Schedule 2."*¹³⁹⁹ The Schedule mentioned "10mg", "20mg" and "40mg" tablets, "packed" and in "bulk" form. It also indicated technical specifications.¹⁴⁰⁰ Lundbeck, GUK and Merck KGaA confirmed to the Commission that Merck (GUK)'s commitment *"not to launch" "the citalopram products"* concerned products produced **with Natco API**.¹⁴⁰¹ Merck (GUK)'s commitment was all-encompassing in that it covered citalopram products based on Natco's API in all forms, that is to say in *"raw material, bulk product and finished pack form"*.
- (765) The duration of Merck (GUK)'s commitment not to launch Natco citalopram, to which Merck (GUK) *"has agreed"* on 24 January 2002, followed from *"the terms of the Agreement"*. Article 11.1 provided that *"this Agreement shall be for a period of twelve months commencing on the Effective Date"*. The *"Effective Date"* was defined in Article 1.1 as *"the date of delivery of the Products by GUK to the Company"*, which was determined in Article 2.2 as *"31/1-2002"*.¹⁴⁰² Merck (GUK)'s commitment not to launch Natco citalopram therefore started on 24 January 2002 (*"has agreed"*) and lasted initially until 31 January 2003. The first extension extended Merck (GUK)'s commitment to 31 July 2003, the second extension to 6 January 2004.¹⁴⁰³ However, Lundbeck terminated the agreement with Merck (GUK) with effect from 1 November 2003. As of 1 November 2003, Merck (GUK) became free again to launch citalopram products based on Natco's API, and, in fact, immediately launched those products and offered licenses to other generic companies.¹⁴⁰⁴
- (766) In relation to Merck (GUK)'s commitment not to launch Natco citalopram, in reply to the Statement of Objections, Lundbeck argued that Merck (GUK) was free to market

¹³⁹⁸ Highlighting added. Point C of the preamble, see recital (267) above.

¹³⁹⁹ Highlighting added. See footnote 547 above.

¹⁴⁰⁰ See recital (720) above.

¹⁴⁰¹ See recital (766) and footnote 1435 below.

¹⁴⁰² Note that the Schedule indicated as date *"January 25th"* for the first *"delivery"*, ID 8, page 218.

¹⁴⁰³ See recitals (289) and (301) above.

¹⁴⁰⁴ See recital (756) above. The same duration applies to all other Merck (GUK) commitments discussed in sections 12.2.5.2 to 12.2.5.4 below.

citalopram medicine from other producers than Natco in the United Kingdom: *"Nothing in the GUK UK Agreement directly (or indirectly) prevented GUK from marketing citalopram products based on API produced by other – non-infringing – suppliers"*.¹⁴⁰⁵ Similarly, GUK argued that the cease and desist obligation is limited to "Products" as defined in "Schedule 2" (that is to say Natco citalopram). The limitation to Natco products would further derive from Article 2.1 ("Products" that *"could give rise to a claim"*, Points B and C of the preamble (products that might be *"infringing"*), and the factual context.¹⁴⁰⁶ Lundbeck's and GUK's argument is based on the provisions of the agreement which oblige Merck (GUK) not to launch the citalopram products from Natco (preamble B and C, the definition of "Products" in Article 1.1 and Articles 2.1, 2.2 and 2.3). However, the Commission considers that Merck (GUK)'s obligation not to sell citalopram medicine from other generic API producers than Natco derives not from these provisions, but from other provisions, as explained in section 12.2.5.4 below.

- (767) The Commission concludes that Merck (GUK)'s commitment not to launch during the term of the agreement citalopram products based on Natco API provided Lundbeck with certainty that Merck (GUK) would not launch Natco citalopram products, whether in *"raw material, bulk product"* or *"finished pack form"*. In particular, Merck (GUK) would no longer launch the 8 million tablets made from Natco API ready for sale in the United Kingdom, and the additional bulk citalopram on order. Nor would it sell Natco citalopram tablets or Natco API to other generic companies *"in the Territory"* that were eager to launch in the United Kingdom, including in particular Ivax.
- (768) The Commission further concludes that Merck (GUK)'s obligations existed irrespective of whether or not Natco citalopram medicine would infringe Lundbeck's process patents. It should be recalled that the agreement itself did not specify any patent that Lundbeck would have alleged to be infringed.¹⁴⁰⁷ In the absence of the agreement, Lundbeck would have had to face the likelihood that Merck (GUK) would already in January 2002 have sought to enter the United Kingdom market with Natco citalopram. While Lundbeck could have started infringement litigation against Merck (GUK), evidence shows that the parties thought at the time that a court might not have found Lundbeck's patents, namely the crystallisation patent, valid and infringed. In fact, shortly before concluding the agreement, Merck (GUK) internally concluded: *"the patent on the compound and the process we are using expires in Jan"* and *"none of the published patent applications disclosed in the letter constitute a problem"*.¹⁴⁰⁸ Moreover, in February 2002, a month after having concluded the agreement, Merck (GUK) stated: Lundbeck's *"patent is considered to be weak"*.¹⁴⁰⁹ Lundbeck did not have the power under patent law to conclude by itself on the exclusionary scope of its own patents and unilaterally decide that Natco citalopram would be infringing, in particular because its potential competitor, Merck (GUK), disagreed.

¹⁴⁰⁵ See ID 5394, page 141.

¹⁴⁰⁶ See ID 6026, pages 10-11.

¹⁴⁰⁷ See further recital (815) below.

¹⁴⁰⁸ See recitals (248) above.

¹⁴⁰⁹ See recital (280) above.

- (769) Also, the Commission observes that there was no counterpart to Merck (GUK)'s commitments in the form of any commitment from Lundbeck that it would refrain from infringement proceedings if Merck (GUK) entered the market with generic citalopram medicine after expiry of the agreement.¹⁴¹⁰ The agreement therefore postponed the issue of potential generic market entry by Merck (GUK); it was not aimed at resolving or terminating any underlying patent dispute.¹⁴¹¹
- (770) Merck (GUK)'s commitment not to launch Natco citalopram "*in raw material, bulk product and finished pack form*" was complemented by three additional commitments, which are analysed in sections 12.2.5.2, 12.2.5.3 and 12.2.5.4 below.

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In its reply to the Statement of Objections, Merck KGaA repeatedly pointed out that "*by simple lapse of time, the possibility for Lundbeck to request an interim injunction decreased*" as well as in view of the fact that Lundbeck did not respond to Merck (GUK)'s letters attempting to clarify the patent situation. In Merck KGaA's view, therefore, "*the UK Agreement also settles definitively the risk of an interim injunction [...] imply[ing] a de facto waiver by Lundbeck of its right to request an interim injunction post-term.*" The agreements therefore had an "*inbuilt limitation on Lundbeck's ability to obtain interim injunctions after their expiry.*" See ID 5960, pages 268 and 269; see also pages 21, 151-152 and 265, ID 6755, pages 12-13 and 15, recitals (284) and (290) and footnote 688 above.

As concerns the issue of "*simple lapse of time*" and the lack of answers to Merck (GUK)'s letters, which, in Merck KGaA's view, would have "*settle[d] definitively the risk of an interim injunction*", first, the Commission observes that when concluding the restrictive agreement Merck (GUK) could not know whether or not Lundbeck would respond to its letters. It was therefore not due to any provision in the agreement, but instead due to Lundbeck's later, not foreseeable conduct of not responding to Merck (GUK)'s letters that the risk of interim injunctions may have been reduced. In any case, as explained above, fact is that the agreements did not resolve or terminate any patent dispute. Merck (GUK) still had the full risk of infringement litigation after expiry of the agreement. See also footnote 593 above. Second, the "*simple lapse of time*" corresponds exactly to the "*delay*" in competing or the "*time*" that Lundbeck intended to buy. In fact, some months before the agreement was concluded, Merck (GUK) found that "*it is now time to move forward in readiness for the legal action from Lundbeck*" and to prepare for "*actions to pre-empt any injunction*". However, after the agreement, Merck (GUK) was no longer in a rush: "*launch is now delayed*"; resolving these questions was now likely "*to take a year or so*". See recitals (245), (246) and (275). With respect to the argument of the "*de facto waiver*" and the "*inbuilt limitation on Lundbeck's ability to obtain an interim injunction*", the Commission notes that these are not reflected in the wording of the agreement. Any limitation on Lundbeck's ability to obtain an interim injunction was therefore not inbuilt, but rather dependent on whether Lundbeck would later decide to defend its rights by responding to Merck (GUK)'s letters identifying the relevant patent infringement issues.

Merck KGaA further claimed that the United Kingdom agreement "*did avoid litigation that would have been brought by Lundbeck as a matter of certainty*". See ID 5960, page 266, see further pages 267-268. Similarly, GUK argued that "*the Settlement Agreements [...] allowed GUK to successfully launch generic citalopram at the expiry or termination of the agreements almost 18 years prior to the expiry of Lundbeck's crystallisation patent*". See ID 6026, page 29. However, the Commission notes that on the one hand it was quite possible that the parties may have had to litigate later. A year after concluding the agreement, Merck (GUK) observed: "*we may have to prove our non-infringement at some stage as well if we were to launch our own product in the future.*" (See recital (288) above) This could have become a reality for Merck (GUK), had Lundbeck prevailed against Lagap. In this case, legal proceedings would have started with a delay of 21 months (see footnote 593). On the other hand, the fact that Lundbeck did not bring any litigation against Merck (GUK), if it really considered Merck (GUK) to be infringing which is not clear, was rather due to reasons unrelated to the United Kingdom agreement. In fact, after Lundbeck settled the Lagap trial, generics entered; Lundbeck explained: "*As preventing infringement by other processes could not have affected the generic presence, any spending of Lundbeck's resources [...] would have become worthless.*" See ID 5394, page 17. Hence, expenditure in form of any further defence of its patent(s) would have been "*futile*". See ID 6026, page 27. This means that it was not the agreement that "*allowed GUK to successfully launch*" but instead rather the fact that Lagap *de facto* opened up the market for generics.

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The Commission observes that the agreement did not contain any non-challenge clause.

These additional commitments contributed to preventing Merck (GUK)'s launch of Natco citalopram and other citalopram for the term of the agreement.

12.2.5.2. Merck (GUK)'s commitment to "*deliver up*" its Natco citalopram products in stock and on order to Lundbeck

- (771) Merck (GUK) committed to deliver up its Natco citalopram products in stock and on order to Lundbeck in Articles 2.2 and 2.3 of the United Kingdom Agreement. Firstly, Merck (GUK) committed in Article 2.2 to "*...deliver up the Products [in stock] in the amounts set out in the Schedule.*" The Schedule's "*25th January delivery*" of products listed around 8 million tablets in the strengths of "*10mg*", "*20mg*" and "*40mg*" to be immediately delivered to Lundbeck.¹⁴¹² These were the tablets Merck (GUK) had produced for launch in the United Kingdom. Secondly, Merck (GUK) committed in Article 2.3 "*...to deliver up Products [on order] as per Schedule ... tak[ing] place upon 2 April 2002*". The "*April 2nd delivery*" of the Schedule foresaw future delivery by Merck (GUK) to Lundbeck of "*Active Substance 173 KG*".¹⁴¹³
- (772) Through Merck (GUK)'s commitment to deliver up the citalopram products it had on stock and on order, Lundbeck obtained certainty that these would not reach the market anywhere in the EEA, whether through Merck (GUK) or another generic company to which Merck (GUK) could have sold the products.¹⁴¹⁴ Lundbeck, of course, had no use for Merck (GUK)'s citalopram products, because it lacked the required marketing authorisation for selling Natco citalopram products on the market. In fact, as explained to Merck (GUK), Lundbeck took the products "*out of circulation*" and destroyed them.¹⁴¹⁵

12.2.5.3. Merck (GUK)'s commitment not to license its United Kingdom marketing authorisations for Natco citalopram products to any other generic supplier

- (773) Merck (GUK) committed in Article 2.7 that it "*will not grant duplicates in favour of any third party of its marketing authorisation during the Term for marketing use in the Territory*" (that is to say in the United Kingdom).¹⁴¹⁶ This commitment was complemented by Article 2.6, in which Merck (GUK) had to give Lundbeck "*warranty*" that "*...it has a marketing authorisation for the sale...*" of Natco citalopram products in the United Kingdom.¹⁴¹⁷ In other words, Merck (GUK) first had to give the "*warranty*" that it had a marketing authorisation for Natco citalopram products in the United Kingdom (and therefore posed a competitive threat), and then to commit in Article 2.7 not to license out this marketing authorisation or its duplicates to other generic companies.
- (774) Through this commitment, therefore, Lundbeck obtained certainty that no other generic undertaking could come to the United Kingdom market with Natco citalopram with the help of Merck (GUK)'s marketing authorisation(s). The facts show that this commitment was highly relevant to achieve total market exclusion of

¹⁴¹² See recital (267) above. Merck (GUK) accepted this commitment "*in consideration of the payment of the sum of £2 million*".

¹⁴¹³ See recital (267) above. Merck (GUK) accepted this commitment "*in consideration of the payment [...] of the further sum [...] of £1 million*".

¹⁴¹⁴ See recital (263) above and recital (810) below. For Merck KGaA's arguments concerning this commitment see further recital (782) above and footnote 1491 below.

¹⁴¹⁵ See recital (267) above.

¹⁴¹⁶ See recital (267) above.

¹⁴¹⁷ See recital (267) above.

Natco's citalopram in the United Kingdom, because absent this commitment, Merck (GUK) could, and probably would, have licensed any of its (six) Natco citalopram marketing authorisation duplicates (which it obtained in June 2002) to other generic companies.¹⁴¹⁸ This was no longer possible. As a result, also other generic companies could no longer launch Natco's generic citalopram in the United Kingdom. Specifically, as mentioned before, already in January 2003, Merck (GUK) was in negotiations with Ivax for supplying Natco citalopram.¹⁴¹⁹ However, in view of the extension of its United Kingdom agreement with Lundbeck, Merck (GUK) postponed its negotiations with Ivax. Only when it faced Lundbeck's termination of the United Kingdom agreement as of 1 November 2003, it started offering Ivax and other generic companies again supply contracts for the United Kingdom market.¹⁴²⁰

12.2.5.4. Merck (GUK)'s commitment to "exclusively purchase" finished citalopram products from Lundbeck

- (775) Merck (GUK) committed in Article 3.2 to *"exclusively purchase the Finished Products from the Company [Lundbeck Limited, Lundbeck's United Kingdom subsidiary] for resale by GUK and its Affiliates in the Territory [the United Kingdom]."* The term *"Finished Products"* was defined in the agreement as *"products containing citalopram in finished pack form to be supplied by the Company [Lundbeck Limited] to GUK pursuant to this Agreement"*. Whereas Point C of the preamble stated that Merck (GUK) *"agreed not to launch"* the generic citalopram products it had developed for entry in the United Kingdom, Point D of the preamble provided *"[t]he parties have further agreed that GUK shall purchase its requirements of the Finished Products from the Company [Lundbeck Limited]..."*¹⁴²¹
- (776) The Commission considers that the commitment to exclusively purchase citalopram from Lundbeck prevented Merck (GUK) from entering with any other generic citalopram. With respect to the meaning of Article 3.2, in March 2010 the Commission had asked Lundbeck in a request for information: *"With respect to Article 3.2 of the agreement, does this Article mean that Generics UK was not allowed to buy citalopram from any other source than Lundbeck for the duration of the agreement for sale in the UK?"* Lundbeck replied: *"Under the agreement, Generics UK undertook not to buy citalopram for the sale in the UK from any source other than Lundbeck."*¹⁴²² In the same reply, Lundbeck explained in a narrative of its own: *"Generics UK agreed to exclusively purchase its requirements of citalopram from Lundbeck for resale in the UK."*¹⁴²³
- (777) In reply to the Statement of Objections, Lundbeck contested its own previous statements by saying that: *"This response was obviously intended to refer to the citalopram (i) in finished pack form and (ii) produced by Lundbeck, as provided clearly in the GUK UK Agreement...Had the Commission asked more specifically*

¹⁴¹⁸ See recital (741) above.

¹⁴¹⁹ See recital (291) above.

¹⁴²⁰ See recital (306) above.

¹⁴²¹ See recital (267) above.

¹⁴²² See ID 823, page 51.

¹⁴²³ See ID 823, page 23, see also recital (272) above. See further ID 823, footnote 33 (page 15): *"This agreement also provided that Generics UK would exclusively purchase citalopram products from Lundbeck for resale in the UK."* As concerns GUK, when asked in 2010, GUK explained in this respect that it was *"unable to address the specific question [...]"*. See ID 660, page 11.

whether the GUK UK Agreement imposed an exclusive purchase obligation, the response would have more specifically been that the GUK UK Agreement imposed no such exclusive purchase obligation, since GUK remained free to buy citalopram API and non-Lundbeck citalopram in finished pack form from any third party."¹⁴²⁴

Lundbeck's argument has two parts: (a) Merck (GUK) was free to buy citalopram API from third parties; and (b) Merck (GUK) was free to buy non-Lundbeck citalopram in finished pack form from third parties. In support of its dual argument, Lundbeck pointed to the definition of "*Finished Products*" in the agreement, that is to say "*citalopram in finished pack form to be supplied by the Company [Lundbeck Limited] to GUK pursuant to this Agreement*". In its reply, GUK made basically the same argument.¹⁴²⁵

- (778) The Commission does not accept the second part of Lundbeck's new argument, namely that the agreement left Merck (GUK) free to buy citalopram in finished pack form from other suppliers than Lundbeck. Lundbeck, and similarly GUK, argued in the reply to the Statement of Objections that "*The exclusive purchase obligation only applied to **Lundbeck's** citalopram in finished pack form.*" (Emphasis added)¹⁴²⁶ This argument appears to be based on an apparent tautology between Article 3.2 and the definition of "*Finished Products*" in the agreement, in the sense that both refer to Lundbeck. Lundbeck and GUK seem to argue that if the definition of "*Finished Products*" was introduced into Article 3.2, Merck (GUK) was only obliged to exclusively purchase the "*products containing citalopram in finished pack form to be supplied by Lundbeck to GUK*", that is to say "Cipramil", from Lundbeck for resale in the United Kingdom. In other words, Merck (GUK) only had to buy Lundbeck products from Lundbeck. *A contrario*, so Lundbeck and GUK seem to argue, Merck (GUK) would be free under the agreement to buy other products, including citalopram in finished pack not supplied by Lundbeck, from any other supplier.
- (779) The Commission observes that if this interpretation were correct, the word "*exclusively*" in Article 3.2 and the wording in preamble (D) of the agreement that "*GUK shall purchase its requirements of the Finished Products from the Company*" would no longer have any meaning. It goes without saying that only Lundbeck could provide Merck (GUK) with "*products containing citalopram in finished pack form to be supplied by Lundbeck to GUK*". Merck (GUK) could not buy such products from anyone else than Lundbeck. An obligation on Merck (GUK) to "*exclusively*" purchase products to be supplied by Lundbeck only from Lundbeck would therefore make no sense. If this were the intention of the parties, they could have simply stipulated that Merck (GUK) would buy citalopram medicines from Lundbeck, without any exclusivity provision. However, Merck (GUK) committed itself to "*exclusively purchase*" Lundbeck citalopram medicines for resale in the United Kingdom and to "*purchase its requirements of Finished Products*" from Lundbeck. The normal and obvious meaning of such an exclusive purchase obligation is that one is not allowed to purchase citalopram in finished pack form from any other supplier. Structurally, moreover, Merck (GUK)'s obligation not to launch generic citalopram (from Natco) in Point C of the preamble, is directly followed by Point D which provides that "[t]he parties have further agreed that GUK shall purchase its

¹⁴²⁴ ID 5394, page 144.

¹⁴²⁵ ID 6026, pages 10-11. See, however, footnote 1423.

¹⁴²⁶ ID 5394, page 144. For GUK's argument, see ID 6026, pages 10-11.

requirements of Finished Products" from Lundbeck. The commitment to purchase "its requirements" of (finished) citalopram (exclusively) from Lundbeck appears therefore to be the other side of Merck (GUK)'s commitment not to launch its generic citalopram.

- (780) That this was the intention of the parties follows, not only from the fact that Lundbeck in first instance clearly explained the agreement in this manner to the Commission, but moreover from the negotiations leading up to the conclusion of the agreement, where Merck (GUK) noted: "*Lundbeck do not want a generic on the market*".¹⁴²⁷ Moreover, from the implementation of the agreement, there is no indication that Merck (GUK) intended to – or believed it was free to – sell generic citalopram products in the United Kingdom during the term of its agreement with Lundbeck.
- (781) The first part of Lundbeck's and GUK's argument, namely that under the United Kingdom agreement Merck (GUK) remained free to buy citalopram API from any third party, bases itself on the wording in Article 3.2 that Merck (GUK) committed itself to buy "*the Finished Products*" exclusively from Lundbeck and that "*Finished Products*" were defined as "*products containing citalopram in finished pack form...*" Again *a contrario*, Lundbeck and GUK argued in their reply to the Statement of Objections that under the United Kingdom agreement Merck (GUK) was therefore free to buy citalopram API from any third party. Based on a literal interpretation of the wording used in these provisions, Merck (GUK) may indeed have not been restrained in Article 3.2 from buying citalopram API from third parties.
- (782) However, with respect to Natco, Merck (GUK) had, according to the preamble of the agreement, already agreed "*not to launch the Products*" [that is to say Natco generic citalopram medicine].¹⁴²⁸ This meant that Merck (GUK) no longer had any incentive to buy citalopram API from Natco for the United Kingdom, even if it were free to do so, as it could not use this API to produce and sell citalopram tablets in the United Kingdom during the term of the agreement. In fact, Merck (GUK) asked "*orders to be pushed out*".¹⁴²⁹ Moreover, since the agreement with Lundbeck also prohibited Merck (GUK) from selling its marketing authorisations for citalopram products of Natco to any third parties,¹⁴³⁰ third parties were also unlikely to be interested in buying Natco citalopram API or tablets from Merck (GUK), even if Lundbeck had not bought up Merck (GUK)'s entire Natco material, including in particular the one on order (or that Merck (GUK) could still order¹⁴³¹).
- (783) Moreover, with respect to API purchases, and "finished dosage form" purchases of citalopram, by Merck (GUK) from other third parties than Natco, any such purchase would have violated Article 1.3 of Merck (GUK)'s contract with Schweizerhall/Aceto, which provided that the MG Group would cover 100% of its annual demand of citalopram API with Schweizerhall/Aceto.¹⁴³² Merck KGaA and GUK confirmed Merck (GUK)'s inability to enter the United Kingdom market with generic citalopram from other sources, whether in API form or in form of finished

¹⁴²⁷ See recital (255) above.

¹⁴²⁸ See recital (763) above.

¹⁴²⁹ See recital (296) above.

¹⁴³⁰ See section 12.2.5.3 above.

¹⁴³¹ See recital above.

¹⁴³² See recital (234) above, ID 670, page 53.

products resulting from that agreement. *"GUK was contractually obliged to source all its requirements for citalopram API from Schweizerhall/Natco for a period of eight years".*¹⁴³³ *"GUK could not purchase citalopram API from any other supplier without violating its agreement with Natco."*¹⁴³⁴ According to Merck KGaA, the agreement with Lundbeck was therefore not tailored to prohibit all market entry of generic citalopram, because already under Merck (GUK)'s agreement with Natco such entry was in any case impossible.¹⁴³⁵

- (784) As far as API purchases from other third parties are concerned, these were therefore not a realistic option for Merck (GUK). Also, according to preamble (D) of the agreement with Lundbeck, Merck (GUK) would buy *"its requirements of the Finished Products"* from Lundbeck. The agreement with Lundbeck provided detailed provisions for volumes to be ordered and profit amounts to be guaranteed. If therefore Merck (GUK) had bought citalopram API from a third party, with a view to producing and selling finished products itself, Lundbeck could have complained under the agreement that Merck (GUK) failed to buy *"its requirements of the Finished Products"* from Lundbeck. Even if Merck (GUK) had in theory been able to circumvent these terms of the agreement,¹⁴³⁶ it internally considered (albeit related to the EEA agreement) that *"if we do sign any agreement at a fair price there will be no attempt at 'circumventing' it"*.¹⁴³⁷ It is therefore hardly surprising, as GUK points out, that *"...there is no evidence in the file [...] that GUK ever tried [...] to use or switch to another product or process [...] during the settlement period"*, even if it were formally free to do so.¹⁴³⁸ As for the possibility for Merck (GUK) to sell citalopram API purchased from other suppliers than Natco to third parties, there is no apparent reason why third parties would not buy the citalopram API directly from the

¹⁴³³ See ID 5960, pages 22.

¹⁴³⁴ ID 6026, page 12.

¹⁴³⁵ In its reply to the Statement of Objections, Merck KGaA therefore claimed inverse cause and effect. It argued that *"[t]he fact that GUK could not sell citalopram from any other supplier resulted from the fact that GUK had entered into a contractual arrangement with Natco..."* In turn, its inability to sell Natco material resulted from the settlement agreement with Lundbeck. For Merck KGaA's arguments, which also relate to the agreement covering the rest of the EEA, see ID 5960, pages 32, 133-134, 269, 276-277 and 307-308. A similar point was made by GUK: *"...for reasons wholly unrelated to the Settlement Agreements, GUK was legally restricted from purchasing citalopram API from any other source"*. See ID 6026, pages 11-12. The Commission notes, however, that since the United Kingdom agreement and the one relating to the rest of the EEA were concluded in view of Merck (GUK)'s agreement with Schweizerhall for the purpose of eliminating the generic threat posed by Merck (GUK), both set of agreements cannot be separated from each other. Indeed, Merck KGaA's and GUK's argument confirms that following Merck (GUK)'s agreement with Schweizerhall, Merck (GUK) inevitably could no longer enter with generic citalopram from other sources, even if this had been formally possible under the agreement with Lundbeck, which in turn restricted entry with Natco's citalopram. In that sense, both agreements reinforced each other. Regarding the extent of Lundbeck's awareness of the content of Merck (GUK)'s contract with Schweizerhall, see footnote 1569.

¹⁴³⁶ In its reply to the Statement of Objections, GUK argued that *"it would have been impossible for GUK, within the time frame of the settlement agreement"* to switch to another API supplier. As a result, *"...the agreement [...] should [not] be read to have been intended to extend to such a switch..."* See ID 6026, pages 12-13. Similar arguments were made by Merck KGaA that pointed out that Tiefenbacher did not want to deal with Merck (GUK) any longer because of Merck (GUK)'s deal with Lundbeck. See ID 5960, page 135. However, even if switching to another source had been difficult at the time, this certainly neither explains nor justifies any commitment which restricted Merck (GUK)'s autonomy in this respect.

¹⁴³⁷ See recital (330) above.

¹⁴³⁸ See ID 6026, page 13.

producer, rather than via Merck (GUK). All in all, Merck (GUK) simply had no incentive under the agreement with Lundbeck to buy citalopram API from other third parties, even if it were free to do so.

- (785) In conclusion on the scope of the exclusive purchasing obligation, the Commission considers that Article 3.2 prevented Merck (GUK) from bringing any other generic citalopram medicines in finished form to the United Kingdom market. In particular, Merck (GUK) gave up its ability to "...*clever[ly] chang[e] the raw material sources...*".¹⁴³⁹
- (786) This commitment of Merck (GUK) through which it gave up its freedom to launch other generic citalopram existed irrespective of whether or not other generic citalopram medicine that Merck (GUK) might have sold in the United Kingdom would be found to be infringing any of Lundbeck's process patents. Again, relevant process patents were not even identified in the agreement. GUK argued that "*it is clear from the contemporaneous documents that Lundbeck took the view that there were no non-infringing processes available for the production of citalopram on a commercial basis. [...] It is therefore not reasonable to conclude that the agreements were intended to extend to non-infringing product.*"¹⁴⁴⁰ Lundbeck could not have obtained this certainty and complete exclusion of Merck (GUK) from the generic market for citalopram products in the United Kingdom through court enforcement of its process patents, even if Lundbeck had been successful in these efforts with respect to Natco's citalopram, which the parties considered far from evident when the agreement was concluded. In fact, Lundbeck did not have the power under patent law to conclude by itself on the exclusionary scope of its own patents and unilaterally decide that each and every generic citalopram would be infringing its patents.

12.2.6. Lundbeck transferred considerable value to Merck (GUK) in exchange for Merck (GUK)'s commitments under the agreement

- (787) The same wording in the preamble that Merck (GUK) "*has agreed not to launch the Products [that is to say Natco products] subject to payment in accordance with the terms of the Agreement*" (Highlighting added) shows that Merck (GUK)'s willingness not to go ahead with the launch of Natco citalopram products, complemented by the other commitments identified in section 12.2.5¹⁴⁴¹, was directly linked to, indeed dependent on, the payments Lundbeck agreed to make in the agreement. This causal link is further evidenced by the fact that internally Merck (GUK) had made its agreement not to launch dependent on whether "*...the numbers stack[ed] up*".¹⁴⁴² Lundbeck's value transfers were therefore a clear inducement to Merck (GUK) to give up its independent efforts to enter the United Kingdom market and to accept the commitments identified in section 12.2.5. The words "*payment in accordance with the terms of the Agreement*" meant all of the payments foreseen in the agreement together.
- (788) It should be noted, in this respect, that the totality of payments made by Lundbeck to Merck (GUK) in the initial year of the agreement ensured Merck (GUK) a profit of GBP 7 million, roughly equal to what Merck (GUK) had expected to make in the

¹⁴³⁹ See recital (351) above.

¹⁴⁴⁰ See GUK's reply to the Statement of Objections, ID 6026, page 13.

¹⁴⁴¹ See in particular recital (769) above.

¹⁴⁴² See recitals (748) and (755) and footnote 1324 above.

first year if it had entered the United Kingdom market with Natco product, but without any of the efforts and risks inherent in such market entry (and without any of the consumer savings resulting from lower generic prices).¹⁴⁴³

- (789) These payments consisted, first of all, in GBP 3 million Lundbeck agreed to pay for Merck (GUK)'s stock of Natco material. This payment represented the re-sale value of that material, not the purchase cost. Of the GBP 3 million, roughly GBP 2 million was profit for Merck (GUK).¹⁴⁴⁴ In other words, Lundbeck was willing to pay Merck (GUK) the same price for the Natco product as if it had been sold on the market, on condition only that Merck (GUK) accepted that the product would never be sold on the market. The payment of the resale value in turn strongly suggests that these payments were not the result of a normal commercial relationship between suppliers. Instead, they had all the features of a consideration, paid by Lundbeck, for Merck (GUK)'s commitment not to enter. Had Merck (GUK) instead sold its generic citalopram on the market, it would have also earned the resale value. Merck (GUK)'s stock, which Lundbeck could not sell, had no value to Lundbeck.
- (790) Secondly, Lundbeck agreed to transfer to Merck (GUK), in the initial year of the operation of the agreement, GBP 5 million in guaranteed profits through the exclusive distribution agreement. Article 6.2 of the agreement provided that *"If the market price for the Finished Products decreases during the Term, then the Company [Lundbeck] agrees to reduce the Cost Price accordingly to ensure that GUK is guaranteed to realise Net Profits of £5 million on sales of the Volume (or pro rata if GUK orders less than the Volume)."* In its reply to the Statement of Objections, Merck KGaA argued that the fact that profits of "£5 million" were guaranteed would not mean that *"payments are not related to distribution services"*.¹⁴⁴⁵ However, this payment of GBP 5 million in guaranteed profits, and those guaranteed profits paid for the prolongations, served not so much to compensate Merck (GUK) for any services valuable to Lundbeck. Rather it served as a reward for Merck (GUK)'s acceptance not to sell Natco citalopram; this is evident not only from the fact that it is not normal commercial practice to guarantee a fixed level of profits whatever may happen in the market, but also from two other provisions in the agreement:
- In the same Article 6.2, Lundbeck guaranteed Merck (GUK) a profit of GBP 5 million irrespective of whether or not Lundbeck decided to sell any of its citalopram tablets to Merck (GUK) and irrespective of whether Merck (GUK) performed any distribution functions for Lundbeck: *"For any month in which the Company [Lundbeck] fails for any reason to deliver Finished Products ordered by GUK it shall ensure that GUK is paid such amount as is equal to the Net Profit GUK could reasonably have expected to make...had the Finished*

¹⁴⁴³ See recital (274) above.

¹⁴⁴⁴ In reply to the Statement of Objections, GUK claimed that the Statement of Objections *"fails to subtract the cost of supply [...] from the value of the payment received by GUK"*. See ID 6026, page 79. However, the cost of supply was correctly subtracted in the calculations contained in footnote 564, which estimated the value of Lundbeck's payment for GUK. However, the value that Lundbeck transferred amounted nevertheless to GBP 3 million, because Lundbeck received in return citalopram, which was of no use to Lundbeck and destroyed. See recital (267) above.

¹⁴⁴⁵ ID 5960, pages 278-279, 323 and 324-325. Also those guaranteed profits during the prolongations of the agreement (see recital (793) below) were, in Merck KGaA's view, paid for distribution services. See also the arguments made by GUK in its reply, ID 6026, pages 79 and 80.

Products been delivered." This was not a normal damage clause in case Lundbeck was unable to deliver, but rather an *"option for Lundbeck to pay a monthly fee instead of delivery Finished Products in case the market price goes down..."*¹⁴⁴⁶ In other words, Lundbeck wanted to have from the beginning the option of not distributing any citalopram via Merck (GUK), but accepted that it would always, whether or not Merck (GUK) performed any distribution services, have to pay GBP 5 million of profits to Merck (GUK) in the first year of the agreement in the form of monthly "fees". In this manner Lundbeck kept control over the market and over Merck (GUK). While Merck (GUK) had committed to exclusively purchase citalopram from Lundbeck and could no longer sell its own finished products or those manufactured by third parties, Merck (GUK) did not have any enforceable right to obtain supplies from Lundbeck. The fact that the fees were on a monthly basis indicates that they were directly linked to the envisaged monthly result of Merck (GUK)'s generic United Kingdom market exclusion. In other words, every month that Merck (GUK) did not sell generic product to the United Kingdom market was worth around GBP 400 000 to Lundbeck, and following the second extension GBP 750 000,¹⁴⁴⁷ irrespective of whether Merck (GUK) distributed any brand product for Lundbeck.

- In Article 1.1 the volume of 125 000 packs of 28 tablets of Cipramil 20 mg *"notionally to be ordered by GUK from the Company [Lundbeck]... is set out in this Agreement by way of a mechanism to ensure (if and to the extent that such volume is achieved) that GUK receives Net Profits as set out in clause 6.2."*¹⁴⁴⁸ This shows that the distribution agreement served as a "mechanism" to ensure that Merck (GUK) received GBP 5 million in the first year of operation of the agreement.

- (791) These provisions indicate that the profit guarantee of GBP 5 million was in fact not related to any distribution services Merck (GUK) would perform for Lundbeck. The profit guarantee served rather, as recognised in the preamble¹⁴⁴⁹, as an important part of the overall package of profit that Lundbeck paid to Merck (GUK) in return for Merck (GUK) accepting not to sell Natco citalopram products or any other generic citalopram products in the United Kingdom giving Lundbeck full control over Merck (GUK)'s market conduct¹⁴⁵⁰.
- (792) Moreover, the agreement operated in such a manner that if Merck (GUK) ordered more than the agreed quantity of 125 000 packs, the price from Lundbeck to Merck (GUK) for those packs was increased so as to ensure that Merck (GUK) continued to receive GBP 5 million per year but not more, even if Merck (GUK) successfully sold much larger quantities of Lundbeck citalopram. Such a mechanism is also not normal

¹⁴⁴⁶ See recital (266) above.

¹⁴⁴⁷ See recital (301) above.

¹⁴⁴⁸ Shortly before concluding the distribution agreement of 24 January 2002, Lundbeck had made a proposal for a differently structured distribution agreement, whereby Merck (GUK) would also gain GBP 5 million profits until January 2003. This supports the conclusion that the transfer of GBP 5 million profits was a given, already agreed, whereas the parties still had to find the means to transfer that value to Merck (GUK). See recital (265) above.

¹⁴⁴⁹ See recital 12.2.6 above.

¹⁴⁵⁰ In this respect, see further recitals (798) and (800) below.

commercial practice in a distribution agreement, as distributors normally make more profit the more products they sell.¹⁴⁵¹

- (793) Finally, that Lundbeck's payments to Merck (GUK) under the distribution agreement did not mirror any benefits to Lundbeck of the distribution agreement, but rather served to reward Merck (GUK) for staying out of the United Kingdom market with generic product, is illustrated by events at the time of the second extension of the agreement. After the first extension of the agreement had expired on 31 July 2003, Lundbeck proposed to reduce Merck (GUK)'s guaranteed profit in the distribution agreement to GBP 250 000 per month instead of the GBP 400 000 per month agreed in the first extension. Lundbeck's stated reason for the decrease had nothing to do with any changes to the distribution services offered by Merck (GUK), but with the fact that there were now *"several members in the "club"..."*¹⁴⁵², meaning more generic suppliers with whom Lundbeck had concluded agreements for the United Kingdom and with whom Lundbeck thus had to share part of its profits. Internally, Lundbeck considered that *"Given an expected monthly turnover of £3M we can go up to more than £1M per month since the other agreements "only" involve a cost of ~£400 k together..."*¹⁴⁵³ This consideration also had nothing to do with any value of Merck (GUK)'s distribution services for Lundbeck. As it happened, Merck (GUK) and Lundbeck did not agree on the extension and as a result, Merck (GUK) started selling GBP several millions worth of Natco citalopram into the United Kingdom market in just a couple of days.¹⁴⁵⁴ On August 5, 2003, Lundbeck managed to re-establish the deal with Merck (GUK). The price tag for Lundbeck had, however, increased to GBP 750 000 of guaranteed profits per month, without any change in the distribution services offered by Merck (GUK).¹⁴⁵⁵ These considerations and events show clearly that the level of guaranteed profits Lundbeck paid to Merck (GUK) under the exclusive distribution agreement was based not on any value to Lundbeck of Merck (GUK)'s distribution services but rather on the value to Lundbeck of Merck (GUK) not selling Natco citalopram.
- (794) Lundbeck booked both the GBP 3 million expenses for Merck (GUK)'s stock and the GBP 5 million guaranteed profit in the initial year of the agreement in an internal Business Development document as a *"Cost"* for which Lundbeck gained *"Time"*,¹⁴⁵⁶ and Merck (GUK) as profits.¹⁴⁵⁷ In the first extension of the agreement, Lundbeck transferred another GBP 2.4 million to Merck (GUK) in the form of guaranteed profits and in the second agreement yet another GBP 2.25 million as guaranteed profits. In total over the entire duration of the agreement, Lundbeck transferred to Merck (GUK) value of GBP 12.65 million (GBP 3 million for Merck (GUK)'s stock and GBP 9.65 million as guaranteed profit), corresponding to around EUR 19.4 million.¹⁴⁵⁸ As has been analysed in recitals (198) to (201) above, the avoidance of generic entry Lundbeck achieved through the agreement with Merck (GUK) was worth a lot more to Lundbeck than the value Lundbeck transferred to Merck (GUK).

¹⁴⁵¹ Compare recital (293) above.

¹⁴⁵² See recital (298) above.

¹⁴⁵³ See recital (298) above.

¹⁴⁵⁴ See recital (755) above.

¹⁴⁵⁵ See recitals (298) and (301) above.

¹⁴⁵⁶ See recital (286) above.

¹⁴⁵⁷ See recital (294) above.

¹⁴⁵⁸ See recital (307) above.

(795) In conclusion on the causal relationship between the payment and the commitments, the distribution agreement cannot adequately explain why Lundbeck would guarantee Merck (GUK) fixed profits of GBP 9.65 million between 24 January 2002 and 1 November 2003, irrespectively of whether Lundbeck actually sold any product to Merck (GUK), irrespectively of any market developments that might occur, and with widely varying monthly profit transfers for unchanged distribution services. The guarantee of profits of GBP 9.65 million served therefore, together with the cash payment of GBP 3 million for Merck (GUK)'s stock, to persuade Merck (GUK) to accept to:

- refrain from selling Natco citalopram products or any other generic citalopram products in the United Kingdom;
- deliver up its stock to Lundbeck; and
- refrain from passing on Natco citalopram products or any of Merck (GUK)'s United Kingdom marketing authorisations for Natco citalopram products to any third parties.

Merck (GUK) further accepted that Lundbeck could unilaterally decide whether to sell any of its citalopram tablets to Merck (GUK) at all (provided Merck (GUK) received as payment such amount as was "*equal to the Net Profit*").¹⁴⁵⁹

Arguments of the parties

(796) In its reply to the Statement of Objections, Lundbeck recognised that "*The distribution agreement was part of the value transfer under the settlement, which explains why GUK and Lundbeck agreed on guaranteed profits.*" Lundbeck argued, however, that the value transfer should be seen as gross value transfer. It alleged certain benefits of distribution without any quantification; these alleged benefits would have lowered the overall costs of the settlement.¹⁴⁶⁰ In its reply to the Statement of Objections, Merck KGaA also claimed a certain, unspecified value to Lundbeck of the distribution services, which would have lowered the value transfer. Thus, it would not be clear whether the value transfer before the extension amounted indeed to GBP 7 million. Merck KGaA further claimed, without quantification, an improvement of its position for the subsequent launch of generic citalopram.¹⁴⁶¹ GUK, in reply to the Statement of Objections, argued that the Statement of Objections "...*fails to take into account GUK's distribution costs, warehousing costs and opportunity costs...*"¹⁴⁶²

(797) In fact, even though Lundbeck already had a well-developed distribution system of its own in the United Kingdom through its subsidiary Lundbeck Limited, the analysis in recitals (790) to (795) not necessarily mean that the distribution agreement with Merck (GUK) was entirely useless to Lundbeck or that Merck (GUK) performed the distribution services without any costs.¹⁴⁶³ Anyhow, Merck (GUK), from its side,

¹⁴⁵⁹ See further recitals (798) and (800) below.

¹⁴⁶⁰ ID 5394, pages 144 and 146.

¹⁴⁶¹ ID 5960, pages 278-279. For the latter argument, see recital (800) below.

¹⁴⁶² ID 6026, page 79.

¹⁴⁶³ As concerns the use to Lundbeck of sales by Merck (GUK), for instance, Merck (GUK) wrote on 11 December 2011 in an internal assessment of the envisaged deal: "*We could sell UK Lundbeck product to target the PI [parallel imports].*" See recital (255) above. These parallel imports, mainly caused by exchange rate fluctuations, were a nuisance to Lundbeck.

appears to have been interested in selling Lundbeck product and wanted the profits: *"This will give us a good T/O [turnover] as well as the profit."*¹⁴⁶⁴ Merck (GUK)'s profits on citalopram were capped in the agreement with Lundbeck based on Merck (GUK) sales of 125 000 packs per month and did not increase with additional sales by Merck (GUK). However, it has to be considered that on the one hand Merck (GUK) had the power under the agreement to lower the amount of distributed packs and thereby increase its margin, depending on what it considered most advantageous, and on the other hand that irrespective of distribution and opportunity costs, Merck (GUK) was in a position to ensure that it received guaranteed profits.¹⁴⁶⁵ As concerns any alleged but unsubstantiated "distribution costs", "warehousing costs", "opportunity costs"¹⁴⁶⁶, the Commission observes that Merck (GUK) received the value transfers (as "guaranteed profits") from Lundbeck and listed these transfers in March 2003 as "profits" without making any deductions.¹⁴⁶⁷ In the Commission's view, this is what ultimately matters.

- (798) As concerns the alleged benefit of Merck (GUK)'s distribution services to Lundbeck or, for later launch, for Merck (GUK), what matters in the Commission's view is that the provisions of the agreement made it factually impossible for Merck (GUK) to enter with Lundbeck's own product into significant competition with Lundbeck. Firstly, the agreement gave Lundbeck the right to stop or reduce at any moment its sales of Lundbeck citalopram to Merck (GUK), provided it continued to pay a monthly fee. Lundbeck considered the use of this option in particular if prices were to drop significantly in the United Kingdom market.¹⁴⁶⁸ Secondly, the agreement contained a recommended sales price for Merck (GUK), which Merck (GUK) in practice followed. Thirdly, Lundbeck determined the price of the citalopram tablets it sold to Merck (GUK) in such a way that Merck (GUK) could never earn more from Lundbeck than GBP 5 million in the first year. This provision eliminated any profit incentive for Merck (GUK) to lower the price of the Lundbeck citalopram it sold below the sales price Lundbeck had recommended or to sell significantly larger quantities of Lundbeck product, as that would only reduce Merck (GUK)'s profit margin per product sold and could never increase total profits.¹⁴⁶⁹

¹⁴⁶⁴ See recital (255) above.

¹⁴⁶⁵ After Merck (GUK) had for some time been buying more than 125 000 packs per month, considering its opportunity costs, it came to consider in April 2003 that *"we are fooling ourselves with Cipramil... I know it's a bit negative but it is disguising some underlying issues. With good sales our shareholders will expect good profit – which as you can see below is not likely to happen."* (See recital (293) above. In relation to this quote, GUK argued that the Statement of Objections did not sufficiently consider GUK's costs, see ID 6026, page 80.) Merck (GUK) went on to compare its margin for Cipramil of 13% with the core business, 21%, "Sales from Reports", 25%, and another product, 71%. It concluded: *"Given that we make some £400k in each of Cipramil and [other product] (once everyone had had a piece of it!) and our overheads are close to £2m per month we are struggling to make a profit pre R&D and NTR."* See ID 673, page 479. What matters in the Commission's view is that Merck (GUK) had the freedom to decide, and in fact decided, that it would be *"slowing the rate of sale to say 150k ish a month to improve the gross margin."* See recital (293) above.

¹⁴⁶⁶ Note that with respect to the latter, these depended on Merck (GUK)'s own decision regarding the amount of packs it would order from Lundbeck for distribution.

¹⁴⁶⁷ See recital (294) above.

¹⁴⁶⁸ See recital (790) above.

¹⁴⁶⁹ See recital (295) above. In reply to the Statement of Objections, Merck KGaA criticised this reasoning as flawed by pointing to Article 6.2: *"If the market price for the Finished Products decreases during the Term, then the Company agrees to reduce the Cost Price accordingly to ensure that GUK is guaranteed*

- (799) Finally, reimbursement levels in the United Kingdom were linked to generic entry into the market, not to any increase in the number of suppliers of the originator product. Thus, by turning Merck (GUK) into an exclusive supplier of its own product, Lundbeck avoided any impact on the United Kingdom reimbursement level for citalopram, which Merck (GUK)'s (and Arrow's) entry as a supplier of generic product would have had. This guaranteed Lundbeck continued high profits on its sales of citalopram. Consumer interests were hurt, however, in that significant price decreases for citalopram that in all likelihood would have resulted from generic entry were prevented for the duration of the agreement.
- (800) For the reasons mentioned in recitals (798) and (799), the agreement with Lundbeck also cannot be seen as a pro-competitive supply agreement that allowed Merck (GUK) early market entry or substantially facilitated later market entry. Firstly, by distributing citalopram that was Lundbeck branded, Merck (GUK) became dependent on Lundbeck and could not build up any brand recognition as (generic) supplier of citalopram. Secondly, Merck (GUK) was getting ready, at the time when it concluded the agreement with Lundbeck, to enter the United Kingdom market with its own generic product. The positive impact on competition in the United Kingdom of such generic entry by Merck (GUK), for which there was a real concrete and realistic possibility, would have been much greater than Merck (GUK)'s distribution of Lundbeck's branded citalopram, especially if Merck (GUK)'s generic entry had been rapidly followed by other generic suppliers, such as Arrow. Moreover, the supply of Lundbeck's branded citalopram to Merck (GUK) was left at Lundbeck's discretion. Lundbeck could elect not to supply Merck (GUK) and to pay the guaranteed profit instead. Merck (GUK) did not have any right under the agreement to source citalopram products from third party suppliers even if their citalopram did not infringe Lundbeck's patents and Merck (GUK) could not terminate the agreement with Lundbeck as long as Lundbeck continued to pay the guaranteed profit. Integrating Merck (GUK) into Lundbeck's own distribution network was therefore a solution for Lundbeck that did not endanger its *de facto* exclusive position on the United Kingdom market, whereas Merck (GUK)'s generic entry would clearly have endangered that position. Thirdly, there is no indication in the file nor any substantiation of Merck KGaA's argument that Merck (GUK)'s distribution of Lundbeck branded citalopram during the term of the agreement would have "*enabled GUK to improve its procedural position for the subsequent launch of generic citalopram*" after the expiry of the agreement¹⁴⁷⁰; moreover, even if this had been the case, it would not affect the conclusion that Merck (GUK) was paid for staying out of the market during the term of the agreement.
- (801) Concerning the value transfer overall, the Commission notes that neither of the parties adequately rebutted the Commission's conclusions on the value transfer by providing additional, legitimate reasons. In reply to the Statement of Objections, Merck KGaA merely argued that "*compensation*" is "*part of any settlement agreement*". The value transfer in the present case would simply have reflected "*GUK's negotiating power*" (or "*the leverage*"), which would mean that there was

to realise Net Profits of £5 million." However, it is not clear how this provision could provide a profit incentive to Merck (GUK) to lower its market price as Merck (GUK)'s guaranteed profits would remain the same under the agreement and thus not increase, even when the market price decreased.

¹⁴⁷⁰

See ID 5960, page 279.

"no essential link" between the payment and the supply element or the staying out of the market.¹⁴⁷¹ Closely related is Merck KGaA's argument that *"financially beneficial side effects for both parties involved"* in a legitimate settlement should be irrelevant, even if generic entry is delayed. In its view, the *"reverse way' reveals nothing about the competitive nature"* of an agreement.¹⁴⁷² The Commission notes firstly that the "essential link" between the payment and the staying out of the market clearly results from the terms of the agreement itself according to which Merck (GUK) *"has agreed not to launch the Products [that is to say Natco products] subject to payment in accordance with the terms of the Agreement"*. Secondly, the facts show that *"GUK's negotiating power"* regarding the United Kingdom agreement was a direct function of the competitive threat it posed to Lundbeck as potential generic entrant in the United Kingdom.¹⁴⁷³ Generic entry by Merck (GUK) in the United Kingdom, in fact, would have likely resulted in a steep decline of Lundbeck's sales and profits, and correspondingly lower consumer prices. The Commission concludes that *"negotiating power"* which essentially consists of the offer by a potential competitor not to enter with generic citalopram cannot justify the acceptance of payments in return for market exclusion commitments.¹⁴⁷⁴ As concerns the direction of the payment, the direction of the payments is assessed together with the commitments given by the parties. Combined, as shown in sections 9.2.2 and 10.2 above, both are highly relevant for assessing under Union competition rules whether an agreement restricted competition.¹⁴⁷⁵

Conclusion

- (802) The Commission concludes from the facts described in this section 12.2.6 that Lundbeck transferred considerable value to Merck (GUK) in exchange for Merck (GUK)'s commitments under the agreement not to launch generic citalopram. This value transfer was not only part of an arrangement allowing Merck (GUK) to distribute some of Lundbeck's citalopram in the United Kingdom, if Lundbeck decided to deliver citalopram packages to Merck (GUK). The value transfer was designed to induce Merck GUK to enter into the agreement and to give up its plan to enter independently the market. The analysis of section 12.2.5 and this section of the objective elements of the agreement moreover shows that the primary objective of the agreement, which lasted from 24 January 2002 until 1 November 2003, was to ensure that Merck (GUK) did not enter the generic market for citalopram products in the United Kingdom for the duration of the agreement. Any benefits to Lundbeck of the distribution agreement were secondary and could not adequately explain several of the provisions of the agreement nor the strong increase in the monthly fee Lundbeck agreed after Merck (GUK) in August 2003 had started to sell generic products for five days. Nor is the primary objective of generic market exclusion in any way put into question by other possible objectives, if these existed, such as to use the time while the anti-competitive agreement was in force for making certain progress in resolving possible patent law issues between Merck (GUK) and

¹⁴⁷¹ Merck KGaA argued this both for the United Kingdom agreement and the agreement related to the rest of the EEA, see ID 5960, page 277, 280, 313, 315 and 319. Similar Lundbeck, ID 5394, page 287. See footnote 1324. This argument basically questions the causal link.

¹⁴⁷² ID 5960, page 192. See also ID 5960, pages 159-167.

¹⁴⁷³ See recital (793) above.

¹⁴⁷⁴ See recital (660) above.

¹⁴⁷⁵ See further recitals (643) to (644) and section 11.5 above.

Lundbeck. As the Court of Justice has stated, agreements are caught by the prohibition of Article 101(1) of the Treaty, when "*they **also** have the aim of dividing up the market or restricting competition in other ways* (emphasis added)."¹⁴⁷⁶ This confirms that an agreement to restrict competition does not become legal simply because it may also have had other, legitimate objectives.¹⁴⁷⁷ It results from all these considerations that Lundbeck paid Merck (GUK) to accept to give up for the term of the agreement its independent efforts to enter the market, and thereby shared its monopoly rents with Merck (GUK).

12.2.7. Intentions of the parties

- (803) This section deals with the intentions of the parties regarding the aim of the agreement. Merck (GUK)'s intentions relevant for the existence of potential competition have already been analysed in sections 12.2.3 and 12.2.4 above.
- (804) Chapter 6 of this Decision has described Lundbeck's overall strategy to protect its "*golden egg*"¹⁴⁷⁸ against generic entry on citalopram. Probably the most revealing quote regarding Lundbeck's attitude and intentions with respect to delaying generic entry is the following quote from a Lundbeck Business Development document with the title "generic citalopram update 22 11 02":

"It is like a poker game

- *We have been dealt a mediocre hand – no aces, a couple of queens and some small uneven cards*
- *But we have a large pile of \$\$\$ at our side*
- *We call it – "the art of playing a losing hand **slowly**"*

Our strategy

- *Our objective : To create a window of opportunity for the Cipraleth switch*
- *Focus on EU and particularly the northern European markets – the generic markets*
- *Three main tactics:*
 - *Influencing the authorities*
 - *Patent defence, mainly process patents*
 - *Deal making.*"¹⁴⁷⁹

¹⁴⁷⁶ Case 35/83, *BAT Cigaretten-Fabriken GmbH v Commission*, ECR 1985, p. 363, paragraphs 27 and 28. See recital (600) above.

¹⁴⁷⁷ "*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...*", Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd and Barry Brothers*, 2008 [2008] ECR I-8637 paragraph 21. For Lundbeck's and Merck KGaA's arguments in this respect see recital (814) below.

¹⁴⁷⁸ See recital (120) above.

¹⁴⁷⁹ See recital (131) above, emphasis in the original. In reply to the Statement of Objections (see ID 5394, pages 81-82), Lundbeck offered its own interpretation of this document, which would show a legitimate business strategy. However, Lundbeck's interpretation failed to sufficiently explain the link inherent in this document between "*Deal making*" in relation to the "*large pile of \$\$\$*" and (avoiding competition from) generic citalopram.

- (805) Lundbeck's specific intentions with respect to the United Kingdom market are well reflected in the following document of Lundbeck from 21 May 2002:

"UK Strategy

6 Jan Product patent expired

24 Jan Merck Generic UK deal for 12 months

24 Jan Arrow Generics deal till 1 Jan 2003

8 Feb Injunction against Arrow Generics [voluntary, as stipulated in the agreement]

22 Feb Alparma deal till 1 July 2003

15 Mar Warning letters to Lagab (Novartis) & Ratiopharm

Mar Injunction against Alparma [voluntary, as stipulated in the agreement; in fact, however, no injunction took place¹⁴⁸⁰]

May Cipralex [escitalopram] launch... "¹⁴⁸¹

- (806) The facts described in Chapter 6 and the above quote show that Lundbeck's agreements with Merck (GUK), Arrow, Alparma and Ranbaxy were not isolated incidents, but were part of a coherent overall strategy by Lundbeck to delay generic entry into the United Kingdom market, with a view to continuing high turnover and profits on citalopram for as long as possible and introducing the successor product escitalopram before generic entry on citalopram had taken place.
- (807) Lundbeck's budgeted and actual sales figures for the United Kingdom, as described in recitals (198) to (202) above, show that Lundbeck's 'investment' of EUR 54.2 million for the four agreements covering the United Kingdom, which prevented widespread generic entry in the United Kingdom between January 2002 and October 2003, generated additional budgeted Lundbeck sales of citalopram and escitalopram in the United Kingdom in the period concerned of EUR [40-110]* million, whereas additional actual sales were EUR [0-120]* million.
- (808) After Lundbeck had launched escitalopram in the United Kingdom on 10 June 2002, five months after its first agreements with Merck (GUK) and Arrow preventing generic into the United Kingdom, an internal Lundbeck document announced triumphantly:

"Launching Cipralex before generic competition in the UK – top result."¹⁴⁸²

For Lundbeck, *"The immediate goal after launch [of escitalopram] will be to switch loyal Citalopram prescribers into loyal escitalopram prescribers".¹⁴⁸³* The avoidance of generic sales of citalopram in the United Kingdom before the launch of escitalopram, and gaining a year and four months to establish escitalopram in the

¹⁴⁸⁰ See recitals (536) and (537). See also ID 222, page 14.

¹⁴⁸¹ See recital (198) above.

¹⁴⁸² See recital (204) above. See further recitals (196) to (206) above.

¹⁴⁸³ See recital (139) above.

market before widespread generic entry took place in the United Kingdom¹⁴⁸⁴ was therefore very important to Lundbeck.

- (809) As for Lundbeck's and Merck (GUK)'s intentions, Lundbeck's general strategy of making deals with generic undertakings that prevented their generic entry with citalopram in the United Kingdom in exchange for considerable sums of money was reflected in Lundbeck's negotiations with Merck (GUK), and noticed by Merck (GUK)¹⁴⁸⁵. Merck (GUK)'s report from a meeting with Lundbeck on 11 December 2001 stated: *"Lundbeck do not want a generic on the market. However they could compensate us for the profit we would have made etc."*¹⁴⁸⁶ Moreover, shortly before, Merck (GUK) had internally considered its two business options, one of which was generic entry and the other one "[s]upplied by Lundbeck", *"How to achieve the same profit figure?"*¹⁴⁸⁷ These statements clearly show that Lundbeck's key objective towards Merck (GUK), which seemed likely to become, perhaps with Arrow, the first company to enter the United Kingdom market with generic citalopram, was to stop it from entering the market with generic product. It also shows that Lundbeck was willing to pay Merck (GUK) the profits Merck (GUK) could have expected from generic entry if Merck (GUK) accepted not to enter. Merck (GUK) estimated those profits at between GBP 7 million and GBP 9.7 million in the first year, in a best case scenario.¹⁴⁸⁸ The GBP 5 million in guaranteed profits from the distribution agreement in the first year was therefore, together with the GBP 2 million of profits for Merck (GUK)'s stock, a crucial part of Lundbeck's compensation to Merck (GUK) for the profits Merck (GUK) estimated it could have made in the same period had it entered the market with Natco product. Finally, the statement shows that there can have been no misunderstanding on Merck (GUK)'s part that the money it was going to receive from Lundbeck was compensation *"for the profits we could have made etc"* in exchange for complying with Lundbeck's wish that it did *"not want a generic on the market."* Merck (GUK), in fact, switched between independent generic launch and Lundbeck's compensation for staying out of the market depending on where the "numbers stacked up" best.¹⁴⁸⁹
- (810) Lundbeck's statement to Merck (GUK) that *"As I know you are aware the guys at the Head office are very keen to receive the quantities of products as promised in the*

¹⁴⁸⁴ The first generic entry on citalopram in the United Kingdom took place in October 2002 in small quantities. Widespread generic entry into the United Kingdom market occurred only after October 2003, when Lundbeck settled the Lagap litigation. See recital (208) above.

¹⁴⁸⁵ Merck (GUK) had taken note in February 2001 of Lundbeck's strategy *"to buy up the world's supply"* and *"to buy out all the processes and so on"* (see footnote 468 above). With respect to Lundbeck's acquisition of VIS still, Merck (GUK) had internally observed *"there is a marvellous antitrust case in here"* and had considered it *"clearly a blatant attempt to stop them from providing Citalopram [...] Anti trust if one saw it"*. It considered even legal action against Lundbeck, which it dropped, however, because Merck (GUK) did not expect any direct benefit. (See footnote 445 above) The moment it became a potential supplier of generic citalopram itself, Merck (GUK) must have understood, why it became itself a target of Lundbeck's anti-generic deal making strategy. It is therefore not credible to argue in this respect that Merck (GUK) suffered from information asymmetry concerning Lundbeck's intentions. See Merck KGaA's reply, ID 5960, page 272. In any case, such information asymmetries, as shown, would have hardly been significant.

¹⁴⁸⁶ See recital (255) above.

¹⁴⁸⁷ See recital (243) above.

¹⁴⁸⁸ See recital (239) above.

¹⁴⁸⁹ See recitals (748) and (755) above, and recital (814) below.

initial discussions"¹⁴⁹⁰ demonstrates that it was important for Lundbeck that Natco's material in Merck (GUK)'s warehouse would be transferred to Lundbeck to make sure that it could not reach the market. Merck (GUK) knew this material would be taken "*out of circulation*".¹⁴⁹¹ Regarding generic citalopram available for the market, Merck (GUK) stated: "*Currently they are taking legal action with the Dutch HA [health authority] re the Tiefenbacher [sic] active. If this is successful then we would have the only available product.*"¹⁴⁹² This shows that Merck (GUK) knew that it may well have the only "*available product*", that is to say the only generic citalopram. "*Available product*" suggests at the same time that Merck (GUK) considered that its product could be successfully brought to the market.¹⁴⁹³

- (811) The timing of the agreement with Merck (GUK) is also an indication of the true purpose of the agreement. With respect to the agreement's beginning, Lundbeck considered internally on 19 November 2001: "*As soon as their [Merck (GUK)'s] UK approval [for Natco citalopram] is a reality, we should be ready to enter an agreement...*"¹⁴⁹⁴ The timing of the conclusion of the agreement with Merck (GUK), including the distribution part, was therefore dictated not by any perceived urgent need on Lundbeck's side to obtain, in addition to its own sales network in the United Kingdom, an extra distributor, but by Merck (GUK)'s readiness to enter the United Kingdom market with generic product. With respect to the agreement's ending, Lundbeck terminated the agreement with Merck (GUK) immediately after Lundbeck had settled its litigation with Lagap.¹⁴⁹⁵ As the settlement with Lagap allowed Lagap, and in its wake other generic suppliers buying citalopram from Matrix, to freely enter the United Kingdom market, there was no longer any purpose for Lundbeck to continue paying Merck (GUK) on a monthly basis for staying out of that market.¹⁴⁹⁶
- (812) In reply to the Statement of Objections, Merck KGaA argued the parties' intention was "*to bring certainty to an uncertain patent situation*".¹⁴⁹⁷ Closely related is

¹⁴⁹⁰ See recital (263) above.

¹⁴⁹¹ See recital (267) above. In its reply to the Statement of Objections, GUK pointed out that Lundbeck's intention to take Merck (GUK)'s Natco citalopram "*out of circulation*" was not very effective as Merck (GUK) was only precluded from "*marketing, distribution and sale*" of Natco citalopram, allowing stock-building. See ID 6026, page 14. However, it is not clear whether following the agreement with Lundbeck stock-building was still a viable option for Merck (GUK) considering the risk of a limited shelf-life of citalopram. In reality, Merck (GUK) asked "*orders to be pushed out*". See recital (296) above.

¹⁴⁹² See recital (255) above.

¹⁴⁹³ Merck KGaA's argument submitted in reply to the Statement of Objections that it did or could not know that generic competition may be hindered by its commitment to stay out of the market in the rest of the EEA is therefore not credible. See ID 5960, pages 295-299 (for the rest of the EEA). Nor would it be relevant considering that Merck (GUK) was (one of) the first generic undertaking(s) ready to launch in the United Kingdom.

¹⁴⁹⁴ See recital (245) above.

¹⁴⁹⁵ See recital (208) above.

¹⁴⁹⁶ Lundbeck argued in reply to the Statement of Objections that since end of 2002, almost a year after conclusion of the agreement, the parties initially implicitly and later explicitly linked their agreement to the Lagap litigation. See ID 5394, pages 138-139. For Merck KGaA's arguments submitted in reply to the Statement of Objections see, for example, ID 5960, pages 35-36 and 150-155. However, the Lagap trial concerned citalopram produced with a different process (that is to say Matrix). The Lagap trial therefore could not clear the way for the launch of Natco citalopram in case Lundbeck had prevailed. See further recitals (682)-(689) above.

¹⁴⁹⁷ See ID 5960, page 265.

Lundbeck's argument that it intended to enforce its patent rights.¹⁴⁹⁸ However, as already noted in section 12.2.4, Lundbeck's subjective interpretation of its patent rights was not shared by its competitor Merck (GUK))¹⁴⁹⁹. The Commission observes that the parties brought indeed certainty of no competition to a possibly uncertain situation with potential competition, however, by way of rent sharing. This rent sharing led to an alignment of competing interests, absent of which Merck (GUK) may have well entered (in fact, it actually did so in August 2003).¹⁵⁰⁰ The intention of bringing certainty to an uncertain patent situation or of enforcing patents can under these circumstances not be separated from the anti-competitive intention related to market exclusion that is combined with rent sharing. Regarding "certainty" that the agreement allegedly created, it strikes that the parties did not resolve any potential patent dispute.¹⁵⁰¹

- (813) In its reply to the Statement of Objections, Merck KGaA further argued that its intention "*was to seek clarification of the patent situation with Lundbeck*".¹⁵⁰² Similarly, GUK submitted that "*the Settlement Agreements were intended to (i) create a framework in which GUK could identify as best as possible any concrete risk of infringement; (ii) enable the parties to solve the patent issues within a limited period of time*" and (iii) enable GUK "*to defeat an application for injunction*" and exclude the risk of a successful injunction.¹⁵⁰³ A similar argument was made by Lundbeck.¹⁵⁰⁴
- (814) The Commission notes that the clarification of the patent situation during the term of the agreement may have been one of the parties' intentions.¹⁵⁰⁵ This is in any event doubtful given that the agreement does not mention any specific patent that Lundbeck considered Merck (GUK) would have infringed. However, Lundbeck's objective in its negotiations with Merck (GUK) was also generic market exclusion. It was this objective, for which Lundbeck paid. Merck (GUK), in turn, agreed to stay out of the market because ("*subject to*"), and as long as, the numbers stacked up; it started "*working with the brand originator*" and postponed its entry plans.¹⁵⁰⁶ These facts reveal a clearly anti-competitive intent of rent sharing in return for market exclusion. Other objectives that Lundbeck or Merck (GUK) may have pursued are therefore irrelevant, whether these would be legitimate or not absent the rent sharing.¹⁵⁰⁷

¹⁴⁹⁸ Lundbeck claimed that it "*entered into the Agreements in order to safeguard and enforce its valid process patents, and prevent irreparable harm that would have resulted from the entry of infringing generic products onto the market*". See in particular ID 5394, pages 3-5, 7, 111-125 and 140-141. This argument is rebutted in section 11.2 above.

¹⁴⁹⁹ See, amongst others, the preamble and recital (753) above.

¹⁵⁰⁰ See recitals (243) and (748) above.

¹⁵⁰¹ See recital (769) above.

¹⁵⁰² See ID 5960, pages 273-274. In support Merck KGaA pointed to preamble C and Article 2 of the agreement.

¹⁵⁰³ See ID 6026, page 22, and more generally pages 19-29.

¹⁵⁰⁴ See ID 5394, pages 134-137.

¹⁵⁰⁵ See, for example, the documents quoted in recitals (284) and (303) above.

¹⁵⁰⁶ See recitals (755) and (800) above. In light of these facts, also Merck KGaA's allegation cannot be accepted that Merck (GUK)'s objective would have not been to delay its own generic entry. See ID 5960, page 274.

¹⁵⁰⁷ See recitals (602) and 0 above.

- (815) As concerns GUK's claim that the parties intended to create a framework to identify "*as best as possible any concrete risk of infringement*" during the term of the agreement, the Commission considers that in reality, there was no such framework. Firstly, the agreement itself did not even identify any specified patent that Lundbeck would have claimed Merck (GUK) was infringing. Secondly, instead, Merck (GUK)'s patent counsel wrote letters to Lundbeck, while Lundbeck felt apparently no obligation under the agreement to respond and, in fact, did not respond. Still at the expiry of the United Kingdom agreement after 21 months, Lundbeck had not bothered identifying towards Merck (GUK) those precise patents (if any), it alleged to be infringed.¹⁵⁰⁸ Had the parties truly intended to identify any "*concrete risk of infringement*" "*as best as possible*", they would have certainly known how to agree on an effective mechanism to resolve these allegedly existing issues, swiftly.
- (816) Taken together, the evidence regarding the intentions of the parties confirms the objective elements of the analysis. They show that both parties made an agreement of which they knew the essence to be that Lundbeck paid Merck (GUK) the profits it could have hoped to make had it entered the United Kingdom market with Natco citalopram products, with all the commercial risks attached, on condition that Merck (GUK) gave up, through the various commitments analysed in section 12.2.5, its intention to sell generic finished products in the United Kingdom for the duration of the agreement. In summary, Merck (GUK) recorded Lundbeck as saying in its meeting with Merck (GUK) on 11 December 2011: "*Lundbeck do not want a generic on the market. However they could compensate us for the profit we would have made etc.*"¹⁵⁰⁹ This consideration was at the core of the intentions of the parties when they concluded their agreement. The Commission concludes that both parties knew or should have known that their agreement was anti-competitive.

12.2.8. *The agreement restricted competition to an appreciable degree in the United Kingdom*

- (817) The Commission refers to sections 6.6 and 11.9 for its considerations on the appreciable degree to which the agreements in question restricted competition and to section 13.2 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 States¹⁵¹⁰, the Commission does not have to prove an appreciable restriction of competition, but that in any case each (set of) agreement(s) did restrict competition to an appreciable degree.¹⁵¹¹
- (818) In the specific case of Merck (GUK), the Commission notes that the agreement with Lundbeck covered the United Kingdom, where Lundbeck's market share at the time when it concluded the agreement with Merck (GUK) considerably exceeded 10%.¹⁵¹²

¹⁵⁰⁸ See recital (330) above.

¹⁵⁰⁹ See recital (255) above.

¹⁵¹⁰ See recital (724) above. For the effect on trade between Member States of each (set of) agreement(s), see chapter 13 below.

¹⁵¹¹ See in particular section 6.6 above. The Commission notes, in this respect, that since each (set of) agreement(s) covered the United Kingdom, where Lundbeck succeeded through the agreements in preventing widespread generic competition from January 2002 to October 2002, each (set of) agreement(s) restricted competition to an appreciable degree in at least one of the markets covered by the agreement.

¹⁵¹² See recital (215) above.

12.2.9. Conclusion on restriction by object

- (819) The facts described and assessed in legal terms in sections 12.2.1 to 12.2.4 above show that at the time the undertakings Merck (GUK) and Lundbeck concluded their agreement of 24 January 2002, they were potential competitors in the United Kingdom market for citalopram. As analysed in section 12.2.5 above, under the agreement, Merck (GUK) accepted a number of commitments which ensured that Merck (GUK) would not compete with Lundbeck with (generic) citalopram in the United Kingdom for the term of the agreement, whether with the Natco product Merck (GUK) had purchased or any other generic citalopram product. As analysed in section 12.2.6 above, Lundbeck transferred considerable value to Merck (GUK) in exchange for Merck (GUK)'s acceptance of these commitments. Section 12.2.7 has shown that this agreement formed part of Lundbeck's strategy to delay generic entry for citalopram and that Merck (GUK) knew or should have known that Lundbeck's transfer of value to it served to persuade Merck (GUK) to accept the commitments in question and thereby to eliminate the incentive for Merck (GUK) to continue its independent efforts to enter the United Kingdom market with citalopram for the term of the agreement.
- (820) Given that Merck (GUK)'s acceptance of these limitations on its commercial autonomy was achieved not by the strength of Lundbeck's patents, but by the transfer of value from Lundbeck to Merck (GUK), the Commission considers that these limitations constitute restrictions of competition within the meaning of Article 101(1) of the Treaty.
- (821) Moreover, since these limitations on Merck (GUK)'s commercial autonomy, obtained by Lundbeck through the transfer of considerable value to Merck (GUK), were by their very nature injurious to the proper functioning of normal competition and followed directly and necessarily from the clauses of the agreement itself, the Commission considers that they are restrictions of competition by object. Indeed, the provisions of the agreement considered together and in their context make it clear that it was an objective aim, a necessary consequence of the agreement to make it impossible, for the term of the agreement, for Merck (GUK) to sell any citalopram in the United Kingdom, in exchange for the transfer of value from Lundbeck.
- (822) Merck (GUK)'s commitment not to sell products containing citalopram existed irrespective of whether or not such citalopram would infringe Lundbeck's process patents. Lundbeck could not have obtained this complete exclusion of Merck (GUK) from the citalopram market in the United Kingdom through court enforcement of its process patents against the process used to produce the citalopram tablets of Merck (GUK), even if Lundbeck had been successful in these efforts, which, in the parties' views expressed at the time, was far from evident when the agreement was concluded.¹⁵¹³
- (823) As explained, there was no commitment from Lundbeck in the agreement that Lundbeck would refrain from infringement proceedings if Merck (GUK) entered the market with generic citalopram after expiry of the agreement.¹⁵¹⁴ Moreover, the

¹⁵¹³ The commitments therefore fell both within the scope of Lundbeck's patents and outside. As explained in recitals (659) and (660) above, the Commission also considers such commitments within the scope of the patent illegal if they are induced by a transfer of value from the originator undertaking.

¹⁵¹⁴ See recital (769) above.

agreement did not identify any process patents that Lundbeck would have alleged to be infringed. The agreement therefore essentially ensured that Merck (GUK) could not sell generic citalopram during the term of the agreement, without any guarantee of market access thereafter.

(824) The Commission therefore concludes that the agreement examined in this section, including in particular the facts that:

- Lundbeck and Merck (GUK) were at the moment when they concluded their agreement at least potential competitors in the United Kingdom market, and actual competitors before the second extension of their agreement of 6 August 2003;
- Lundbeck transferred significant value to Merck (GUK) in the agreement;
- through Merck (GUK)'s acceptance of the obligation *"not to launch the Products subject to payment in accordance with the terms of this Agreement"*¹⁵¹⁵ and instead to *"exclusively purchase" "its requirements" "of the Finished Products"* from Lundbeck, this transfer of value was linked to the acceptance by Merck (GUK) of the limitations on entry in the agreement, notably Merck (GUK)'s commitment not to sell Natco's generic citalopram medicine, or any other generic citalopram, in the United Kingdom between 24 January 2002 and 1 November 2003;
- the transferred value corresponded roughly to the profits Merck (GUK) expected if it had successfully entered the market;
- Lundbeck could not have obtained those limitations on entry through enforcement of its process patents, the obligations on Merck (GUK) in the agreement going beyond the rights granted to holders of process patents; and
- the agreement contained no commitment from Lundbeck to refrain from infringement proceedings if Merck (GUK) entered the market with generic citalopram after expiry of the agreement,

constitutes a restriction of competition by object.

12.3. The agreement between Lundbeck and Merck (GUK) regarding the EEA excluding the United Kingdom restricted competition by object under Article 101(1) of the Treaty

12.3.1. Introduction

(825) The general factual context for the legal assessment of the agreements dealt with in this Decision has been set out in chapters 4 to 6 above. The specific factual context for the legal assessment of the Merck (GUK) agreement related to the EEA excluding the United Kingdom has been set out in sections 3.2, 3.3 and 7.3 above. The general legal context for the assessment of the agreements dealt with in this Decision has been set out in chapters 8 to 11 above. The specific legal assessment of the Merck (GUK) agreement related to the United Kingdom with was concluded before the agreement related to the rest of the EEA has been made in section 12.2. That assessment is also relevant for the Merck (GUK) agreement related to the EEA (excluding the United Kingdom), which was linked to the Merck (GUK) agreement

¹⁵¹⁵ See recital (267) above.

for the United Kingdom.¹⁵¹⁶ Moreover, many of the factors that made Merck (GUK) a potential competitor to Lundbeck in the United Kingdom market also made it a potential competitor to Lundbeck in the remaining EEA.¹⁵¹⁷ The current section will make a specific legal assessment of the Merck (GUK) agreement related to the EEA excluding the United Kingdom, examining its compliance with Article 101(1) of the Treaty, based in particular on the criteria identified in recital (661) and the other factors mentioned in recital (662) above. This assessment will be made in the manner indicated in recital (735) above, taking into account the actual content and objectives of the agreement, the legal and economic context of the agreement, the implementation of the agreement and the intentions of the parties.

12.3.2. The agreement between Lundbeck and Merck (GUK) was an agreement between undertakings within the meaning of Article 101(1) of the Treaty

- (826) Article 101(1) of the Treaty prohibits "agreements between undertakings" that restrict competition. For the general legal assessment of these quoted terms, the Commission refers to section 9.3 above. An agreement within the meaning of Article 101(1) of the Treaty can be said to exist when there is a concurrence of wills between two parties regarding the future behaviour of one or both of them. An undertaking is any entity engaged in an economic activity, such as offering goods or services on a given market, regardless of its legal status and the way in which it is financed. In the present case, Lundbeck and Merck (GUK) were at the time of events economic entities that offered goods on given markets. They were therefore undertakings. As for the "Settlement Agreement" these two undertakings concluded on 22 October 2002 for the EEA excluding the United Kingdom, this document, as signed by H. Lundbeck A/S and Generics [UK] Limited (Merck (GUK)), reflected a concurrence of wills between these two undertakings with respect to the commitments embodied in that document. It therefore qualifies as an agreement between undertakings within the meaning of Article 101(1) of the Treaty.

12.3.3. Lundbeck and Merck (GUK) were at least potential competitors in the EEA (excluding the UK) at the time they concluded their agreement

- (827) For its general legal assessment of potential generic competition for citalopram in the relevant period, the Commission refers to section 9.4 above. By the time Merck (GUK) and Lundbeck entered into a "Settlement Agreement" on 22 October 2002 covering the EEA excluding the United Kingdom, Lundbeck's compound and original process patent had expired in virtually all Contracting Parties to the EEA Agreement (in Austria Lundbeck's compound patent expired in April 2003 only).¹⁵¹⁸ Markets in the EEA were therefore essentially open to generic citalopram, provided it met regulatory requirements as to quality, safety and efficacy, as confirmed by a marketing authorisation. Generic undertakings with a business plan to sell generic citalopram in the EEA (here: excluding the United Kingdom) and a realistic prospect to obtain supplies of generic citalopram medicines and an accompanying marketing authorisation in the near future were potential competitors to Lundbeck and to each other.¹⁵¹⁹ Generic market entry at that time, in particular by several generic companies simultaneously, would, based on existing experience, in all probability

¹⁵¹⁶ Regarding the link see, for example, recital (326) above.

¹⁵¹⁷ Merck (GUK) relied for generic launch on Natco citalopram across the EEA.

¹⁵¹⁸ See recital (111) above.

¹⁵¹⁹ See section 9.4 above.

have set off an intense process of price competition that would have reduced prices for citalopram (in any case generic citalopram and possibly also Lundbeck branded citalopram) quickly and steeply.

- (828) At the time of the conclusion of the agreement, Merck (GUK) had a (development and) supply agreement dated 15 May 2001 with Schweizerhall Pharma International GmbH for generic citalopram API produced by Natco. This agreement made Schweizerhall for a period of eight years the preferred API supplier for certain designated EEA countries (namely Germany, France, Finland, Norway, Sweden, Belgium, the Netherlands, Spain and Italy), and Merck (GUK) the "preferred customer". Merck (GUK) would use this API to produce finished dosage forms of citalopram and agreed with Schweizerhall to apply for marketing authorisation in those designated countries.¹⁵²⁰ Lundbeck's offer to Natco to purchase Natco's citalopram API or intermediates had already been rejected in February 2001¹⁵²¹. Before concluding the agreement, Merck (GUK) was able to build up considerable stocks of Natco citalopram for launch.¹⁵²²
- (829) On 3 May 2002, NM Pharma, Merck (GUK)'s Swedish supplier, received a marketing authorisation in Sweden and started selling on the Swedish market on 21 May 2002.¹⁵²³ NM Pharma also had a strong distribution network in Norway and intended to use its Swedish marketing authorisation to obtain marketing authorisations in Norway, Finland, Denmark, the Netherlands, Belgium and Spain through the 90 day mutual recognition procedure.¹⁵²⁴
- (830) Merck (GUK), from its side, intended to follow a similar mutual recognition procedure based on its own United Kingdom marketing authorisation (which it had obtained on 9 January 2002¹⁵²⁵) for Ireland, France, Germany, Austria, Italy, Portugal and Greece. Merck (GUK) planned to also use other Merck Generics' subsidiaries for generic citalopram sales.¹⁵²⁶ Together, Merck (GUK) and NM Pharma could thus within a matter of months be in possession of marketing authorisations for Natco citalopram for most EEA markets. In September 2002, one month before Merck (GUK) and Lundbeck concluded their agreement, Lundbeck assessed internally that Merck (GUK) and NM Pharma would obtain marketing authorisations in these countries by October or November 2002 and that generic Natco citalopram would "*hit the market in Q1 2003.*"¹⁵²⁷
- (831) Point D of the preamble of the agreement recognised Merck (GUK)'s role as potential competitor of Lundbeck in the EEA: "*GUK is a distributor in the Territory of pharmaceutical products containing Citalopram manufactured by or on the basis*

¹⁵²⁰ See recital (235) above.

¹⁵²¹ See recitals (229) to (232) above.

¹⁵²² See recital (332) above.

¹⁵²³ See further recitals (836) and (837) below.

¹⁵²⁴ See recital (326) above.

¹⁵²⁵ See recitals (258) and (741) above.

¹⁵²⁶ See recital (328) above. In Germany, Merck dura had been selling citalopram from Tiefenbacher since April 2002, but Merck dura could have switched to Natco citalopram once a marketing authorisation for Natco citalopram had been obtained in Germany.

¹⁵²⁷ See recital (342) above. After concluding the agreement with Lundbeck and during the agreement's operation, Merck obtained further marketing authorisations based on Natco's Master Drug File in Austria, Belgium, Norway, Denmark, Luxemburg, Germany, Finland, Portugal, Ireland and France. See recital (347) above.

of deliveries from Natco Ltd.”¹⁵²⁸ With respect to the geographic scope, this recognition encompasses the entire Territory for which the agreement was concluded. The agreement further explained “...GUK has sold in the Territory [Citalopram] since the launch (31 May 2002) to 1 October 2002...”¹⁵²⁹

- (832) The Commission concludes that these facts evidence concrete realistic possibilities of Merck (GUK)'s market entry with generic citalopram in one or more Contracting Parties of the EEA Agreement (excluding the United Kingdom) in the near future. Moreover, Merck (GUK) actually entered the market in May 2002 in Sweden for five months through the Swedish supplier NM Pharma.¹⁵³⁰ As recognised by the parties in the agreement itself, Merck (GUK) and Lundbeck were therefore at least potential competitors at the time they concluded their agreement in October 2002, and actual competitors in Sweden before concluding the agreement. Indeed, the very fact that Lundbeck agreed to transfer considerable value to Merck (GUK) if it accepted not to enter other EEA markets than the United Kingdom with generic citalopram for the term of the agreement shows that Lundbeck considered that Merck (GUK) market entry in one or more EEA markets other than the United Kingdom was plausible and that Lundbeck perceived Merck (GUK) as a competitive threat to its position in those markets.

12.3.4. The possibility of infringement of Lundbeck's process patents did not prevent Merck (GUK) from being at least a potential competitor to Lundbeck

Introduction

- (833) This section responds to the arguments raised by Lundbeck¹⁵³¹, Merck KGaA¹⁵³² and GUK¹⁵³³ claiming that there could be no potential competition between Lundbeck and Merck (GUK) when they concluded their agreement because both parties considered at that time that Natco citalopram, on which Merck (GUK)'s generic citalopram was based, may have infringed Lundbeck's crystallisation patent.¹⁵³⁴ This section will show that at the time of the conclusion of the agreement in October 2002, despite Merck (GUK)'s concerns over Lundbeck's process patents, Merck (GUK) had real concrete possibilities of continuing selling generic citalopram in Sweden and entering other EEA markets in the near future. Moreover, evidence shows that the parties thought that a court might not have found Lundbeck's patents valid and infringed.
- (834) With respect to the patent situation in the EEA for generic citalopram, the Commission refers to its general considerations in recitals (745) and (746) above. These general considerations, notably those regarding the inherent difficulty of enforcing process patents and regarding the risk that a court might hold the crystallisation patent invalid, also apply, in principle, to other Contracting Parties of the EEA Agreement.

¹⁵²⁸ See ID 8, page 228.

¹⁵²⁹ ID 8, page 229.

¹⁵³⁰ See further recital (837) below.

¹⁵³¹ ID 5394, pages 13, 148-156; see also pages 117-139. Regarding Lundbeck's claim that Natco citalopram was infringing see footnote 1300 above.

¹⁵³² In particular ID 5960, pages 112-159, 193-246, and 282-307. See also pages 247-265.

¹⁵³³ ID 6026, pages 9-70. See also recital (630) above.

¹⁵³⁴ Merck (GUK) considered also another of Lundbeck's patents problematic, see recital (248) above.

Merck (GUK)'s market entry and contemporaneous evidence on the patent situation

- (835) With respect to the patent situation for Natco citalopram, the Commission refers to its considerations in recitals (747) to (761) above; recital (753) in particular analyses the parties' contemporaneous views on the risk of patent infringement. A number of those considerations also apply, in principle, to other Contracting Parties of the EEA Agreement than the United Kingdom.
- (836) In reply to the Statement of Objections, Merck KGaA argued that Merck (GUK) "*could not be certain that it would prevail in patent litigation against Lundbeck*" in other EEA markets.¹⁵³⁵ The Commission considers that potential competition precisely existed, because it was far from certain whether a judge would have found Lundbeck's patents to be valid and infringed by Merck (GUK). For instance, with respect to the risk of infringing Lundbeck's process patents in Sweden at the time, Merck (GUK) considered in June 2001 that "*There is also a high risk (75%) that [if we sell Natco citalopram in Sweden via NM Pharma] they [Lundbeck] will sue us on the grounds of process or quality or both...If we are sued we perceive there will be a low risk (15%) of being enjoined based on the fact that we clearly follow the synthetic process as disclosed in the basic patent. If we are enjoined we believe we have a high potential of winning [the main proceeding] (90%).*"¹⁵³⁶ All in all, Merck (GUK) therefore considered in June 2001¹⁵³⁷ that if it sold Natco citalopram in Sweden there was only a chance of slightly more than 11% per cent¹⁵³⁸ that it would be enjoined and of just over 1% that it would be enjoined and lose the main infringement proceeding.¹⁵³⁹
- (837) Merck KGaA further claimed that "*[a]bsent the EEA Agreement, GUK would not have pursued independent market entry in the countries for which it received marketing authorisations during 2002 and 2003...*"¹⁵⁴⁰ It should not be considered a

¹⁵³⁵ ID 5960, pages 283-290 and 300-301. In support of its argument, Merck KGaA pointed in particular to documents quoted in recitals (241), (331), (338), (355), (357) and footnote 688. See also recital (356) above. Regarding Merck KGaA's argument of "clearing the way" see recitals (757) to (760) above, which are relevant also for the remaining EEA.

¹⁵³⁶ See recital (313) above.

¹⁵³⁷ Whether this risk estimate already considered infringement risks from Lundbeck's crystallisation patent or not could not be established with certainty, see footnote 622.

¹⁵³⁸ $0.75 \text{ times } 0.15 = 0.1125$.

¹⁵³⁹ $0.75 \text{ times } 0.15 \text{ times } 0.1 = 0.01125$.

¹⁵⁴⁰ See ID 5960, pages 300-301. In reply to the Statement of Objections, GUK further submitted that the Commission should have established the likelihood of entry under any scenario in every EEA market, see ID 6026, pages 95-99. Similar arguments were made by Lundbeck, ID 5394, pages 153-156. However, firstly, performing such an exercise is not required, because the agreement clearly covered the entire EEA (without the United Kingdom). As the agreement made it impossible for Merck (GUK) for the duration of the agreement to seek entry throughout the EEA (without the United Kingdom), all EEA markets (excluding the United Kingdom) were effectively foreclosed to Merck (GUK) reducing or eliminating Merck (GUK)'s incentives to compete through pursuing its independent efforts to enter. Therefore, it is no longer possible to reconstruct absent the agreement which national markets Merck (GUK) would have exactly entered and when. In this respect, it also has to be borne in mind that the very nature of potential competition implies that actual competition is not yet certain, although in the present case, Merck (GUK) did actually enter through NM Pharma in Sweden. As concerns NM Pharma, it was sufficient to demonstrate that Merck (GUK) stopped supplying the Swedish market through NM Pharma, and thus competing. Secondly, recital (838) above identifies by name all the national markets in the EEA where, shortly before the agreement with Lundbeck was concluded, Merck (GUK) and NM Pharma intended to sell in the near future. This covered most EEA Contracting Parties

potential competitor, because *"in all likelihood GUK's citalopram would have been excluded from the market rapidly after launch"*.¹⁵⁴¹ Merck KGaA also claimed *"it is evident that Lundbeck would initiate legal proceedings against NM Pharma in Sweden shortly"*.¹⁵⁴² The Commission notes that the only market where Merck KGaA's and GUK's allegations were ever put to the test was, in fact, Sweden. As already explained in recital (829), in reality Merck (GUK) started selling Natco citalopram through NM Pharma on the Swedish market on 21 May 2002.¹⁵⁴³ Shortly thereafter, during negotiations for the EEA agreement, Lundbeck threatened Merck (GUK) with infringement litigation against NM Pharma in Sweden;¹⁵⁴⁴ this shows that Lundbeck perceived Merck (GUK) as a competitive threat.¹⁵⁴⁵ On 23 October 2002, after five months of *"encouraging"*, very profitable sales with huge growth rates¹⁵⁴⁶ NM Pharma complained to Merck (GUK) about the market withdrawal which Merck (GUK) was imposing: *"Please be informed that Lundbeck has not claimed that NM Pharma is infringing any patent rights, nor do we have knowledge of any request for a preliminary injunction or other legal action against NM Pharma."*¹⁵⁴⁷ Lundbeck's plan of June 2002 to *"pursue NM Pharma in court"*¹⁵⁴⁸ thus never materialised, although Lundbeck had not hesitated to bring injunction proceedings against Ratiopharm, Biochemie and Gea in Sweden, while internally concluding *"This left only NM Pharma in Sweden"*.¹⁵⁴⁹ In October 2002, while preparing a justification letter for its market withdrawal to NM Pharma, Merck (GUK) wondered: *"any idea why it is that Lundbeck have not tried to sue?"*¹⁵⁵⁰ Contrary to the parties' argument that Merck (GUK) would have not pursued independent market entry, these facts show that Merck (GUK) actually entered through NM Pharma in Sweden, that is to say in the "Territory". Its generic citalopram was not excluded from the market. Nor can it be considered as *"evident"* that Lundbeck would have initiated infringement litigation; in fact in Sweden, it did not. Merck (GUK) could have therefore pursued similar efforts to enter with generic citalopram in other EEA markets.

- (838) Internally, moreover, even after Lundbeck's crystallisation patent had been granted in Sweden on 16 April 2002 and by the EPO on 4 September 2002, Merck (GUK) considered that the Natco process was *"not infringing"*.¹⁵⁵¹ On 23 October 2002, one day after concluding the agreement with Lundbeck, Merck (GUK) wrote in an

and the by far largest markets. This is the relevant point in time to determine whether potential competition existed.

¹⁵⁴¹ ID 5960, page 293. See further pages 292-295, 304-305, and 314.

¹⁵⁴² ID 5960, page 294, pointing to the e-mail discussed in recital (326) above; see also GUK's reply, ID 6026, page 50 and its arguments at pages 64-66: *"it was certainty that Lundbeck would have initiated litigation the instant that GUK attempted to enter the market"*.

¹⁵⁴³ See recital (325) above. These sales suggest that Merck (GUK) was pursuing its United Kingdom strategy of "either entry" or a "lucrative deal" with Lundbeck also outside the United Kingdom.

¹⁵⁴⁴ See recital (326) above.

¹⁵⁴⁵ See recital (613) above.

¹⁵⁴⁶ See recitals (325) and (336) above. In September 2002, Lundbeck's attempts to conclude an agreement with NM Pharma in Sweden failed, when NM Pharma informed Lundbeck it could not, under NM Pharma's Antitrust Policy, enter into such discussions with Lundbeck. See recital (190) above.

¹⁵⁴⁷ See recital (356) above.

¹⁵⁴⁸ See recital (335) above.

¹⁵⁴⁹ See ID 904, page 265.

¹⁵⁵⁰ See footnote 692 above.

¹⁵⁵¹ See recital (323) above.

internal assessment of the agreement in relation to the Union: *"We are 100% confident that our evidence will show that we do not infringe any of their IP on this product..."*¹⁵⁵² On 24 October 2002, Merck (GUK)'s [employee function]* considered: *"NM know the patent position; we've shown them our evidence and argued before to them directly that there are a large number of patents and that we still don't infringe...including the crystalline base patent... I've tried a different tac, but I am not going to admit that we were wrong in our assessment of the patent situation."*¹⁵⁵³ Long time after having concluded the agreement, on 1 October 2003, Merck (GUK) still considered *"the Natco process follows the prior art and if Lundbeck allege that the process infringes then their claim must be invalid."*¹⁵⁵⁴ Merck (GUK)'s view was also reflected in the preamble of the agreement itself, where Merck (GUK) made clear that *"the validity"* of Lundbeck's patents *"is not admitted by GUK"* and disputed *"that the production method used by Natco Ltd. and/or GUK infringes Lundbeck's intellectual property rights"*.¹⁵⁵⁵

Conclusion

- (839) In sum, the facts analysed in this section 12.3.4 indicate that in October 2002, had it not been for Lundbeck's agreement with Merck (GUK) excluding Merck (GUK) from the other EEA markets than the United Kingdom, there would have been a considerable likelihood that Merck (GUK) would not only have continued to sell Natco citalopram in Sweden via NM Pharma but would in the immediate future also have sought market entry with Natco citalopram products in other EEA markets, whether directly, via other Merck Generics subsidiaries or via NM Pharma. The agreement itself in Point D of the preamble made clear: *"GUK is a distributor in the Territory of pharmaceutical products containing Citalopram..."*¹⁵⁵⁶ Even if Merck (GUK)'s sales of Natco citalopram products in EEA markets might have been countered by infringement proceedings from Lundbeck, Merck (GUK) believed that it had at least a realistic chance that courts would find that the Natco product did not infringe any Lundbeck patents or that Lundbeck's process patents would be overturned. All these factors were conducive to the success of Merck (GUK)'s market entry.
- (840) NM Pharma's successful launch before the conclusion of the agreement, not hindered by any legal action of Lundbeck, vividly demonstrates that Merck (GUK) was a serious potential competitor also in other EEA markets irrespective of potential patent issues, and that these markets were in principle open to generic competition.

¹⁵⁵² See recital (354) above. In reply to the Statement of Objections, Merck KGaA observed that this quote does not suggest that there would not have been any litigation risk. It argued that Merck (GUK)'s employees *"cannot have known for sure"* (ID 5960, pages 304-305) and pointed to the same e-mail which continued stating: *"but in order to [show that we do not infringe] we undoubtedly will have to take part in some long complex court cases which could delay us for some time to come with regard to the full commercial exploitation of the product we now have approved."* See also GUK's reply, ID 6026, page 56. However, Merck (GUK)'s assessment reflects a considerable probability that it was indeed non-infringing and could have not been stopped from selling its generic citalopram through litigation by Lundbeck. See also footnote 1557 below.

¹⁵⁵³ See recital (357) above. See also recital (748) above.

¹⁵⁵⁴ See recital (304) above. In reply to the Statement of Objections, Merck KGaA and GUK correctly pointed out that nevertheless, there was uncertainty as the entire conversation quoted in recital (304) above would show. See ID 5960, pages 303-304; ID 6026, pages 46-48.

¹⁵⁵⁵ See recital (348) above.

¹⁵⁵⁶ See recital (831) above.

The possibility of launch was not purely theoretical but a plausible assumption. The Commission therefore concludes that Lundbeck's process patents did not prevent Merck (GUK) from being an actual competitor through NM Pharma in Sweden, and from being a potential competitor to Lundbeck at the time they concluded their agreement in the remaining Contracting Parties of the EEA Agreement (excluding the United Kingdom).¹⁵⁵⁷

12.3.5. Commitments accepted by Merck (GUK) in the agreement related to the EEA (excluding the UK) with Lundbeck

- (841) In the agreement with Lundbeck related to the EEA (excluding the United Kingdom) of 22 October 2002, Merck (GUK) accepted two sets of commitments: (i) the commitment not to launch citalopram products based on Natco's API and based on API from other API producers; (ii) the commitment to use all reasonable efforts to ensure that Natco ceases to supply citalopram products in the Territory. The Commission establishes below in the remainder of this section 12.3 that these commitments limited Merck (GUK)'s freedom of action on EEA markets other than the United Kingdom and constitute restrictions of competition in breach of Article 101 of the Treaty. These commitments are examined in this section in turn.

12.3.5.1. Merck (GUK)'s commitment to cease the sale and supply of pharmaceutical products containing citalopram in the territory

- (842) According to Article 1.1 of the "*Settlement Agreement*" dated 22 October 2002 related to the EEA excluding the United Kingdom, Merck (GUK) committed, "*subject to payment of the Settlement Amount*" to "*cease the sale and supply of pharmaceutical products containing Citalopram in the Territory to its Affiliates and/or any third party (including, without limitation, ceasing to sell and supply NM Pharma AB) during the term of this Agreement...*" The agreement listed specific patents, namely the national equivalents of Lundbeck's crystallisation patent; regarding the possibly underlying dispute, the agreement stated "*the outcome [of litigation ...] cannot be predicted with absolute certainty*".¹⁵⁵⁸
- (843) Regarding the "*Citalopram*" covered by Merck (GUK)'s commitment to "*cease the sale and supply of pharmaceutical products containing Citalopram*", the Commission considers that this commitment was all-encompassing and covered any citalopram.
- (844) In any case, the Commission considers that the commitment made it in any case contractually impossible for Merck (GUK) to continue to sell generic citalopram produced by Natco in the EEA excluding the United Kingdom (the "Territory") during the term of the agreement, including to other Merck Generics subsidiaries and to NM Pharma. The term of the agreement was 12 months.¹⁵⁵⁹ This commitment provided Lundbeck with certainty that Merck (GUK) would no longer sell Natco citalopram through NM Pharma or launch generic citalopram based on Natco API itself in those EEA markets covered by the agreement. Merck (GUK)'s obligations existed irrespective of whether or not Natco citalopram medicine would infringe

¹⁵⁵⁷ See recital (838) above.

¹⁵⁵⁸ See recital (348) above.

¹⁵⁵⁹ See Articles 3.1 and 1.2.

Lundbeck's process patents.¹⁵⁶⁰ That the "Citalopram" mentioned in the agreement covered Natco citalopram is confirmed by the parties.¹⁵⁶¹

- (845) Lundbeck argued in its reply to the Statement of Objections that the words "*pharmaceutical products containing Citalopram*" in Article 1.1 should be interpreted to mean "*pharmaceutical products containing Citalopram from Natco*", based on the fact that Merck (GUK) had intended to sell Natco citalopram products and based on preambles D, F and G of the agreement.¹⁵⁶² The Commission sees no justification for this restrictive interpretation. Firstly, such an interpretation is in contradiction with the plain meaning of the words used in Article 1.1. The drafters of the agreement knew very well how to use precise language to designate citalopram from Natco. For instance, preamble D says that "*GUK is a distributor in the Territory of pharmaceutical products containing Citalopram manufactured by or on the basis of deliveries from Natco Ltd. ("Natco")*". When then Article 1.1 says that "*GUK shall cease the sale and supply of pharmaceutical products containing Citalopram in the Territory...during the term of this Agreement*" this obviously means something more than just citalopram from Natco. This interpretation is further supported by preamble G which explains that "*GUK has disputed that the production method used by Natco Ltd. and/or GUK infringes Lundbeck's intellectual property rights*". "And/or" means necessarily also other than Natco's GUK citalopram production methods. Secondly, it does not follow logically that simply because Merck (GUK) had intended to sell citalopram from Natco or had a contract to buy all its requirements from Natco until 2008, its commitment to refrain from selling during the term of the agreement should also be limited to citalopram from Natco. Quite the contrary, given that Lundbeck did "*not want a generic on the market*", as it told Merck (GUK) in the context of the United Kingdom agreement¹⁵⁶³, making it thereby an objective aim of the agreement, it was logical for Lundbeck to take no risk and to insist that Merck (GUK) should not sell any generic citalopram, whether from Natco or any other API supplier ("*and/or*"). By buying an already existing marketing authorisation, Merck (GUK) could have entered markets in the EEA without much delay. Thirdly, this restrictive interpretation would be inconsistent with Article 1.3 of the Agreement. Article 1.3 states that "*During the term of this Agreement, Lundbeck undertakes not to initiate legal proceedings against GUK based on any of the patents set out in Appendix A provided that GUK observes the obligations set out in Article 1.1.*" If the obligation under Article 1.1 were limited to not selling Natco citalopram, as Lundbeck now argues, Lundbeck would have been prevented from taking legal action against sales by Merck (GUK) of citalopram from other API suppliers, as

¹⁵⁶⁰ See recital (892) below.

¹⁵⁶¹ See recital (845) above and footnote 1562 below.

¹⁵⁶² See ID 5394, pages 157 to 159; similar arguments were made by Merck KGaA and GUK in their reply to the Statement of Objection mainly based on the preamble, ID 5960, pages 135-136, 307-308 and 316-317 and ID 6026, pages 15-17. Merck KGaA further argued that Merck (GUK) would have been bound to purchase citalopram from Natco and no other generic citalopram would have been available. See ID 5960, pages 308-309. A similar argument was made by GUK in ID 6026, pages 11-14. However, contracts may be terminated. It is not clear that no other generic citalopram would have been available given that Lagap had launched beginning of October 2002 with apparently non-infringing Matrix product in the United Kingdom. Moreover, as explained before, even if switching to another source had looked difficult at the time of concluding the agreement, this certainly neither explains nor justifies any commitment which restricted Merck (GUK)'s autonomy in this respect.

¹⁵⁶³ See recital (255) above.

Merck (GUK) would still have been complying with its obligations under Article 1.1. That Lundbeck would voluntarily give up any legal defence against Merck (GUK)⁷ sales from other API suppliers than Natco is, however, difficult to imagine.¹⁵⁶⁴ Fourthly, even if the preambles of the agreement had left any uncertainty with respect to the correct interpretation of the precise obligations for Merck (GUK) deriving from Article 1.1, this would not have changed the anti-competitive result in the present case of Merck (GUK) being excluded from the generic citalopram market as a document of Merck (GUK) shows: "*if we [Merck (GUK)] do sign any agreement at a fair price there will be no attempt at 'circumventing it'*"¹⁵⁶⁵. This latter document also shows why it is not surprising, as Merck KGaA pointed out, that there was no sign that Merck (GUK) made, or could have made, any attempt to source generic citalopram. Contrary to Merck KGaA it is therefore also irrelevant, whether or not Tiefenbacher could or would have supplied Merck (GUK), and on which terms. Finally, whether or not *ex post facto* other generic companies entered during the term of the agreement is also irrelevant. This is not only so, because *ex ante* the parties could not know whether other generic companies would enter, but also because entry of other generic companies could not put into question the commitments Merck (GUK) made in Article 1.1.

- (846) The Commission concludes on this point that through Article 1.1 of the agreement, Merck (GUK) committed not to sell and not to supply any generic citalopram in the EEA excluding the United Kingdom during the term of the agreement, including to other Merck Generics subsidiaries and to NM Pharma. The broad scope of this commitment clearly exceeded the substantive scope of Lundbeck's process patents since it also necessarily included citalopram that would not infringe those patents. Lundbeck could not have obtained this complete exclusion of Merck (GUK) from citalopram markets in other countries than the United Kingdom through court enforcement of its process patents even if Lundbeck had been successful in litigation efforts, which was far from evident when the agreement was concluded. These two aspects, that Merck (GUK) was prohibited from selling citalopram from any supplier whatsoever and whether or not the citalopram in question infringed Lundbeck's patents, indicate that the objective aim of the agreement was to exclude Merck (GUK) completely from the generic market for citalopram in the other Contracting Parties of the EEA Agreement than the United Kingdom for the term of the agreement.
- (847) It should be noted, moreover, that there was no counterpart to these commitments in the form of any commitment from Lundbeck that it would refrain from infringement proceedings in the period after expiry of the agreement, if Merck (GUK) entered the market with generic citalopram at that time. The agreement therefore postponed the issue of potential generic market entry by Merck (GUK); it did not aim at resolving or terminating any patent dispute.¹⁵⁶⁶ Moreover, even though Article 1.5 stipulated that during the term of the agreement the parties would use all reasonable efforts to

¹⁵⁶⁴ See in this respect recital (246) above. See also recital (367) above, where Merck (GUK) is quoted as saying: "...we have an agreement with Lundbeck not to sell in Europe until sometime around the end of October this year... We agreed not to sell citalopram in our EU markets for 1 year..."

¹⁵⁶⁵ See recital (330) above.

¹⁵⁶⁶ Merck (GUK) considered there may be a need to "take on any legal actions Lundbeck might care to engage in" in case of "launch at a later date" (that is to say after expiry of the agreement). See recital (864) below.

resolve their disagreement, Merck (GUK) had to conclude after a year that *"we have written several times to Lundbeck asking for their views and in order to resolve the issues as per the agreement. We have not received a response from them."*¹⁵⁶⁷ Finally, the agreement itself foresaw in Article 4 that after termination, *"any party shall be entitled to exercise and prosecute any intellectual property rights [...] as such party sees fit."*¹⁵⁶⁸

12.3.5.2. Merck (GUK)'s commitment to use all reasonable efforts to ensure that Natco ceases to supply citalopram products in the Territory

- (848) According to Article 1.1 of the agreement, Merck (GUK) committed to *"use all reasonable efforts to ensure that Natco ceases to supply Citalopram and products containing Citalopram in the Territory for the term of this Agreement."* The provision was given teeth by Article 1.2 of the agreement, which provided that *"it is expressly understood and agreed that Lundbeck shall not be required to make any payment pursuant to this Article 1.2 which has not yet fallen due in the event that Natco supplies Citalopram or products containing Citalopram in the Territory during the terms of this Agreement."* Through this commitment Lundbeck tried to ensure, and Merck (GUK) accepted to *"use all reasonable efforts"*, that Natco did not supply citalopram to other Contracting Parties of the EEA Agreement than the

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See recital (367) above. Although Lundbeck did in fact initially respond to some of the letters of Merck (GUK) lawyers, the responses were clearly not considered satisfactory by Merck (GUK). In this exchange of letters, Merck (GUK)'s lawyers repeatedly asked Lundbeck to indicate which patents it thought Merck (GUK) might infringe. In relation to these letters, the parties also argued that the agreement served to "clear the way"; for this argument see recitals (757) to (760) and (815) above; those considerations also apply in the present context. In relation to Article 1.5, in its reply to the Statement of Objections, GUK argued: *"The approach [of Article 1.5] was based on the requirements imposed by the Paroxetine judgment..."* See ID 6026, page 25. However, the Paroxetine judgment was a United Kingdom judgment and could by its very nature not impose any requirements for other EEA countries. Moreover, the Paroxetine judgment required generic undertakings *"to cause the litigation to start" "as soon as [... the generic undertaking] settled upon [...] intending to sell"*. See footnotes 312 and 680 above. Lundbeck further claimed that *"the parties implicitly, and then explicitly linked the agreement to the Lagap proceedings"*. See ID 5394, pages 152-153; similar arguments were made by Merck KGaA, ID 5960, pages 154, 292, 300 and 305, and GUK, ID 6026, pages 25-28. However, there is no evidence in the agreement to support this claim. With respect to certain internal documents that observe Lundbeck's litigation activities throughout the EEA, these are not sufficient to demonstrate that the parties *"implicitly, and then explicitly"* linked the EEA agreement, which moreover excluded the United Kingdom market, to the Lagap litigation which concerned only the United Kingdom. See also recitals (682)-(689) and footnote 1496. This does not mean that the Lagap United Kingdom litigation did not have the potential to help clarifying to a certain extent the scope and interpretation of the crystallisation patent also for other jurisdictions, as Merck KGaA claimed (ID 5960, pages 154-155). However, before it came to that point Lundbeck quickly settled the case to avoid precisely that (i.e. it settled for *"[a]voiding a humiliating defeat which would be used against us in other jurisdictions"*, see recital (161) above). Regarding Merck KGaA's arguments related to interim injunctions (for example ID 5960, pages 309-310) see further footnote 1410. Merck KGaA and GUK further highlighted uncertainty with respect to patent issues (ID 5960, pages 136-140; ID 6026, pages 36-51 and 64-66) and recitals (229), (248), (284) and (303) above). However, uncertainty in itself does not justify the acceptance of payments for market exclusion commitments.

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For Merck KGaA's and GUK's arguments in relation to Article 4 of the EEA agreement see footnote 680 above. Note that Merck (GUK) did not commit in the agreement to refrain from challenging Lundbeck's patents before the courts (even if it had little incentive to do so as long as it was being paid not to sell). Lundbeck, from its side, did agree in Article 1.3 not to initiate legal proceedings against Merck (GUK), but only as long as Merck (GUK) complied with its commitment not to sell generic product. As long as Merck (GUK) refrained from selling, there was in any case, with or without this provision, little incentive for Lundbeck to start legal proceedings against Merck (GUK).

United Kingdom via any other generic suppliers than Merck (GUK).¹⁵⁶⁹ Whether through the efforts of Merck to soothe Natco¹⁵⁷⁰ or otherwise, the desired result of keeping Natco out of the EEA was in fact achieved and Lundbeck paid Merck (GUK) the full amount agreed.¹⁵⁷¹ This provision shows that the objective aim of the agreement was not only to exclude Merck (GUK) from EEA markets with Natco citalopram but also Natco as API supplier to the EEA.

- (849) In its reply to the Statement of Objections, GUK argued that Merck (GUK) had *"neither the legal nor the economic ability to restrict sales by Natco, given its dependence on Natco's supplies"*. GUK's commitment could therefore not even in theory restrict competition.¹⁵⁷² However, the Commission observes that firstly, through the commitment Merck (GUK) restricted its commercial autonomy, because it committed to *"use all reasonable efforts to ensure that Natco ceases to supply Citalopram"*; this is not put into question by GUK. Secondly, Merck (GUK) accepted that all future instalments to be paid by Lundbeck would be subject to Merck (GUK) successfully influencing Natco to stay out of the market. It is likely that a party only accepts such a clause, if it considers having influence on the result that has to be reached (that is to say no Natco product on the market). In fact, thirdly, Natco wrote to Merck (GUK) *"...there is no other licence of formulation with Natco as a source [...] after the unexpected shortcut of needs end of last year [...] there is tremendous uncertainty about when exactly the originally projected quantities will be picked up. This makes us extremely nervous, as you are our only customer."* (Highlighting added.)¹⁵⁷³ This illustrates that Natco considered that it depended on Merck (GUK) for coming to the market. Finally, considering on the one hand Natco's dependency on Merck (GUK) (of which Merck (GUK) was aware) and on the other hand the fact that GUK achieved the contract's goal that Natco stayed out of the market including by pointing out in a letter litigation risks (without, however, mentioning Lundbeck's exclusion payments¹⁵⁷⁴, see recital (352) above), GUK cannot credibly claim that its commitment was not liable to restrict competition. In fact, Lundbeck rewarded Merck (GUK) by paying all instalments for the success that Natco stayed out of the market.
- (850) The Commission therefore concludes that Merck (GUK)'s commitment had the purpose to eliminate Natco as an API supplier to the EEA markets covered by the

¹⁵⁶⁹ A comparison of the draft agreement of 6 June 2002 and the agreement actually concluded on 22 October 2002 indicates that Lundbeck must have been aware that Merck (GUK) was not the exclusive distributor of Natco in the EEA. See recitals (330) and (331). See also ID 5960, page 321. In its reply to the Statement of Objections, however, GUK argued that because Lundbeck would have incorrectly believed at the time that Natco had an exclusive supply agreement with Merck (GUK), Article 1.1 therefore could not, and did not, reflect a concurrence of wills. See ID 6026, pages 17-18. However, even if GUK's allegation were correct which does not appear to be the case, this argument misses that Article 1.1 imposed on Merck (GUK) a clear and agreed obligation to *"use all reasonable efforts to ensure that Natco ceases to supply Citalopram"*. As the parties' concurrence of wills regarding this obligation was clearly expressed in their agreement, possible hidden beliefs or motives of Lundbeck must remain irrelevant. See also footnote 1571.

¹⁵⁷⁰ See recital (352) above.

¹⁵⁷¹ See recital (363) above.

¹⁵⁷² See ID 6026, page 18.

¹⁵⁷³ See recital (352) above.

¹⁵⁷⁴ See recital (352) above.

agreement, a result Lundbeck had failed to obtain in direct negotiations with Natco.¹⁵⁷⁵

12.3.6. *Lundbeck transferred considerable value to Merck (GUK) in exchange for Merck (GUK)'s commitments under the agreement*

- (851) Article 1.1 of the agreement explicitly made Merck (GUK)'s commitments to stop selling Natco citalopram in other Contracting Parties of the EEA Agreement than the United Kingdom and to try to prevent Natco from supplying citalopram API to those countries "*subject to payment of the Settlement Amount*". This shows a direct link between the payment by Lundbeck of money and Merck (GUK)'s acceptance of the commitments identified in section 12.3.5 above. In the absence of any other counter-performance by Merck (GUK), Lundbeck's payment of EUR 12 million was therefore a clear inducement to Merck (GUK) to give up its independent efforts to enter other EEA markets than the United Kingdom and to try to prevent Natco from supplying citalopram in those markets. In other words, Lundbeck paid Merck (GUK) to stay out of the markets in question and on condition that Natco would stay out as well.
- (852) This is confirmed by the wording of Article 1.2 which stated: "*In consideration of the settlement arrived at between the parties hereto Lundbeck shall pay to GUK EURO 12 million (the "Settlement Amount")*". The words "*in consideration of*" again show a clear link between this payment by Lundbeck and Merck (GUK)'s commitments to stop selling Natco citalopram in other Contracting Parties of the EEA Agreement than the United Kingdom and to try to prevent Natco from supplying citalopram API to the EEA. In the absence of any other counter-performance by Merck (GUK) than its commitments to stop selling Natco citalopram in other EEA Contracting Parties than the United Kingdom and to try to prevent Natco from supplying citalopram API to the EEA, it is clear that the entire amount of EUR 12 million was a transfer of value from Lundbeck to Merck (GUK) to persuade Merck (GUK) to accept those commitments.
- (853) The agreement provided in Article 1.2 that Lundbeck would pay the settlement amount in twelve monthly instalments, the last payment being made "*upon the day of expiry of this Agreement*." Article 1.2 made clear, Lundbeck would only continue its payments as long as Merck (GUK) respected its commitments and succeeded in keeping Natco out of the market.¹⁵⁷⁶ This shows that Lundbeck's payments were directly related to the desired result that both Merck (GUK) and Natco effectively stayed out of the EEA markets in question. In fact, Merck (GUK) and Natco stayed out of the market during the term; the agreement and the payments continued for the full year, until 22 October 2003.
- (854) In its reply to the Statement of Objections, in contradiction to Merck KGaA (for whom the value transfer was pegged to Merck (GUK)'s expected profit)¹⁵⁷⁷ and contesting the calculations contained in recital (350), GUK argued that the value transfer did not constitute a transfer for foregone profits but "*primarily covered the external and internal costs in relation to API supply, distributor compensation and*

¹⁵⁷⁵ See recitals (229) to (232) above.

¹⁵⁷⁶ See recital (848) above.

¹⁵⁷⁷ See footnote 682.

own API processing costs."¹⁵⁷⁸ In support of this claim, GUK pointed in particular to two documents. First, GUK submitted that the profit projections Merck (GUK) had prepared on 6 May 2002 for one year of sales of Natco citalopram after market entry in the EEA¹⁵⁷⁹ would also contain a "cost" column with estimated costs for two different scenarios of EUR 7.2 million and EUR 8.6 million (in case of sales), respectively. These amounts, in GUK's view, would reflect the initial payment sought by GUK of EUR 7.5 million.¹⁵⁸⁰ Therefore, in GUK's view, Lundbeck's payments "*primarily covered the external and internal costs*". The Commission notes, first, that GUK's argument is in plain contradiction to contemporaneous evidence. Merck (GUK)'s internal overview of March 2003 characterised Lundbeck's payments of EUR 12 million clearly and simply as profits.¹⁵⁸¹ Secondly, the documents to which GUK pointed do not support its argument. From the outset it should be noted that Merck (GUK)'s cost projections of the time do not allow the conclusion that those costs would have also occurred, if Merck (GUK) had either not entered or if it had entered only after expiry of the agreement with Lundbeck (in which case it could still sell its stock). In this respect, however, GUK referred to an internal e-mail exchange of 9 and 10 October 2002, which would show in its view that "*...GUK's out-of-pocket costs for API already purchased from Natco in fact amounted to USD 5.1 million (575 kgs at US\$ 3,792,000 for API on hand and on order and 222 kgs at US\$1,302,000 for finished product from the API)*".¹⁵⁸² The Commission notes, however, that according to GUK's e-mail of 9 October 2002, the "575 kgs" at "US\$3,792,000" concerned merely "API on order by Alpha". "On order" suggests that Merck (GUK) had not yet spent that money. In fact, an e-mail of one day later, 10 October 2002, reported: "*I have already put Alpha on hold*".¹⁵⁸³ This means that the "API on order by Alpha", that is to say "575 kgs" at "US\$3,792,000" do not appear to have created any costs for Merck (GUK). Merck (GUK), moreover, did not expect any problems with extending the shelf life of the citalopram raw material already ordered. This means that Merck (GUK)'s API on stock could still be sold later (namely after expiry of the agreement), thereby generating returns. In fact, Merck (GUK) considered at the time that following the deal "*we could start [...] use up most of the existin[g raw material]*". Overall, Merck (GUK) concluded the e-mail exchange which GUK invokes with the conclusion that the proposed deal "*gives us a strong result even taking the below into account*".¹⁵⁸⁴ "The below" referred to Merck (GUK)'s analysis of risks and costs arising from the purchase of API and tablets "*on hand*" and "*on order*".

- (855) Concerning the value transfer overall, the Commission concludes that neither of the parties rebutted the Commission's conclusions on the value transfer by providing

¹⁵⁷⁸ ID 6026, page 82.

¹⁵⁷⁹ See recital (350) above.

¹⁵⁸⁰ ID 675, pages 38-44; ID 682, page 184 (recital (329)). Other documents quoted by GUK are ID 673, page 374 (recital (331)); ID 682, page 190 (recital (332)); ID 683, page 1 (recital (333)); and ID 848, page 39 (recital (337)).

¹⁵⁸¹ See recital (363) above. It should be noted that in that contemporaneous overview, Merck (GUK) did not deduce any costs.

¹⁵⁸² ID 673, pages 386-389 (recital (345)).

¹⁵⁸³ ID 673, page 387 (see recital (345)). The value of 397 Kgs "*on hand at Alpha*" was not specified.

¹⁵⁸⁴ ID 673, page 387 (see recital (345)).

different, legitimate reasons.¹⁵⁸⁵ However, in reply to the Statement of Objections, Merck KGaA claimed that there was no "causal link" between the payment and Merck (GUK)'s commitments given in the agreement; the payment would have simply reflected Merck (GUK)'s negotiating power.¹⁵⁸⁶ The Commission considers on the point of negotiating power that the facts have shown that "*GUK's negotiating power*" regarding the agreement related to the EEA (excluding the United Kingdom) was a direct function of the competitive threat it posed to Lundbeck as potential generic entrant in those EEA markets. The risk for Lundbeck was entry by Merck (GUK) like in Sweden, which would have likely resulted in a steep decline of Lundbeck's profits and correspondingly lower consumer prices.¹⁵⁸⁷

- (856) With respect to the implementation of the agreement, the facts show that Merck (GUK) intervened several times to prevent other Merck Generics subsidiaries from selling Natco citalopram before the expiry of the agreement with Lundbeck. This happened in Austria and France.¹⁵⁸⁸
- (857) The Commission concludes that the above analysis of the objective elements of the agreement shows that in exchange for a payment by Lundbeck to Merck (GUK) of EUR 12 million, Merck (GUK) committed itself to stop selling Natco citalopram in other Contracting Parties of the EEA Agreement than the United Kingdom and to try to prevent Natco from supplying citalopram API to those countries for the period between 22 October 2002 and 22 October 2003.¹⁵⁸⁹

¹⁵⁸⁵ See also recital (801) above. In reply to the Statement of Objections, parties mainly referred to their respective "negotiating power". For Lundbeck see ID 5394, pages 30-32, for Merck KGaA ID 5960, pages 317-321, for GUK's arguments see recital (854) above.

¹⁵⁸⁶ ID 5960, page 319. See also recital 0 above.

¹⁵⁸⁷ See further recital (801) above.

¹⁵⁸⁸ See recital (367) above.

¹⁵⁸⁹ In reply to the Statement of Objections, Merck KGaA argued that the SO failed to take into consideration that "*in most countries where GUK obtained marketing authorisations, other generics were on the market before GUK*". ID 5960, pages 295-299. In Merck KGaA's view, the SO "*failed to establish that GUK aimed at delaying generic entry*" by other generic companies. In Merck KGaA's view, "*the EEA Agreement can therefore not constitute a restriction by object*" (page 299). However, the restriction of competition by object results from the fact that Merck (GUK) committed itself not to enter in EEA markets (excluding the United Kingdom) in exchange for the value transfer. As a result, Natco citalopram was effectively eliminated from those EEA markets covered by the agreement. Lundbeck "had to deal with one generic API source less", and could wait whether other generic companies would manage to come and to stay on the market. The Commission's conclusions under "Legal and economic context of the agreement" demonstrate that Merck (GUK)'s and Natco's citalopram constituted an important source of actual or potential competition. As far as Merck KGaA's argument suggests that individually it could not restrict competition, because there was already abundant generic citalopram competition, the Commission notes that the file does not suggest, nor did Merck KGaA argue, let alone demonstrate, that the market would have already been saturated with generic citalopram at the time the agreement was concluded. In fact, the opposite appears to be true. In February 2003 Merck (GUK) concluded that an overview table "*show[ed] two things: only three markets have generic competition (Sweden, Netherlands and Germany) and only 2536 kilograms have been sold which includes Natco, Matrix, Max, Sumika, Ranbaxy and Fermion material as all those companies are presenting non-infringing material in the market place...*" Moreover, "*the only market fully genericised [which does not even mean: saturated] was Germany*". See recital (362) above.

12.3.7. Intentions of the parties

- (858) This section deals with the intentions of the parties regarding the aim of the agreement. Merck (GUK)'s intentions relevant for the existence of potential competition have already been analysed in sections 12.3.3 and 12.3.4 above.
- (859) Lundbeck's general strategy to delay generic entry has already been described in chapter 6 and briefly summarised in recital (803) above.
- (860) The specific intentions of both parties with respect to this agreement are apparent from a contact between Merck (GUK) and Lundbeck in May 2002. Merck (GUK) told Lundbeck that *"The UK deal has been very beneficial for Lundbeck"* and that Merck (GUK) was *"interested in a new deal."* Lundbeck then asked Merck (GUK) for a *"valuation of a deal"*.¹⁵⁹⁰ In response, Merck (GUK) collected internal sales forecasts for the Contracting Parties of the EEA Agreement concerned and calculated that it could hope to make EUR 14 million in profits in the first year after market entry.¹⁵⁹¹ The *"valuation of a deal"* was therefore based on an assessment of the profit Merck (GUK) could expect from selling Natco citalopram in EEA markets.
- (861) After Lundbeck had offered EUR 7.5 million for a deal, a Merck (GUK) employee wrote: *"If Merck and Natco are Lundbeck's worst nightmare they can afford to pay more for the advantage they get. Our patent position is strong..."*¹⁵⁹² Finally, after much haggling about the price Merck (GUK) asked for staying out of the market, Merck (GUK) could report: *"We have an 'agreed offer' on the table...The deal is for 12 months which means that, depending on a possible further lucrative extension, we could start manufacture again mid-2003 and use up most of the existin[g raw material]."*¹⁵⁹³ The core elements of the deal are again clear from this quote: *"12 months"* of delay in generic entry by Merck (GUK) in exchange for a *"lucrative"* reward.
- (862) This *"lucrative"* award of EUR 12 million corresponded in fact to the profits Merck (GUK) could have hoped to make if it had sold Natco citalopram in a number of EEA markets in the year following the date of the agreement.¹⁵⁹⁴ This meant that if Merck (GUK) was willing to give up its intentions to sell generic citalopram in other EEA markets than the United Kingdom and succeeded in preventing Natco from selling in the EEA through other suppliers, Lundbeck was willing to pay Merck (GUK) the same level of profit without any of the efforts and commercial risks inherent in Merck (GUK) pursuing its own independent commercial strategy.
- (863) Making the payment to Merck (GUK) dependent on Natco remaining out of EEA markets for the term of the agreement also shows that Lundbeck's intentions of market exclusion in this agreement even went beyond those in the earlier agreement with Merck (GUK) regarding the United Kingdom, to the extent that the latter only dealt with Merck (GUK)'s own sales, not those of its generic supplier Natco.¹⁵⁹⁵

¹⁵⁹⁰ See recital (326) above.

¹⁵⁹¹ See recital (328) above.

¹⁵⁹² See recital (330) above.

¹⁵⁹³ See recital (345) above.

¹⁵⁹⁴ See recital (350) above.

¹⁵⁹⁵ It is possible that at the time of the conclusion of the United Kingdom agreement, in January 2002, Lundbeck believed that Merck (GUK) was Natco's exclusive distributor in the United Kingdom.

- (864) One day after the agreement, Merck (GUK) in an internal assessment gave the following reasons for entering into the agreement with Lundbeck:

"We are 100% confident that our evidence will show that we do not infringe any of their IP [intellectual property] on this product but in order to do this we undoubtedly will have to take part in some long complex court cases which could delay us for some time to come with regard to full commercial exploitation of the product we now have approved.

As always we are happy to defend our rights in this case but we felt on balance that the collaboration with Lundbeck was the better option for the TIME BEING. The agreement allows us to obtain a return on our investment in this product and does not in any way compromise our ability to launch at a later date and take on any legal actions Lundbeck might care to engage in. All-round given the short term nature of the agreement (12 months) we feel this is the option we should choose at this time."¹⁵⁹⁶

The "full commercial exploitation" and "return on our investment in this product" Merck (GUK) is talking about in fact refers to the EUR 12 million Lundbeck paid to Merck (GUK) for not selling the product for a year.¹⁵⁹⁷

- (865) With respect to additional intentions of the parties concerning patent issues which are to a certain degree evidenced by Point H of the preamble and certain other documents¹⁵⁹⁸, the Commission refers to its considerations in recitals (809) to (815) and in footnote 1410 above. As already explained, clearly anti-competitive objectives, to be paid profits by the competitor for withdrawing from the market¹⁵⁹⁹, are not put into question by additional objectives related to uncertain patent rights that Lundbeck or Merck (GUK) may have pursued.
- (866) The Commission concludes from the facts described in this section 12.3.7 that both parties knew or should have known that their agreement was anti-competitive.

However, by October 2002, when it concluded the agreement for the rest of the EEA, Lundbeck knew better. See footnote 681 above.

¹⁵⁹⁶ See recital (354) above.

¹⁵⁹⁷ In reply to the Statement of Objections, Merck KGaA argued that GUK "was deterred from market entry [...] notably [by] the grant of the crystallisation patent [...] and the beginning of the Lagap litigation on 14 October 2002". See ID 5960, pages 300-301. However, internal contemporaneous reflections of Merck (GUK) such as "we do not have a patent problem at all" as witnessed "by expert statements" suggest that instead rather the "valuation of a deal", that is to say Lundbeck's compensation for staying out of the market, and "depending on a possible further lucrative extension", that is to say the amount of time Lundbeck was ready to pay for, were the determining factors for Merck (GUK) in deciding whether to stay out of the market. In fact, it concluded "if we do sign any agreement at a fair price there will be no attempt at 'circumventing it' with the necessary result that "we [Merck (GUK)] could start manufacture again mid-2003." See footnote 1317. When Merck (GUK) considered to "start manufacture again mid-2003", the patent term of the crystallisation patent played virtually no role while all that mattered was whether Lundbeck would stop paying ("depending on a possible further lucrative extension"). In fact, Merck (GUK) did enter with Natco API, the production process of which was not changed, in various national markets during the term of the crystallisation patent.

¹⁵⁹⁸ See in particular recitals (331), (348) and (355). In reply to the Statement of Objections, Lundbeck (ID 5394, pages 157-159), Merck KGaA (ID 5960, pages 312-316) and GUK (ID 6026, pages 19-29) argued that this was their main objective.

¹⁵⁹⁹ See recital (857) above.

12.3.8. The agreement restricted competition to an appreciable degree in other EEA Contracting Parties than the UK

- (867) The Commission refers to sections 6.6 and 11.9 for its considerations on the appreciable degree to which the agreements in question restricted competition and to section 13.2 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 States¹⁶⁰⁰, the Commission does not have to prove an appreciable restriction of competition, but that in any case each (set of) agreement(s) did restrict competition to an appreciable degree.¹⁶⁰¹
- (868) In the specific case of Merck (GUK), the Commission notes that the agreement with Lundbeck covered other Contracting Parties of the EEA Agreement than the United Kingdom. In most national markets within Contracting Parties of the EEA Agreement other than the United Kingdom Lundbeck held at the time when it concluded the agreement with Merck (GUK) market shares considerably exceeding 10%.¹⁶⁰² The appreciable effect on competition of this agreement was even greater because the agreement also aimed at ensuring that Merck (GUK)'s API supplier Natco ceased to supply citalopram to the EEA.

12.3.9. Conclusion on restriction by object

- (869) The facts described and assessed in legal terms in sections 12.3.1 to 12.3.4 above show that at the time the undertakings Merck (GUK) and Lundbeck concluded their agreement of 22 October 2002, they were potential competitors in the EEA markets for citalopram covered by this agreement. As analysed in section 12.3.5 above, under the agreement, Merck (GUK) accepted a number of commitments which ensured that Merck (GUK) would not compete with Lundbeck with citalopram in those EEA markets covered by the agreement during its term, whether with the Natco product Merck (GUK) had purchased or any other generic citalopram product. The agreement also had the purpose to ensure that Natco would not supply other generic companies with API in those EEA markets. As analysed in section 12.3.6 above, Lundbeck transferred considerable value to Merck (GUK) in exchange for Merck (GUK)'s acceptance of these commitments. Section 12.3.7 has shown that this agreement formed part of Lundbeck's strategy to delay generic entry for citalopram and that Merck (GUK) knew or should have known that Lundbeck's transfer of value to it served to persuade Merck (GUK) to accept the commitments in question and thereby to eliminate the incentive for Merck (GUK) to continue its independent efforts to enter with citalopram the EEA markets covered by the agreement during its term.
- (870) Given that Merck (GUK)'s acceptance of these limitations on its commercial autonomy was achieved not by the strength of Lundbeck's patents, but by the transfer of value from Lundbeck to Merck (GUK), the Commission considers that these

¹⁶⁰⁰ See recital (724) above. For the effect on trade between Member States of each (set of) agreement(s), see chapter 13 below.

¹⁶⁰¹ See in particular section 6.6 above. The Commission notes, in this respect, that since each (set of) agreement(s) covered the United Kingdom, where Lundbeck succeeded through the agreements in preventing widespread generic competition from January 2002 to October 2002, each (set of) agreement(s) restricted competition to an appreciable degree in at least one of the markets covered by the agreement.

¹⁶⁰² See recital (215) above.

limitations constitute restrictions of competition within the meaning of Article 101(1) of the Treaty.

- (871) Moreover, since these limitations on Merck (GUK)'s commercial autonomy, obtained by Lundbeck through the transfer of considerable value to Merck (GUK), were by their very nature injurious to the proper functioning of normal competition and followed directly and necessarily from the clauses of the agreement itself, the Commission considers that they are restrictions of competition by object. Indeed, the provisions of the agreement considered together and in their context make it clear that it was an objective aim, a necessary consequence of the agreement to make it impossible, for the term of the agreement, for Merck (GUK) to sell any citalopram in the EEA markets covered by the agreement, in exchange for the transfer of value from Lundbeck.
- (872) Merck (GUK)'s commitment not to sell products containing citalopram existed irrespective of whether or not such citalopram would infringe Lundbeck's process patents. Lundbeck could not have obtained the complete exclusion of Merck (GUK) from citalopram markets in the EEA through court enforcement of its process patents against the process used to produce the citalopram tablets of Merck (GUK), even if Lundbeck had been successful in these efforts, which, in the parties' views expressed at the time, was far from evident when the agreement was concluded.¹⁶⁰³
- (873) As explained, there was no commitment from Lundbeck in the agreement that Lundbeck would refrain from infringement proceedings if Merck (GUK) entered the market with generic citalopram after expiry of the agreement.¹⁶⁰⁴ The agreement therefore essentially ensured that Merck (GUK) could not sell generic citalopram during the term of the agreement, without any guarantee of market access thereafter.
- (874) The Commission therefore concludes that the agreement examined in this section, including in particular the facts that:
- Lundbeck and Merck (GUK) were at the moment when they concluded their agreement at least potential competitors in the EEA markets covered by this agreement;
 - Lundbeck transferred significant value to Merck (GUK) in the agreement;
 - this transfer of value was linked to the acceptance by Merck (GUK) of the limitations on generic entry in the agreement, notably Merck (GUK)'s commitment not to sell any generic citalopram in EEA markets other than the United Kingdom between 22 October 2002 and 22 October 2003;
 - the transferred value corresponded roughly to the profits Merck (GUK) expected if it had successfully entered the market;
 - Lundbeck could not have obtained those limitations on entry through enforcement of its process patents, the obligations on Merck (GUK) in the agreement going beyond the rights granted to holders of process patents; and

¹⁶⁰³ The commitments therefore fell both within the scope of Lundbeck's patents and outside. As explained in recitals (659) and (660) above, the Commission also considers such commitments within the scope of the patent illegal if they are induced by a transfer of value from the originator undertaking.

¹⁶⁰⁴ See recital (865) above.

- the agreement contained no commitment from Lundbeck to refrain from infringement proceedings if Merck (GUK) entered the market with generic citalopram after expiry of the agreement,

constitutes a restriction of competition by object.

12.4. The agreement between Lundbeck and Arrow regarding the United Kingdom restricted competition by object under Article 101(1) of the Treaty

12.4.1. Introduction

- (875) The general factual context for the legal assessment of the agreements dealt with in this Decision has been set out in chapters 4 to 6 above. The specific factual context for the legal assessment of the Arrow UK agreement has been set out in sections 3.2, 3.4 and 7.4 above. The general legal context for the assessment of the agreements dealt with in this Decision has been set out in chapters 8 to 11 above. The current section will make a specific legal assessment of the Arrow United Kingdom agreement, examining its compliance with Article 101(1) of the Treaty, based in particular on the criteria identified in recital (661) and the other factors mentioned in recital (662) above. This assessment will be made in the manner indicated in recital (735) above, taking into account the actual content and objectives of the agreement, the legal and economic context of the agreement, the implementation of the agreement and the intentions of the parties.

12.4.2. The United Kingdom agreement between Lundbeck and Arrow was an agreement between undertakings within the meaning of Article 101(1) of the Treaty

- (876) Article 101(1) of the Treaty prohibits "*agreements between undertakings*" that restrict competition. For the general legal assessment of these quoted terms, the Commission refers to section 9.3 above. An agreement within the meaning of Article 101(1) of the Treaty can be said to exist when there is a concurrence of wills between two parties regarding the future behaviour of one or both of them. An undertaking is any entity engaged in an economic activity, such as offering goods or services on a given market, regardless of its legal status and the way in which it is financed. In the present case, Lundbeck and Arrow were at the time of events economic entities that offered goods on given markets. They were therefore undertakings. As for the "*Agreement*" regarding the United Kingdom these two undertakings concluded on 24 January 2002, this document, as signed by H. Lundbeck A/S on the one hand and Arrow Generics Ltd and Resolution Chemicals Ltd (together referred to in the agreement as ARROW) on the other hand, reflected a concurrence of wills between the undertakings Lundbeck and Arrow with respect to the commitments embodied in the document. It therefore qualifies as an agreement between undertakings within the meaning of Article 101(1) of the Treaty.

12.4.3. Lundbeck and Arrow were at least potential competitors at the time they concluded the agreement

- (877) For its general legal assessment of potential generic competition for citalopram in the relevant period, the Commission refers to section 9.4 above. By the time Arrow and Lundbeck entered into an "*Agreement*" on 24 January 2002 covering the United Kingdom, Lundbeck's basic patent on the citalopram compound (which included the two original processes to produce the compound) had already expired on 5 January 2002 in the United Kingdom. This meant that the citalopram market in the United Kingdom was open to generic competition, as generic citalopram medicine could henceforth be freely sold provided it met regulatory requirements as to quality, safety

and efficacy, as confirmed by a marketing authorisation. Generic undertakings with a business plan to sell generic citalopram in the United Kingdom and a realistic prospect to obtain supplies of generic citalopram medicines and an accompanying marketing authorisation in the near future were potential competitors to Lundbeck and to each other.¹⁶⁰⁵

- (878) As described in section 7.4, from the start of its business in 2001 Arrow identified citalopram *"as a major product that it would market shortly after it began trading."*¹⁶⁰⁶ Arrow planned to enter the United Kingdom market still in January 2002, as soon as the compound patent on citalopram expired.¹⁶⁰⁷ On 22 May 2001, Arrow entered into a contract with Tiefenbacher under which it purchased copies of (future) marketing authorisations Tiefenbacher was applying for in a number of countries, including the United Kingdom.¹⁶⁰⁸ Tiefenbacher's marketing authorisations, including the one purchased by Arrow for the United Kingdom, listed two alternative API suppliers, Cipla and Matrix.¹⁶⁰⁹ Initially, however, at least until the moment when Arrow and Lundbeck concluded their agreement, the product Tiefenbacher delivered to Arrow came from Cipla. On 10 September 2001, Arrow ordered DM 2.8 million worth of citalopram tablets from Tiefenbacher. These tablets contained API from Cipla.¹⁶¹⁰ A first shipment arrived in November 2001 and a second shipment in the second week of January 2002. The total number of tablets in the two shipments together (in strengths of 10, 20 and 40 mgs) was 9 222 000.¹⁶¹¹
- (879) In the lead-up to the agreement with Lundbeck, Arrow was in an intense competition with Merck (GUK) to become the first company to enter the United Kingdom market with generic citalopram after the expiry on 5 January 2002 of Lundbeck's compound patent and original process patent for citalopram.¹⁶¹² On 21 December 2001, when Merck (GUK) learned that Arrow's supplier Tiefenbacher had completed the mutual recognition process for obtaining a marketing authorisation in the United Kingdom for citalopram from Matrix and Cipla, Merck (GUK)'s reaction to this news was: *"...this just about puts them [Arrow] back in pole position [for entering the United Kingdom market first]..."*¹⁶¹³ On 27 December 2001, the United Kingdom Medicines Control Agency issued a positive opinion on Arrow's request for a marketing authorisation in the United Kingdom, meaning that normally the issuing of a marketing authorisation would take place within a couple of weeks at most.¹⁶¹⁴
- (880) On 14 January 2002, Arrow met with Lundbeck and informed Lundbeck that it would *"in the very near future"* offer citalopram from Tiefenbacher for sale in the United Kingdom.¹⁶¹⁵ Lundbeck apparently believed that Arrow was about to launch

¹⁶⁰⁵ See section 9.4 above.

¹⁶⁰⁶ See recital (373) above.

¹⁶⁰⁷ See recital (373) above.

¹⁶⁰⁸ See recital (375) above.

¹⁶⁰⁹ See recital (375) above.

¹⁶¹⁰ See recital (379) above.

¹⁶¹¹ See recital (379) above.

¹⁶¹² See recital (738) above.

¹⁶¹³ See recital (257) above.

¹⁶¹⁴ See recital (383) above. A contemporaneous Lundbeck document of 4 September 2002 stated: *"Following the decision [by the appeal court of Amsterdam rejecting Lundbeck's appeal on 12 July 2002] the MCA, UK...issued the national licences. But normally MCA issues within 14 days – this licence took more than 7 months!(emphasis added)"* See ID 904, page 281.

¹⁶¹⁵ See recital (388) above.

generic citalopram from Tiefenbacher into the United Kingdom.¹⁶¹⁶ As Lundbeck stated in its reply to the Statement of Objections: *"Lundbeck believed (with hindsight, wrongly) that Arrow was about to obtain an MA at the beginning of 2002..."*¹⁶¹⁷ On 23 January 2002, one day before concluding the agreement with Lundbeck, Arrow's subsidiary Resolution Chemicals wrote: *"We launch in UK next week..."*¹⁶¹⁸ Both parties seem therefore to have been convinced at the time of the conclusion of their agreement that the granting of Arrow's marketing authorisation for the United Kingdom was imminent and that Arrow would, in the absence of an agreement with Lundbeck, immediately thereafter launch its Cipla product in the United Kingdom market.

- (881) In a statement to the Commission in reply to the Statement of Objections, [employee name]* claimed that *"in early January 2002, we were very much aware of the fact that due to Lundbeck's objection in relation to the grant of the marketing authorisation in The Netherlands, there would be a delay in obtaining the marketing authorisation for the UK via the mutual recognition process. We believed at the time that this delay could run to several months..."*¹⁶¹⁹ However, the proceedings Lundbeck had launched in the Netherlands in October 2001 against the Dutch marketing authorisation, which served as the basis for the mutual recognition procedure in the United Kingdom, clearly did not prevent the United Kingdom Medicines Control Agency from issuing a positive opinion on Arrow's dossier on 27 December 2001. On 25 January 2002, the Objections Committee of the Dutch Medicines Evaluation Board rejected Lundbeck's objection against the issuing of the Dutch marketing authorisation.¹⁶²⁰ Up until the moment of conclusion of the agreement with Lundbeck on 24 January 2002, Arrow could therefore have expected that either the United Kingdom Medicines Control Agency would, in accordance with its positive opinion, issue a United Kingdom marketing authorisation in days to come or at the latest after this rejection of Lundbeck's objection in the Netherlands. Arrow could not have known, at least not with any degree of certainty, that Lundbeck would appeal this decision in the Netherlands and that in fact the United Kingdom authorities would wait until Lundbeck's appeal had been rejected in the Netherlands in July 2002 before issuing the United Kingdom marketing authorisation.
- (882) However, even if Arrow had expected to be able to sell generic citalopram in the United Kingdom only as of July 2002, this was well within the initial term of the agreement Arrow concluded with Lundbeck (which ended on 31 December 2002; the agreement was then twice extended until 20 October 2003). Even then, therefore, the Commission would still consider that market entry was possible *"with sufficient speed to form a constraint on market participants"*.¹⁶²¹ Indeed, the fact that the ability and likelihood of Arrow's market entry in the near future in the United Kingdom constrained Lundbeck and was perceived by Lundbeck as a competitive threat is clearly shown by the fact that Lundbeck offered Arrow a considerable transfer of value if it accepted not to enter.

¹⁶¹⁶ See recital (391) above.

¹⁶¹⁷ ID 5394, page 193.

¹⁶¹⁸ See recital (390) above.

¹⁶¹⁹ ID 6070, page 6.

¹⁶²⁰ See recitals (168) and (257) above.

¹⁶²¹ See recital (612) above.

- (883) The Commission concludes from the concrete realistic possibility Arrow had at the time of conclusion of the agreement with Lundbeck to enter the United Kingdom market with Cipla citalopram in the near future that Arrow and Lundbeck were at least potential competitors at the time they concluded their agreement. Indeed, the very fact that Lundbeck agreed to transfer considerable value to Arrow if it accepted not to enter the United Kingdom market for the term of the agreement shows that Lundbeck considered that Arrow's market entry was plausible and that Lundbeck perceived Arrow as a competitive threat to its position in that market.

12.4.4. The possibility of infringement of Lundbeck's process patents did not prevent Arrow from being at least a potential competitor to Lundbeck

- (884) With respect to the general patent situation in the United Kingdom for generic citalopram, the Commission refers to its general considerations in recitals (745) and (746) above. These general considerations, notably those regarding the fact that Lundbeck's process patents did not cover all possible processes to manufacture citalopram that met United Kingdom regulatory requirements, the inherent difficulty of enforcing process patents and the distinct possibility that a court might hold the crystallisation patent invalid, also apply to Arrow.
- (885) Under clause 6.1 of Arrow's agreement with Tiefenbacher, Arrow had the option upon written notice from time to time to:
- purchase the medicinal products in bulk exclusively from Tiefenbacher for five years after launch in each Member State;
 - manufacture the medicinal products itself or through third parties with API purchased from Tiefenbacher (with a (lower) royalty percentage for Tiefenbacher); or
 - manufacture the medicinal products itself or through third parties with API sourced from an Arrow affiliate (with a higher royalty percentage for Tiefenbacher).¹⁶²²
- (886) In reply to the Commission's request for information of 9 March 2011, Arrow interpreted this contract with Tiefenbacher as follows: *"The contract did not contain an exclusive purchasing obligation (and indeed no obligation to purchase, only an option to do so)...Arrow Group did discuss a possible supply agreement with Tiefenbacher, but as far as it can ascertain this was never concluded."*¹⁶²³ *Under the terms of the contract, Arrow Group was expressly permitted to supply products sourced from third parties, subject to payment of a royalty to Tiefenbacher if it did so [x]% of gross sales if Arrow Group manufactured its own tablets with Tiefenbacher's API (which would have been sourced from either Cipla or Matrix...), or [y]% of gross sales if it manufactured its own tablets with API from a third party..."*¹⁶²⁴

¹⁶²² See Article 6.1 of the agreement, ID 619, page 4.

¹⁶²³ Clause 6.2 of the agreement of 22 May 2001 provided that Arrow and Tiefenbacher would sign a related Supply Agreement in the course of the duration of the current agreement. However, Arrow reported to the Commission that *"Arrow Group considered entering into a supply agreement with Tiefenbacher in Autumn 2002, but as far as it is aware this was not concluded as agreement could not be reached on its terms."* See ID 1297, page 24.

¹⁶²⁴ See recital (375) above.

(887) With respect to Lundbeck's process patents, Arrow had, in the period preceding the agreement with Lundbeck on 24 January 2002, become worried that Cipla's citalopram could infringe Lundbeck's crystallisation patent application in the United Kingdom, in particular if that patent were granted with all of its claims intact.¹⁶²⁵ Nevertheless, Arrow's conclusion from a meeting with Tiefenbacher on 14 December 2001 was that "[an Arrow employee] *has been through the issues surrounding purification of the base and Cipla nad [sic] Matrix seem to be OK.*"¹⁶²⁶ On 15 January 2002, Arrow was informed by Cipla's United Kingdom agent that Cipla "*is quite happy to defend you in court and will make the necessary information available to the appropriate authorities.*"¹⁶²⁷ On 21 January 2002 Lundbeck sent a "cease and desist" letter to Arrow¹⁶²⁸, to which Arrow replied one day later by stating that "*We have looked at these [patents] in some detail and do not believe that we infringe these patents.*"¹⁶²⁹ On 23 January 2002, one day before the agreement with Lundbeck was concluded, Arrow's subsidiary Resolution wrote: "*We launch in UK next week.*"¹⁶³⁰ That Arrow did not believe its product to be infringing is also spelled out in the preamble of the agreement: "*Whereas ARROW does not consider that it infringes the*

¹⁶²⁵ At this time, Arrow and Tiefenbacher were foremost concerned with possible infringement by Cipla of the product claims in Lundbeck's patent application. As mentioned in recital (151) above, Lundbeck's product claims on the crystalline base of citalopram were later found by the EPO and the Dutch Industrial Property Office to lack novelty and therefore invalid. The United Kingdom crystallisation patent GB 2357762, however, was granted including these product claims (as well as including claims regarding pharmaceutical formulations). This meant that the United Kingdom patent was on the one hand more likely to be infringed than without these claims, but on the other hand also more likely to be found at least partially invalid.

¹⁶²⁶ See recital (382) above.

¹⁶²⁷ See recital (387) above. As mentioned in recital (385) above, this e-mail of 15 January 2002 overtook an earlier e-mail of 11 January 2002, in which Cipla's United Kingdom agent had stated that Cipla was "*...supporting Tiefenbacher against Lundbeck. Apparently, Tiefenbacher's first registration was in Holland and it is against them that they are filing a claim, which Cipla are supporting Tiefenbacher in. As there are several other Indian producers of Citalopram, all of whom are infringing, [Cipla] is not willing to make available [its] process to other third parties, as you told us when we met that under your agreement with Tiefenbacher you are free to buy from anyone paying a [y]% royalty.*" Instead, therefore, Cipla proposed on 15 January 2002 to make the necessary information directly available to the appropriate authorities. Earlier, on 14 December 2001, Arrow had considered that "*Cipla are not forthcoming with the actual detail on the process they use. This requires to be shored up if we wish to claim non-infringement. We could strike a deal with Cipla whereby the process could be shown to the court 'in secret' without us seeing the detail. We will need this at least to avoid an injunction.*" See recital (382) above. Cipla's offer of 15 January 2002 therefore seemed to meet Arrow's requirements to claim non-infringement and avoid an interim injunction before the United Kingdom court. The e-mail of 15 January 2002 is the last recorded message from Cipla on this topic before Arrow concluded the agreement with Lundbeck.

¹⁶²⁸ With respect to Lundbeck's patent application GB 2357762, the crystallisation patent, Lundbeck specifically mentioned in the letter to Arrow claims 1 and 12 to 16. It may be recalled that claim 1 of the corresponding patent at the EPO level was later deleted from the amended claims which were eventually upheld by the EPO in 2009. See recital (166) above. It may also be noted that claims 12 to 16 covered product claims and pharmaceutical composition claims. As mentioned in recital (151) above, Lundbeck's product claims on the crystalline base of citalopram as well as its claims regarding pharmaceutical compositions were later found by the EPO and the Dutch Industrial Property Office to lack novelty and therefore to be invalid.

¹⁶²⁹ See recital (389) above.

¹⁶³⁰ See recital (390) above.

Proprietary Rights and/or consider that the Proprietary Rights are valid or enforceable..."¹⁶³¹

- (888) On 25 January 2002, one day after concluding the agreement with Lundbeck, [employee name]* sent an e-mail to Tiefenbacher stating: "[Arrow employee] *told me about the conversation she had with you last Tuesday* [22 January 2002]. *She said that you suggested that Cipla raw material possibly does infringe Lundbeck's patents, although you were not sure either way*".¹⁶³² It is unclear when exactly [employee name]*, who concluded the agreement with Lundbeck, was informed of this news from Tiefenbacher.¹⁶³³ However, Arrow itself stated to the Commission that it was only "*after it had already entered into the Agreement with Lundbeck dated 24 January 2002*" that Arrow realised that, in Arrow's words, "*its product, developed from Cipla's API, infringed Lundbeck's patent GB 2357762, which had been granted on 30 January 2002*".¹⁶³⁴
- (889) At the moment of concluding the agreement with Lundbeck, there was, in the Commission's view, a concrete, realistic possibility that in the absence of the agreement with Lundbeck, Arrow would have continued to co-operate with Tiefenbacher and Cipla to seek entry to the United Kingdom market with the Cipla product it had purchased and in which it had made a significant investment for a start-up company. In its reply to the Statement of Objections, Arrow stated that "*Arrow placed an order in September 2001 for citalopram stock at a cost of DM 2.8 million and, at Tiefenbacher's choice, was provided with stock using Cipla API. Arrow had therefore made a significant investment in stock. Arrow could not simply demand that Tiefenbacher take this product back and supply product using an alternative source. Under the supply agreement, the risk was entirely with Arrow. In addition, having placed an order for such a significant value of stock, Arrow (as a small start-up company) was not in a financial position to simply write off the value of this stock...*"¹⁶³⁵ This statement implies that if Lundbeck had not made Arrow a lucrative offer to stay out of the United Kingdom market, Arrow would have been unlikely to simply give up its efforts to enter the United Kingdom market with the Cipla citalopram it had purchased, given the significant investment it had made in

¹⁶³¹ See recital (393) above.

¹⁶³² See recital (404) above.

¹⁶³³ The statement by [employee name]* which Arrow submitted in reply to the Statement of Objections did not clarify this point, just stating: "*It then became clear that our fears about the Cipla process were correct and one of Arrow's management team...informed me of a discussion that she had with ...Tiefenbacher. I recorded this in an e-mail to [Tiefenbacher] on 25 January 2002.*" See ID 6070, page 5.

¹⁶³⁴ See recital (413) above. Lundbeck argued in its reply to the Statement of Objections that, in practice, generic companies did not bother to challenge Lundbeck's claim of infringement by Cipla before the court, referring to proceedings in the Netherlands. See ID 5394, page 169. However, those proceedings show that non-infringement was in fact argued before the court by Tiefenbacher and endorsed by the generic companies in question. See ID 5450, page 6. Lundbeck also pointed out that Tiefenbacher stated to the Commission that "*Lundbeck obtained copies of the DMF of Cipla and Matrix, which were included in MA application as substitutes for VIS. It can be assumed that the first batches indeed were produced by base crystallization.*" See ID 5394, page 182 and ID 280, page 5. However, that is an *ex post facto* statement of Tiefenbacher, based on hindsight. What matters to determine whether potential competition existed is the *ex-ante* perspective at the time of events.

¹⁶³⁵ ID 6082, page 18. Arrow stated to the Commission that Arrow "*...at that time generated revenue of only USD 18 million...*" See ID 6082, page 25.

Cipla product and the fact that it was *"not in a financial position to simply write off the value of this stock..."*.¹⁶³⁶

- (890) As mentioned in recital (887) above, before entering into the agreement with Lundbeck, Arrow had repeatedly stated that it believed its Cipla product not to be infringing. In order to seek market entry in the United Kingdom with this product, Arrow could, without exposing itself to considerable financial risk, have used the "clearing the way" *Paroxetine* ruling to ask Lundbeck to sue it for patent infringement before Arrow had actually sold any product.¹⁶³⁷ Once Arrow had obtained the marketing authorisation it expected to receive soon, Arrow could also have initially limited any quantities of Cipla citalopram sold on the United Kingdom market to reduce the risk of having to pay considerable damages, as Lagap later did when it entered the United Kingdom market with Matrix citalopram in October 2002.¹⁶³⁸ In such infringement proceedings, Arrow, supported by Tiefenbacher and Cipla¹⁶³⁹, could have argued the non-infringement or invalidity¹⁶⁴⁰ of Lundbeck's United Kingdom crystallisation patent.¹⁶⁴¹ In Lundbeck's later assessment in the

¹⁶³⁶ Arrow's statement in this recital (889) above contradicts the statement by [employee name]* that *"We felt that we had no option but to agree this [the agreement with Lundbeck] because otherwise Arrow would lose out on its investment in the citalopram project..."* (ID 6070, page 7). The relevant question is not whether accepting the agreement with Lundbeck was a more lucrative option for Arrow than losing out on its investment in Cipla citalopram. That is beyond any doubt. The relevant question is what Arrow would have done in the absence of the agreement with Lundbeck.

¹⁶³⁷ See footnote 312 above.

¹⁶³⁸ In October 2002, the generic supplier Neolab actually started selling Cipla citalopram in the United Kingdom. Lundbeck started infringement proceedings and Neolab accepted voluntary injunctions until judgment was given in the Lagap litigation. Following Lundbeck's settlement with Lagap, Lundbeck also settled with Neolab. As part of the settlement, Lundbeck agreed to reimburse Neolab for damages resulting from the sales of Cipla citalopram Neolab could have made between October 2002 and December 2003. See recital (164) above.

¹⁶³⁹ The Commission recalls that on 15 January 2002, Arrow was informed by Cipla's United Kingdom agent that Cipla *"is quite happy to defend you in court and will make the necessary information available to the appropriate authorities."* See recital (887) above. This was the point in time nearest before Arrow's conclusion of the agreement with Lundbeck. After having concluded the agreement with Lundbeck, Arrow may have become disappointed with Cipla's lack of support, but that is irrelevant from an *ex ante* perspective.

¹⁶⁴⁰ In its reply to the Statement of Objections, Arrow claimed that *"there is no evidence that Arrow had found a way to challenge the validity of Lundbeck's Process Patents."* See ID 6082, page 63. However, in the meeting between Tiefenbacher and Arrow on 14 December 2001, participants noted that Cipla's claimed that its production method *"corresponds to that shown in a 1977 patent."* See recital (382) above. If this 1977 patent involved crystallisation, this could mean that Lundbeck's crystallisation method was not novel, in which case Lundbeck's crystallisation patent could be partially or entirely invalidated based on a comparison between the 1977 patent and Lundbeck's crystallisation patent, that is to say without detailed knowledge of Cipla's production method. By comparison, on 24 January 2002, the [employee function]* of Alpharma, which had purchased the same Cipla product, wrote: *"I have also spoken to Tiefenbacher, and they are still not willing to hand out the route of synthesis. They were quite open, besides that, and are willing to answer any specific questions related to the manufacturing process via Cipla in India (Cipla is the manufacture[r] of the API). It might very well be that we can seek the Lundbeck patent application invalidated without specific knowledge of the Cipla API process. Tiefenbacher strongly believe that they can invalidate the utility models and other applications related to that family. I too believe that."* See recital (506) above.

¹⁶⁴¹ In Arrow's meeting of 14 December 2001 with Tiefenbacher, participants observed that *"Cipla do isolate the base. Cipla's base is of unknown purity but could infringe this patent when granted. Cipla's defence is that they employ a method of purification as disclosed in a 1977 patent."* See recital (382) above. The reference to *"unknown purity"* implies that participants were particularly concerned about the product claims in Lundbeck's United Kingdom patent application. These claims were later

Lagap litigation, this patent had a 60% chance of being declared invalid by a United Kingdom judge.¹⁶⁴² Lundbeck's "enemies" considered this patent to be "*high school chemistry*" and not novel.¹⁶⁴³ Such litigation on the Cipla product and the validity of Lundbeck's crystallisation patent would have been an expression of potential competition. Instead, Arrow's incentive to seek market entry with its Cipla product was eliminated through the transfer of value Lundbeck offered in the agreement. Because each side was entirely satisfied with the agreed status quo of instalment payments to Arrow in exchange for Arrow not entering the United Kingdom market with citalopram that Lundbeck alleged to be infringing, Lundbeck and Arrow soon gave up any effort to actively pursue the infringement proceeding Lundbeck had started one day after the agreement was concluded.

- (891) Secondly, at the latest by 14 December 2001¹⁶⁴⁴, Arrow was aware that Matrix, Tiefenbacher's other API supplier, had a process which did not "*isolate the base in crystalline form*" and was therefore, according to participants in the meeting of 14 December 2001, by implication less likely to infringe Lundbeck's crystallisation patent than Cipla's process, which did "*isolate the base*" and "*could infringe this patent when granted*".¹⁶⁴⁵ In the meeting report, Arrow stated that "*Matrix are much more open with the detail of their process but presumably we cannot switch at this stage*".¹⁶⁴⁶ That Arrow could not switch to Matrix to be in time to launch in the United Kingdom in January 2002, as was Arrow's intention¹⁶⁴⁷, does not mean that Arrow could not have switched to Matrix in the months to come.¹⁶⁴⁸ Matrix later testified in the Lagap litigation that it had used base crystallisation to manufacture

withdrawn or invalidated before the EPO and the Dutch patent office, but were accepted, apparently, by the United Kingdom patent office in granting the patent as requested. This made the United Kingdom crystallisation patent particularly vulnerable to at least partial invalidation by the United Kingdom courts. See recital (151) above. Cipla's general argument for invalidation was that it employed "*a method of purification as disclosed in a 1977 patent*."

¹⁶⁴² See recital (157) above.

¹⁶⁴³ See recital (149) above.

¹⁶⁴⁴ With respect to this meeting, [employee name]* stated to the Commission: "*This document also confirms that by this time, the Arrow team were also aware of Tiefenbacher having an alternative API source, Matrix*." See ID 6070, page 4. See also ID 6082, page 15, where Arrow stated: "*...the possibility of Matrix being an API supplier source for Tiefenbacher subsequently became apparent in late 2001*."

¹⁶⁴⁵ See recital (382) above.

¹⁶⁴⁶ See recital (382) above. It is possible that the Matrix process discussed in this meeting on 14 December 2001 was the Matrix I process rather than the new Matrix process, which included the washing step, and which Matrix claimed to have been using since September 2001. Certainly there was no mention in this meeting of any washing step. It may have been only in May 2002 that Tiefenbacher informed Arrow of the washing step and asked Arrow to apply for a variation. Possibly Tiefenbacher and Matrix wanted to protect the information about the washing step until such time as Matrix had made a patent application covering its new process. However, whether the Matrix process discussed at the 14 December meeting with Tiefenbacher was the old Matrix I process or the new Matrix II process, it is clear from the discussion that participants considered this process less likely to infringe Lundbeck's crystallisation patent than the Cipla process: "*Matrix on the other hand do not isolate the base in crystalline form but convert the base as an oil to the oxalate (twice) and then convert the oxalate to the hydrobromide*" and "*Matrix have taken steps to ensure that they do not isolate the base in a pure form but Cipla do isolate the base. Cipla's base is of unknown purity but could infringe this patent when granted*."

¹⁶⁴⁷ See recital (886) above.

¹⁶⁴⁸ To compare, Alpharma, which had also purchased Cipla citalopram, considered on 19 February 2002: "*The second API supplier Matrix is, also to the best of all knowledge, using a none infringing process and this API could be used without the risk of infringement. It would mean a lot of scrapping and launch delay of roughly 3-4 month*." See recital (518) above.

citalopram from December 2000 to July 2001 (when Lundbeck's United Kingdom patent application was published and allegedly without having exported such product to the EEA), but claimed that it had been using a non-infringing process since September 2001, including for product that had been exported as of March 2002 to the EEA.¹⁶⁴⁹ Therefore, if Arrow had continued to work with Tiefenbacher instead of concluding the agreement with Lundbeck, Arrow could have sold Matrix's new and allegedly non-infringing Matrix II product at the latest at the same time as Lagap, which actually started selling this product in the United Kingdom in October 2002.

- (892) Arrow argued in its reply to the Statement of Objections that *"Arrow had already invested DM 2.8 million to purchase citalopram product from Tiefenbacher and Arrow found itself in a situation where it was unable to sell this product. A purchase of this magnitude was highly significant for a group which at that time generated revenue of only USD 18 million and Arrow was not in a position to risk purchase of further stock in circumstances where Lundbeck alleged that the marketing authorisations granted by the Dutch Medicines Agency (which covered both Cipla and Matrix API) infringed Lundbeck's patents."*¹⁶⁵⁰ With respect to this *ex post facto* statement, the Commission observes that these allegations of Lundbeck pertained to the original production processes of Cipla and Matrix, not to the amended Cipla II and Matrix II processes, which were designed specifically to avoid the risk of infringement of Lundbeck's crystallisation patent. More fundamentally, what matters to assess the existence of potential competition is first and foremost the ability of undertakings to enter the market. As the General Court found in *Visa*: *"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 pressure represented by the likelihood that a new competitor will enter the market if the market becomes more attractive."*¹⁶⁵¹ At the moment when Arrow concluded the agreement with Lundbeck, it was able under its contract with Tiefenbacher to buy citalopram tablets produced with API supplied by Cipla or Matrix, including future versions that could be expected and that would further reduce or eliminate the risk of patent infringement.
- (893) Arrow¹⁶⁵² and Lundbeck¹⁶⁵³ argued that the new Matrix washing process was not part of Tiefenbacher's original application for a United Kingdom marketing authorisation and would require a variation to (the application for) that marketing authorisation. In fact, it took Tiefenbacher until 1 May 2002 to submit the application

¹⁶⁴⁹ See recital (153) above. With respect to the Matrix II process, which included the washing step, Lundbeck stated in its reply to the Statement of Objections that *"It was only in April 2002 that Lundbeck learned for the first time that Matrix might claim a modification in its production process..."*; *"United Nordic Pharma's launch in the Danish market on June 14, 2002, was the first time when Lundbeck learned that Matrix-based citalopram had been launched on the market"*; and *"Generic companies started switching from Cipla's to Matrix's API from the end of September or the beginning of October 2002."* See ID 5394, pages 163-164.

¹⁶⁵⁰ ID 6082, page 25.

¹⁶⁵¹ See recital (611) above.

¹⁶⁵² ID 6082, page 27.

¹⁶⁵³ ID 5394, page 188.

for a type I variation in the Netherlands, as the Reference Member State.¹⁶⁵⁴ At the request of Tiefenbacher, Arrow submitted the United Kingdom application for a variation on 22 May 2002, but this variation was approved only on 23 December 2002.¹⁶⁵⁵ For unknown reasons, Arrow even submitted a second application in July 2002, which was approved only on 4 June 2003.¹⁶⁵⁶ Lundbeck and Arrow argued that it was, therefore, at the earliest as of 23 December 2002, and possibly only after 4 June 2003, that Arrow was authorised to sell the new Matrix product in the United Kingdom.

- (894) That it would take such a long time for Arrow's variation(s) to be approved in the United Kingdom could, however, not be known in January 2002, when Arrow concluded the agreement with Lundbeck. According to a March/April 2002 publication of the United Kingdom Medicines Control Agency in the United Kingdom, the Agency processed all type II variations within 90 days from the acknowledgement letter (and 85% within 60 days), resulting either in an approval or a request for supplementary information. For type I variations, the corresponding figures were 100% in 30 days and 84% in 20 days.¹⁶⁵⁷ Whether an applicant actually obtained approval within these time periods depended on the completeness and accuracy of the information it supplied to the agency. Arrow could, therefore, in January 2002, have expected that Matrix's washing step could be included in the United Kingdom marketing authorisation through a variation within a couple of months or, if the issuing of the marketing authorisation were delayed, could immediately be included in the marketing authorisation as issued.¹⁶⁵⁸ As Lundbeck stated in its reply to the Statement of Objections: *"As Tiefenbacher had obtained a Type I variation to its MA on July 16, 2002 in the Netherlands (the Reference Member State) to include this washing step, the MAs to be subsequently issued in other Concerned Member States were also expected to reflect the variation (even though the MA that Alpharma, Arrow and Lagap obtained in the UK on July 26, 2002 – which included both Cipla and Matrix as API suppliers – did not extend to citalopram purified via Matrix's new washing step)."*¹⁶⁵⁹
- (895) In January 2002, therefore, switching as soon as possible to citalopram API from Matrix, which Tiefenbacher and Arrow in the meeting of 14 December 2001 considered to be less likely to infringe than Cipla's API¹⁶⁶⁰ and which was also covered by Arrow's (application for a) marketing authorisation¹⁶⁶¹, was a concrete possibility to seek market entry that Arrow, as analysed in section 12.4.5 below,

¹⁶⁵⁴ Both parties made a similar argument for the Cipla II process. For Arrow, see ID 6082, page 35. For Lundbeck, see ID 5394, page 201, where Lundbeck claimed *"Obtaining a new Type II variation would have taken some nine to 12 months"*. In fact, in the United Kingdom, Arrow submitted the variation for Cipla's new process on 30 September 2002 and this application was approved by the Medicines Control Agency on 3 February 2003, a period of four months and a few days. See recital (425) above.

¹⁶⁵⁵ ID 1297, page 38. It is unclear whether the variation applied for in the United Kingdom was a type I or a type II.

¹⁶⁵⁶ ID 1297, page 38.

¹⁶⁵⁷ ID 1910, page 16.

¹⁶⁵⁸ In the Netherlands, the type I variation to cover Matrix's washing step, submitted on 1 May 2002, was approved in two and a half months, as was Cipla's patent free purification method (the Cipla II process), submitted in September 2002. See ID 1713, page 1.

¹⁶⁵⁹ ID 5394, pages 226-227.

¹⁶⁶⁰ See recital (382) above.

¹⁶⁶¹ See recital (424) above.

foreclosed through its agreement with Lundbeck. Instead of accepting the competitive risk of making a new investment in a potentially non-infringing product, Arrow preferred to collect the cash instalments from Lundbeck. Arrow had no way of knowing in January 2002 that nine months later Lagap would decide to face Lundbeck's patent challenge and would open the United Kingdom market for generic citalopram.

- (896) Thirdly, because Arrow interpreted its agreement with Tiefenbacher as allowing Arrow to purchase citalopram from other API suppliers than those working with Tiefenbacher¹⁶⁶², and because Arrow had on 11 January 2002 already obtained a certificate of analysis of citalopram offered by Ranbaxy¹⁶⁶³, switching to citalopram API from a new API supplier, in particular Ranbaxy, was also a concrete option for Arrow in January 2002 to seek market entry in the United Kingdom in the near future. Ranbaxy's wholesaler in fact made Arrow a concrete price offer for 500 to 1000 kgs of citalopram API in May 2002¹⁶⁶⁴ and Ranbaxy submitted a European Drug Master File for its API to the United Kingdom authorities in June 2002.¹⁶⁶⁵ Arrow could through a type II variation of its United Kingdom marketing authorisation have switched to Ranbaxy as API supplier within three to four months.¹⁶⁶⁶ Arrow was also in touch with several other API suppliers than Ranbaxy.¹⁶⁶⁷
- (897) Arrow stated to the Commission that "*Arrow had assessed numerous potential suppliers of citalopram API..., but could not obtain a supply from a manufacturer that it was satisfied could demonstrate that it did not infringe Lundbeck's Process Patents.*"¹⁶⁶⁸ This statement, however, is based on the commitments Arrow accepted in the United Kingdom agreement with Lundbeck¹⁶⁶⁹, notably Arrow's commitment not to sell any citalopram which Lundbeck, having tested a sample, alleged to be infringing. Under such circumstances, it is obviously difficult, not to say impossible, to find citalopram API which Arrow could demonstrate to Lundbeck's satisfaction not to infringe Lundbeck's process patents. This does not mean that in the absence of this agreement Arrow would not have had a realistic chance to sell citalopram in the United Kingdom without infringing any Lundbeck patents or by seeking a court ruling invalidating any such patents. In particular Ranbaxy's citalopram did have a realistic chance of being sold in the United Kingdom without infringing any patents of Lundbeck.¹⁶⁷⁰
- (898) As a final realistic concrete option to enter the United Kingdom citalopram market in the near future, Arrow could have relied on Tiefenbacher and Cipla to change Cipla's production process to further reduce or eliminate the risk of patent infringement. Indeed, according to Tiefenbacher, after Cipla had been disappointed in its

¹⁶⁶² See recital (375) above.

¹⁶⁶³ See recital (386) above.

¹⁶⁶⁴ See recital (419) above.

¹⁶⁶⁵ See recital (566) above.

¹⁶⁶⁶ As Ranbaxy itself stated to Lundbeck (see recital (558) above), it was deemed possible to obtain a type II variation to an existing marketing authorisation within three to four months if the information submitted was correct and complete.

¹⁶⁶⁷ See recitals (390), (417), (422), (426), (427), (428), (437), (442) and (443).

¹⁶⁶⁸ ID 610, page 25.

¹⁶⁶⁹ See section 12.4.5 below.

¹⁶⁷⁰ See section 12.7 below.

expectation that Lundbeck's crystallisation patent would not be granted, Cipla soon succeeded in creating a new "*patent free*" purification method based on absorption of silica (the so-called Cipla II process), which was ready for filing as a type I variation on 24 September 2002.¹⁶⁷¹ In the United Kingdom, at Tiefenbacher's request, Arrow submitted the variation on 30 September 2002 and this application was approved by the Medicines Control Agency on 3 February 2003.¹⁶⁷² Although Arrow could therefore have sold allegedly non-infringing Cipla II product in the United Kingdom as of 3 February 2003, making use of this potential route to the market was also foreclosed by the twice-extended agreement with Lundbeck (see section 12.4.5 below). As a supplier of generic medicines, Arrow knew or should have known that it would probably not take very long before Cipla would have found a way around the new obstacle which Lundbeck created with its crystallisation patent application.¹⁶⁷³

- (899) In sum, the facts analysed in this section 12.4.4 show that, after Lundbeck's patent on the compound and the two original production processes had expired, Arrow had real concrete possibilities of entering the United Kingdom market in the near future without infringing any patents of Lundbeck or by obtaining a court ruling finding any such patents invalid. The Commission therefore concludes that Lundbeck's process patents did not prevent Arrow from being a potential competitor to Lundbeck in the United Kingdom market at the time they concluded their agreement.

12.4.5. Commitments accepted by Arrow in the United Kingdom agreement with Lundbeck

- (900) In the agreement with Lundbeck, Arrow accepted several commitments that limited its freedom of action to enter the citalopram market in the United Kingdom.

12.4.5.1. Arrow's commitment not to import or sell "*the said Citalopram*"

- (901) In Article 1.1 of the agreement "*ARROW on its own behalf and on behalf of all associated and related entities undertakes during the term of this Agreement...not in the UK to make, dispose of, offer to dispose of, use or, after the Second Delivery Date... import or keep for disposal or otherwise (1) the said Citalopram or (2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale pending a final unappealable decision in the Infringement Litigation...*".¹⁶⁷⁴
- (902) The term "*the said Citalopram*" was a defined term in the agreement. The fourth recital of the preamble to the agreement stated:

¹⁶⁷¹ In the Netherlands, the type I variation to cover Cipla's patent free purification method (the Cipla II process) was submitted in September 2002 and approved two and a half months later. See ID 1713, page 1.

In its settlement with the generic company Neolab, which had launched Cipla citalopram in the United Kingdom in October 2002, Lundbeck paid Neolab a considerable sum in damages based on Lundbeck's assessment that it had a 90% chance of losing infringement litigation against the Cipla II process, either because it would not be found infringing or because the crystallisation patent would have been found invalid. See ID 845, page 99. See also recital (164) above.

¹⁶⁷² ID 1297, page 38 and ID 6082, page 36..

¹⁶⁷³ See section 9.4.2 above.

¹⁶⁷⁴ Article 2.2 provided that "*In consideration of the undertakings in clause 1.1....*" Lundbeck agreed to transfer considerable value to Arrow. See further section 12.4.6 below.

"Whereas ARROW has obtained a licence from a third party to import into the UK Citalopram not manufactured by Lundbeck or with the consent of Lundbeck ("the said Citalopram", which definition shall for the avoidance of doubt comprise only Citalopram for marketing and sale in the UK and shall exclude Citalopram for marketing and sale in other countries)."

- (903) In Article 3.4 of the agreement, Arrow agreed to deliver all of the citalopram tablets it had already ordered from Tiefenbacher to Lundbeck in two shipments, the second and last shipment to be made by no later than 25 February 2002 (defined in Article 3.4 as *"the Second Delivery"*).
- (904) In reply to the Commission's request for information of 19 March 2010, Arrow confirmed to the Commission that *"The Lundbeck Agreements cover citalopram in any form, including both as an API and a medicine."*¹⁶⁷⁵
- (905) Based on the definition of *"the said Citalopram"* in the fourth recital of the preamble and the definition of *"the second Delivery"* in Article 3.4, the Commission considers that in Article 1.1 Arrow committed itself for the term of the agreement not to sell and, after 25 February 2002, import citalopram, whether API or medicines, from Tiefenbacher. This commitment covered both the citalopram tablets Arrow had ordered (part of which Arrow had already in stock and part of which still had to be imported) and, once Arrow had delivered all of the tablets it had already ordered to Lundbeck by 25 February 2002, any further citalopram Arrow could buy from Tiefenbacher.

Arguments of the parties

- (906) Arrow claimed in its reply to the Commission's request for information of 19 March 2010 that *"The phrase "the said Citalopram" in clause 1.1 of the Agreement referred to the citalopram tablets that Arrow had ordered from Tiefenbacher in September 2001..., which had been produced using an API sourced from Cipla."*¹⁶⁷⁶ Lundbeck also stated in its reply to the Statement of Objections that the term *"the said Citalopram"* referred to *"the citalopram purchased under the agreement concluded with Tiefenbacher on May 22, 2001."*¹⁶⁷⁷
- (907) According to the parties, therefore, the term *"the said Citalopram"* covered the citalopram tablets Arrow had ordered from Tiefenbacher at the time the agreement with Lundbeck was concluded.
- (908) As mentioned in recital (391) above, until as late as 8 February 2002, after the conclusion of the agreement, Lundbeck appears to have been in doubt whether Arrow's citalopram came from Matrix or Cipla. Lundbeck reported to the Commission that on 7 and 8 February 2002, Lundbeck performed an analysis of Arrow's citalopram, as obtained pursuant to the United Kingdom agreement with Arrow. According to Lundbeck, *"The results were consistent with those of the previous analyses [of Cipla material], and Lundbeck therefore concluded that Arrow's products were based on API from Cipla..."*¹⁶⁷⁸ With respect to the tablets

¹⁶⁷⁵ ID 610, page 25.

¹⁶⁷⁶ ID 610, page 25. Quoted with approval by Lundbeck in its reply to the Statement of Objections, see ID 5394, page 194.

¹⁶⁷⁷ ID 5394, page 194.

¹⁶⁷⁸ See recital (411) above.

that had been ordered but not yet delivered, neither Arrow nor Tiefenbacher could be certain whether these would contain citalopram API from Cipla or Matrix, given that, according to Arrow, Arrow left the choice of the source of API supply to Tiefenbacher.¹⁶⁷⁹

- (909) In its reply to the Statement of Objections, Arrow stated: *"Arrow had ordered citalopram from Tiefenbacher and the reference in the UK Settlement Agreement to the said citalopram is to the stock that Arrow had ordered from Tiefenbacher which Arrow was aware had been sourced from Cipla. This is inherent in Recital (6) which refers to Lundbeck having tested the said Citalopram."*¹⁶⁸⁰ The sixth recital of the preamble of the agreement stated *"Whereas Lundbeck has performed laboratory analysis of the said Citalopram..."*. However, in fact Lundbeck has tested samples of Cipla API as well as samples of Matrix API and believed that both production methods used to manufacture those samples infringed its crystallisation patent application. As mentioned in recital (907) above, Lundbeck simply was not certain until after the agreement had been concluded whether the tablets Alpharma already had were made with API from Cipla or Matrix, let alone which API the tablets still to be delivered would contain. The reference in the sixth recital of the preamble is therefore to be understood as referring to the Tiefenbacher citalopram Lundbeck had already tested.
- (910) The mere fact that the tablets still to be delivered could have been made with Matrix API already shows that *"the said Citalopram"* was not limited to Cipla citalopram, as Arrow claimed, but rather referred to Tiefenbacher citalopram, whether made with API from Cipla or Matrix.
- (911) Secondly, it is clear from Article 1.1 that Arrow's commitment covered not just the Tiefenbacher citalopram it had ordered before concluding the agreement with Lundbeck, but also any Tiefenbacher citalopram Arrow could under its contract with Tiefenbacher buy during the term of the agreement with Lundbeck. As mentioned in recital (901) above, Arrow agreed in Article 1.1 of the agreement with Lundbeck *"not in the UK to... after the Second Delivery Date... import or keep for disposal or otherwise (1) the said Citalopram..."* If *"the said Citalopram"* had really meant only the citalopram Arrow had already ordered from Tiefenbacher, as Arrow and Lundbeck claimed, then all of this citalopram would have been delivered to Lundbeck by 25 February 2002 at the latest and there would have been no use whatsoever for the provision in Article 1.1 that Arrow agreed *"not in the UK to... after the Second Delivery Date... import or keep for disposal or otherwise (1) the said Citalopram..."* Indeed, this provision makes sense only if *"the said Citalopram"* also included possible future imports by Arrow of Tiefenbacher citalopram.
- (912) This interpretation is confirmed by the definition of *"the said Citalopram"* in the preamble to the agreement. This definition does not refer to the citalopram Arrow had already ordered, but to Arrow's *"licence from a third party to import into the UK Citalopram not manufactured by Lundbeck or with the consent of Lundbeck ("the said Citalopram...)"* The emphasis in this definition on the *"licence from a third party*

¹⁶⁷⁹ Arrow stated in its reply to the Statement of Objections that *"nor at the time of placing its order would Arrow have had any reason to approach Tiefenbacher to specify a particular source."* See ID 6082, page 17.

¹⁶⁸⁰ ID 6082, page 41.

to import" makes all the difference as this covered by definition any products imported under the Tiefenbacher marketing authorisation for the United Kingdom, including any future imports made during the term of Arrow's agreement with Lundbeck.

- (913) The Commission considers that the notion of "*the said citalopram*" therefore did not only cover the actual citalopram already ordered by Arrow, but also any other citalopram that Arrow had the ability to import under the licence from Tiefenbacher in the course of the operation of the agreement with Lundbeck. This included citalopram from Cipla that could come to be produced with a different and allegedly non-infringing process (such as the Cipla II product which became available in the autumn of 2002) as well as citalopram products from Matrix, including Matrix citalopram produced with a new and allegedly non-infringing process such as the washing method (the so-called Matrix II product, which became available by mid-2002). This notion of "*the said Citalopram*" therefore in itself alone already covered future citalopram products that had not been tested by Lundbeck and that could well be non-infringing.

The sample analysis mechanism did not apply to "*the said Citalopram*"

- (914) The Commission notes that the sample analysis mechanism in Article 1.1¹⁶⁸¹ did not apply to "*the said Citalopram*." This is clear from the structure and wording of Article 1.1, which obliged Arrow "*...not in the UK to make, dispose of, offer to dispose of, use or, after the Second Delivery Date... import or keep for disposal or otherwise (1) the said Citalopram or (2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale pending a final unappealable decision in the Infringement Litigation...*" The purpose of the sample analysis mechanism in this provision was "*to enable Lundbeck to ascertain if there may be an infringement*", thus allowing Lundbeck to "*allege*" that "*any other Citalopram*" infringed its patents. With respect to "*the said Citalopram*", on the other hand, Arrow's obligation was simply not to sell such citalopram and, after the second delivery Date, import such citalopram, without any sample analysis beyond the analysis Lundbeck had already undertaken on previous samples of Cipla I and Matrix I product it had obtained.

- (915) That this was also the interpretation of both parties is clear from their submissions to the Commission. In its reply to the Statement of Objections, Lundbeck divided Article 1.1 into two prongs:

"(1) the said Citalopram...; and

*(2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale."*¹⁶⁸²

¹⁶⁸¹ The functioning of the sample analysis mechanism is further analysed in section 12.4.5.2 below.
¹⁶⁸² ID 5394, page 194.

Lundbeck then stated: *"As to the second prong of Clause 1.1, the SO's interpretation completely ignores an important qualification: The sample analysis mechanism mentioned in Clause 1.1 of the Agreement completes Lundbeck's allegation and enables Lundbeck to determine whether the specific citalopram is infringing."*¹⁶⁸³

From Arrow's reply to the Statement of Objections, it is also clear that Arrow considered the sampling analysis mechanism to apply only to the second prong, given that Arrow, like Lundbeck, presented the obligations in Article 1.1 as:

"(1) the said Citalopram...; and

*(2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale pending a final unappealable decision in the Infringement Litigation..."*¹⁶⁸⁴

Conclusion

- (916) The conclusion from this section 12.4.5.1 is that Arrow agreed in Article 1.1 not to sell the Tiefenbacher citalopram products it had already ordered and not to import or sell future Tiefenbacher citalopram products produced with possibly non-infringing processes, without any prior testing by Lundbeck of samples of such future products. The obligations Arrow accepted in this respect clearly went beyond any rights Lundbeck's process patents could procure. If Lundbeck had succeeded in proving infringement of the citalopram Arrow actually had in possession, which was manufactured with Cipla API, and if Arrow's counter-claim of patent invalidity had failed, the court would have prohibited Arrow to import or sell citalopram as produced by Cipla's infringing production method. Arrow would thus have remained free to import and sell citalopram from Cipla if Cipla had in the meantime switched to another, allegedly non-infringing production method (such as the Cipla II process that became available in the autumn of 2002). Arrow would also have been free to import and sell citalopram from Matrix, including citalopram produced with the allegedly non-infringing Matrix II process, which became available by mid-2002.

12.4.5.2. Arrow's commitment not to make, sell or import any other citalopram which Lundbeck alleged to be infringing

- (917) Even if *"the said Citalopram"* only covered the actual Cipla product which Arrow had ordered, as the parties argued, future imports from Tiefenbacher, including of potentially non-infringing Matrix II and Cipla II products, would in any case be covered by the second notion in Article 1.1, that of *"any other citalopram which Lundbeck alleges to infringe its Proprietary Rights"*, which the Commission will now analyse.
- (918) Article 1.1 of Arrow's agreement with Lundbeck stated that *"ARROW on its own behalf and on behalf of all associated and related entities undertakes during the term of this Agreement...not in the UK to make, dispose of, offer to dispose of, use or, after the Second Delivery Date... import or keep for disposal or otherwise... any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to*

¹⁶⁸³ ID 5394, page 195.

¹⁶⁸⁴ ID 6082, page 41.

provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale pending a final unappealable decision in the Infringement Litigation...".

- (919) In reply to the Commission's request for information of 19 March 2010, Arrow confirmed to the Commission that *"The Lundbeck Agreements cover citalopram in any form, including both as an API and a medicine."*¹⁶⁸⁵ In the same reply, Arrow stated, *"The obligations imposed upon Arrow under the Agreement and in particular **the prohibition on selling citalopram product in the UK** and related terms under the Agreement, were the minimum terms that Lundbeck was prepared to accept in the circumstances...(emphasis added)"*¹⁶⁸⁶

Arguments of the parties

- (920) Lundbeck argued in its reply to the Statement of Objections that *"The Arrow UK Agreement was limited only to infringing citalopram products, because ...the Agreement provided for a mechanism under which Lundbeck would be provided with samples to analyze whether Arrow's products infringed Lundbeck's patents..."*¹⁶⁸⁷ In the same reply, Lundbeck stated: *"...the Agreement did not cover non-infringing citalopram. Of course, if another source of citalopram had been used by Arrow, and this source infringed Lundbeck's patents as shown by Lundbeck's analysis of the samples, that other source would have been covered by the agreement as well..."*¹⁶⁸⁸
- (921) The Commission notes, however, that any conviction Lundbeck might have formed of infringement based on examining impurities in the product would, in the absence of any inspection of the production process itself, still be no more than a subjective belief based on 'fingerprint' analysis which Lagap's expert in the Lagap litigation considered *"highly flawed"*.¹⁶⁸⁹ There was no guarantee whatsoever that Arrow or a court would come to the same conclusion as Lundbeck.
- (922) The patent holder cannot substitute *"...its discretion for the decisions of national courts, which were the proper forum for actions..."*, as the Court of Justice held in *Windsurfing*.¹⁶⁹⁰ In the one case where Lundbeck did go to trial in the United Kingdom and expressed its *"firm and unshakeable confidence that it was impossible for Lagap and its suppliers to be operating a non-infringing process"*, the judge stated that Lundbeck and its independent expert had to admit that this confidence was *"unfounded"*.¹⁶⁹¹ Indeed, even Article 1.1 of the agreement itself states that the sampling would serve *"to enable Lundbeck to ascertain if there **may** be an infringement (emphasis added)."* If then on that basis Lundbeck *"alleges (emphasis added)"* that its patents were infringed, Arrow committed not to make, sell or import such product.
- (923) One cannot be surprised, therefore, that in fact the sampling mechanism was never used during the term of the United Kingdom agreement and was deleted from the subsequent agreement between the two parties regarding Denmark. Arrow argued in

¹⁶⁸⁵ ID 610, page 25.

¹⁶⁸⁶ ID 610, page 27.

¹⁶⁸⁷ ID 5394, page 191.

¹⁶⁸⁸ ID 5394, page 197.

¹⁶⁸⁹ See recital (156) above.

¹⁶⁹⁰ Case 193/83 *Windsurfing International v Commission*, [1986] ECR 611, paragraph 52.

¹⁶⁹¹ See recital (155) above.

its reply to the Statement of Objections that if Arrow had been bound to accept Lundbeck's allegation of infringement, the parties could just as well have simply stated "*Arrow undertakes not to import any citalopram*".¹⁶⁹² This is, in effect, precisely what the parties did in the Danish agreement, realising that a subjective testing mechanism would not prevent Lundbeck from always alleging that a tested product infringed.¹⁶⁹³ In any case, Arrow had no incentive to challenge Lundbeck's allegations of infringement or even submit any products for testing as long as Lundbeck continued its instalments of the agreed transfer of value to Arrow. If ever during the term of the agreement Arrow had actually made, sold or imported any citalopram product which Lundbeck alleged to be infringing, Lundbeck could interpret this as a breach of the agreement. According to Article 2.4 of the agreement, if a court found that Arrow had been knowingly in breach of Article 1.1, Arrow had to pay back to Lundbeck the instalments it had received after the breach.

- (924) Arrow itself explained in its reply to the Commission's request for information of 19 March 2010 that the sampling analysis mechanism "*is a **subjective test of alleged infringement**, not actual infringement. Therefore, citalopram products that have not been found by a court to be non-infringing but do not actually infringe Lundbeck's patents could have been within the scope of article 1.1...*"(emphasis added).¹⁶⁹⁴ Arrow also stated in the same reply: "*Throughout the term of the Lundbeck Agreements, Arrow was under an obligation not to make, dispose of, offer to dispose of or use any citalopram in the UK **that could be alleged** to infringe Lundbeck's Process Patents. Arrow had assessed numerous potential suppliers of citalopram API..., but could not obtain a supply from a manufacturer that it was satisfied could demonstrate that it did not infringe Lundbeck's Process Patents. In these circumstances, there was no commercial advantage in Arrow seeking to market citalopram in the UK, **as Lundbeck could have prevented Arrow from doing so under their agreements***" (emphasis added).¹⁶⁹⁵ Lundbeck stated in its reply to the Commission's request for information of 12 March 2010 that in the agreement "*Arrow agreed not to sell **potentially** infringing citalopram products in the UK*" (emphasis added).¹⁶⁹⁶
- (925) Finally, in the consent orders that parties agreed on 6 February 2002 and later on 30 January 2003 Arrow committed itself "*not, without Lundbeck's consent, in the UK to make, dispose of, offer to dispose of, use or, after 15[th] February 2002 import or keep for disposal or otherwise (1) Citalopram not manufactured by Lundbeck or with the consent of Lundbeck or (2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights (including patent rights to inventions of Citalopram and to processes relating to the manufacture thereof, including but not limited to in*

¹⁶⁹² ID 6082, page 42.

¹⁶⁹³ ID 8, page 255. The Danish agreement of 3 June 2002 simply stated in its Article 1.1 that Arrow agreed not to sell "*products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights in the Territory for the term of this Agreement, however only until a final unappealable and enforceable, judicial decision in the Infringement Litigation, as defined above, has been rendered by the Courts in the UK. The obligations of Arrow under this clause 1.1 shall hereinafter be referred to as the "Consent Injunction".*" See further section 12.5 below.

¹⁶⁹⁴ See recital (394) above

¹⁶⁹⁵ ID 610, page 25.

¹⁶⁹⁶ ID 823, page 20. In its reply to the Statement of Objections, Arrow provided an entirely different explanation about the sampling analysis mechanism. See ID 6082, page 73. This explanation finds no basis in the language of the Agreement or in the earlier statements of Arrow quoted in this recital.

particular GB patents no 2 357 762, 2 356 199 and EP(GB) 171943) and, to enable Lundbeck to ascertain if there may be any infringement during the Term to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale..."¹⁶⁹⁷ In obliging Arrow not to make, sell or import "*Citalopram not manufactured by Lundbeck or with the consent of Lundbeck*" these consent orders even go considerably further than the agreement itself.

- (926) As mentioned in recital (536) above, Lundbeck explained with respect to Alpharma in its reply to the Statement of Objections, "*In UK civil litigation, a consent order merely records an agreement reached between the parties...the consent order...was designed to give Lundbeck the means to enforce the Alpharma Agreement. The consent order enabled Lundbeck, as claimant, to enforce the undertakings given by Alpharma without the need to commence a fresh action. Under English law, had Alpharma breached this consent order, it would have been liable for contempt of court. Moreover, Lundbeck could have immediately obtained a preliminary injunction against Alpharma. Therefore, Lundbeck would have enforced the consent order, rather than the Agreement, in case of breach by Alpharma of its undertakings* (emphasis added)." ¹⁶⁹⁸ The same logically applies for the consent orders with Arrow.¹⁶⁹⁹ Given that Arrow had committed itself in the consent injunction not to make, sell or import any citalopram "*not manufactured by Lundbeck or with the consent of Lundbeck*", the mere fact of making or importing such citalopram would be a violation of the consent injunction, irrespective of whether such citalopram infringed any process patents of Lundbeck, and would, according to Lundbeck, at least have led to the immediate imposition of an interim injunction.
- (927) In light of the above, the Commission does not agree with the statement by [employee name]* that "*This was essentially an agreement to reflect the reality of the Court process, i.e. the need for us to "clear the way" and to engage with the originator to demonstrate why our product was non-infringing. If Lundbeck disputed this, there was a Court mechanism to resolve such a dispute.*"¹⁷⁰⁰ Clearing the way can be done by inviting the originator undertaking to "*sue us now*"¹⁷⁰¹, thereby ensuring that the burden of proving infringement remains with the originator undertaking. This is particularly important for process patents, the infringement (or even more the non-infringement) of which is difficult to prove. In the agreement, the

¹⁶⁹⁷ ID 632, page 4 and ID 645, page 4 respectively. See also recitals (409) and (429) above.

¹⁶⁹⁸ ID 5394, pages 231-232.

¹⁶⁹⁹ Arrow argued in its reply to the Statement of Objections that "*All parties are at liberty to vary an order granted by the Court and accordingly, Arrow would simply have applied to vary the Order on the basis that it believed its product did not infringe Lundbeck's patents. This would then engage the issue of infringement and potentially also validity.*" See ID 6082, pages 46-47. This statement appears to be in contradiction with Lundbeck's view of consent orders. The undertaking given by Arrow in the consent order was not to sell "*Citalopram not manufactured by Lundbeck or with the consent of Lundbeck*", a commitment Lundbeck believed it could enforce "*without the need to commence a fresh action*". In Lundbeck's view, if Arrow had "*breached this consent order, it would have been liable for contempt of court. Moreover, Lundbeck could have immediately obtained a preliminary injunction.*" Considering Lundbeck's view on the enforceability of consent orders, there can be little doubt that Lundbeck would have immediately stopped its instalments to Arrow if Arrow had argued non-infringement or patent invalidation before the United Kingdom court for any citalopram product that Arrow intended to sell during the term of the agreement. In consequence, Arrow had no incentive to raise any such argument.

¹⁷⁰⁰ ID 6070, page 8. See also recital (979) above.

¹⁷⁰¹ See footnote 312 above.

burden of proving non-infringement rested *de facto* on Arrow, which had to somehow convince Lundbeck to refrain from alleging infringement, a task so difficult that Arrow never even attempted it. It can thus be no wonder that, as Arrow stated, "*Arrow had assessed numerous potential suppliers of citalopram API..., but could not obtain a supply from a manufacturer that it was satisfied could demonstrate that it did not infringe Lundbeck's Process Patents.*"¹⁷⁰²

- (928) As for the availability of "*a Court mechanism to resolve such a dispute*", as already mentioned in recital (926) above, according to Lundbeck: "*the consent order...was designed to give Lundbeck the means to enforce the Alpharma Agreement. The consent order enabled Lundbeck, as claimant, to enforce the undertakings given by Alpharma without the need to commence a fresh action. Under English law, had Alpharma breached this consent order, it would have been liable for contempt of court. Moreover, Lundbeck could have immediately obtained a preliminary injunction against Alpharma (emphasis added).*"¹⁷⁰³ In other words, according to Lundbeck, a United Kingdom court would in principle simply have checked whether the consent injunction, voluntarily agreed by Arrow, was being complied with, not whether any patent infringement really existed, which would have involved a long, complex and expensive trial. The very purpose of consent injunctions is to avoid such trials.¹⁷⁰⁴
- (929) It is noteworthy that while Article 2.1 of the agreement stated that "*Lundbeck intends to commence legal proceedings on the merits with the aim to establish whether ARROW has, is or would infringe Lundbeck's Proprietary Rights*", Lundbeck in fact started infringement proceedings with respect to only one of the three patents explicitly mentioned in the agreement, namely GB 2356199: process for the preparation of pure citalopram, by cyanide exchange (the film distillation patent). Tiefenbacher considered that neither Cipla nor Matrix used the process described in this patent, see recital (382) above. Lundbeck stated in its reply to the Statement of Objections that Lundbeck "*realized that it was possible for generic companies to design around the Film Distillation Patent*" and "*renounced enforcing that patent because it lent itself to invalidity claims.*"¹⁷⁰⁵ Lundbeck's crystallisation patent was thus never the subject of legal proceedings between Lundbeck and Arrow.¹⁷⁰⁶

¹⁷⁰² ID 610, page 25.

¹⁷⁰³ As mentioned in recital (926) above, Lundbeck's statement with respect to its consent order with Alpharma logically also applies its consent orders with Arrow.

¹⁷⁰⁴ Although Article 4.1 mentioned that the agreement was to operate "*until a final unappealable, enforceable UK-court decision has been rendered or until 31 December 2002 whichever event occurs first*", in fact, once Lundbeck had, in its infringement proceeding on GB 2356199, obtained a voluntary court order restraining Arrow from marketing any citalopram "*not manufactured by Lundbeck or with the consent of Lundbeck*", "*neither Lundbeck nor Arrow took any steps to progress the proceedings until the proceedings were, by agreement, stayed by way of an order dated 30 January 2003... Lundbeck never issued Particulars of Claim.*" See recital (410) above. Indeed, in the subsequent agreement regarding Denmark, the term "*Infringement Litigation*" was re-defined as the voluntary injunction Lundbeck had obtained on 6 February 2002 in the United Kingdom proceedings, rather than the main infringement proceedings.

¹⁷⁰⁵ ID 5394, page 162.

¹⁷⁰⁶ Lundbeck stated in its reply to the Statement of Objections that "*At the time of filing, Lundbeck claimed an infringement only of the Film Distillation Patent (UK Patent GB 2 356 199), because the Crystallisation Patent had not been granted by January 25, 2002...*" See ID 5394, page 193. However, Lundbeck did not explain why, after the crystallisation patent had been granted, it did not enlarge the infringement proceedings to also cover that patent.

- (930) Arrow stated to the Commission that "*citalopram products that have not been found by a court to be non-infringing but do not actually infringe Lundbeck's patents could have been within the scope of Article 1.1, but that is entirely usual in agreements of this nature* (emphasis added)"¹⁷⁰⁷ These emphasised words would be less of a problem in settlements based on the two parties' assessment of the strength of the patent, where it is in the generic undertaking's commercial interest to contest, if necessary, Lundbeck's unilateral interpretation of test results. But when a settlement agreement contains restrictions which, because of a payment, the generic undertaking no longer has an interest to challenge, such as the unilateral and subjective determination by Lundbeck of the infringing nature of any citalopram product that Arrow might wish to sell, such clauses become problematic indeed. This is all the more so when the agreement is underpinned by a consent order which commits Arrow not to sell "*Citalopram not manufactured by Lundbeck or with the consent of Lundbeck*".
- (931) Lundbeck argued in its reply to the Statement of Objections that "*Had the Agreement encompassed non-infringing citalopram, Arrow would not have tried to seek alternative API suppliers.*"¹⁷⁰⁸ It is true that during the period covered by Arrow's United Kingdom agreement with Lundbeck (initially from 24 January 2002 to 31 December 2002, then extended to 31 March 2003, finally extended until 20 October 2003), Arrow had several exploratory contacts with other API suppliers than Tiefenbacher. However, Lundbeck's argument overlooks that in the period before 3 June 2002 (when Lundbeck and Arrow concluded an agreement that Arrow would not enter the Danish market), Arrow had only agreed with Lundbeck not to sell in the United Kingdom and was therefore free to sell in any other Contracting Parties of the EEA Agreement for which it could obtain marketing authorisations. Ranbaxy's concrete price offer for 500 kgs to 1000kgs of citalopram, for instance, took place on 14 May 2002, before Arrow had agreed not to enter the Danish market. Arrow was at that time also interested in selling in Sweden, which was initially included in the draft agreement with Lundbeck but was in the end excluded. After 3 June 2002, Arrow was still free to sell in other Contracting Parties of the EEA Agreement, including Sweden, if it could obtain a marketing authorisation. Secondly, given that the original United Kingdom agreement with Lundbeck was concluded for less than a year and was thereafter extended twice for periods of several months only, and that the Danish agreement lasted less than ten months, it cannot be surprising that even for the United Kingdom and Denmark, Arrow, which in the autumn of 2002 failed to reach agreement with Tiefenbacher about a supply agreement¹⁷⁰⁹, continued to explore throughout this period possibilities of co-operating with other API suppliers than those used by Tiefenbacher for the time following the expected expiry of the agreement. As Arrow stated in reply to the Commission request for information of 9 March 2011: "*When it first entered the market, Arrow Group purchased tablets from Tiefenbacher...Arrow Group's ultimate goal was always, however, to bring manufacture of the tablets in-house if it could...In October 2003, Arrow Pharm (Malta), Arrow Group's Malta subsidiary, began to produce validation stock, to support an application for a variation of Arrow Group's product licences...Commercial manufacture began once approval had been received in*

¹⁷⁰⁷ See recital (394) above.

¹⁷⁰⁸ ID 5394, page 197. See recitals (422) to (428) above.

¹⁷⁰⁹ ID 1297, page 24. See recital (375) above.

*Sweden in February 2004. Arrow Group's in-house tablets were produced using an API produced by [different API supplier]."*¹⁷¹⁰

- (932) If instead of concluding the United Kingdom agreement with Arrow, Lundbeck had pursued its infringement litigation against Arrow, Lundbeck could, if it had been successful in proving infringement and if Arrow's counter-claim of patent invalidity had failed, have prevented Arrow from marketing the Cipla citalopram Arrow had purchased. But Lundbeck would not have been able to prevent Arrow from making, selling or importing any other citalopram products, whether API or medicines, now or in the future. This is precisely what the Agreement allowed Lundbeck to do.

Conclusion

- (933) In conclusion on this point, this section 12.4.5.2 has shown that Arrow's commitment in Article 1.1 of the agreement with Lundbeck not to make, sell or import "*any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights*" in the United Kingdom for the term of the agreement meant that Arrow was not allowed to make, sell or import any generic citalopram, whether API or medicines, which Lundbeck alleged to infringe its process patents, irrespective of the API supplier and irrespective of whether the manufacturing process used actually infringed any Lundbeck patents or not.

12.4.5.3. Arrow's commitment not to transfer, license or deal in any other way in United Kingdom marketing authorisations for citalopram

- (934) In Article 1.1 of the agreement, Arrow committed itself "*during the Term not to transfer, license, sub-license or otherwise deal in any other way in any UK marketing authorisations relating to any Citalopram referred to in (1) and (2) above.*"

The words "*(1) and (2) above*" referred to "*(1) the said Citalopram*" and "*(2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights*".

- (935) This commitment prohibited Arrow from out-licensing or selling its United Kingdom marketing authorisation for Tiefenbacher citalopram, which it expected to obtain soon, to any third party. This ensured Lundbeck that Arrow's United Kingdom marketing authorisation for Tiefenbacher citalopram, once issued, would not be used by any other undertaking to sell Tiefenbacher's citalopram in the United Kingdom.
- (936) This commitment also prohibited Arrow from in-licensing or purchasing a marketing authorisation of any third party if Lundbeck alleged the citalopram concerned to be infringing. Like the obligation in Article 1.1 not to sell "*any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights*", this ensured Lundbeck that Arrow would not be able to sell in the United Kingdom any other citalopram that Lundbeck alleged to be infringing. That this provision in Article 1.1 was not limited to the selling or out-licensing of Arrow's marketing authorisation, but also extended to the purchasing or in-licensing of marketing authorisations, is clear from the words "*or otherwise deal in any other way in any UK marketing authorisations*", which are all-encompassing.

¹⁷¹⁰

ID 1297, page 29.

12.4.5.4.Arrow's commitment to give the undertakings in Article 1.1 by way of formal court order

(937) Article 1.2 of the agreement stated:

"ARROW agrees during the Term to give the above undertakings to the Court by way of a formal Court Order if requested to do so by Lundbeck during the course of the Infringement Litigation."

(938) As already mentioned in section 12.4.5.2 above, his provision ensured that Lundbeck would be able to obtain a consent order from the United Kingdom Patents Court with which Lundbeck could enforce the commitments Arrow had accepted in Article 1.1 without the need to commence a new infringement action.

12.4.5.5.Arrow's commitment to place the citalopram tablets it had purchased from Tiefenbacher in escrow with Lundbeck

(939) In Article 3.1 of the agreement, Arrow agreed, for security purposes, to deliver at least 5 million of the tablets it had purchased from Tiefenbacher to Lundbeck, to be held in escrow for the term of the agreement. Upon expiry of the agreement, the stock had to be returned to Arrow.

(940) This provision provided additional security to Lundbeck that Arrow would comply with its commitments under Articles 1.1 and 1.2.

12.4.6. Lundbeck transferred considerable value to Arrow in exchange for Arrow's commitments under the agreement

(941) The wording in Article 2.2 of the agreement that *"In consideration of the undertakings in clause 1.1 and ARROW not seeking a cross-undertaking in damages in respect of the period comprising the Term, Lundbeck shall provide ARROW with a total of five million pounds sterling (GBP 5 million)"* shows a clear link between on the one hand Arrow's commitment in clause 1.1 not to make, import or sell - or deal in any marketing authorisation regarding - any citalopram in the United Kingdom which Lundbeck would allege to be infringing and on the other hand Lundbeck's payment of GBP 5 million for the first year of operation of the agreement.

(942) Article 2.4 also created a clear link between Lundbeck's payment and Arrow's commitment under Article 1.1. This provision stated that if a court found that Arrow had been knowingly in breach of Article 1 during the term of the agreement, Arrow would immediately repay Lundbeck the compensation provided under Article 2.2 for the period in which Arrow had been found in breach of Article 1. In other words, if Arrow chose not to comply with its obligation not to sell *"the said Citalopram"* or *"any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights"*, Arrow would no longer be entitled to any further money from Lundbeck.

(943) The wording in Article 2.2 that the payment was also for *"ARROW not seeking a cross-undertaking in damages in respect of the period comprising the Term"* indicates, as Arrow explained to the Commission, that the payment represented *"a broad estimate of what Arrow would have received under a cross undertaking in damages in the event that the Lundbeck Process Patents were not infringed and/or were found to be invalid."*¹⁷¹¹ In other words, since those damages consisted notably

¹⁷¹¹ See recital (398) above.

of the profit Arrow gave up by not entering the United Kingdom market, the payment reflected Arrow's expected profits if Arrow had entered the United Kingdom market without infringing any Lundbeck patents.¹⁷¹² Arrow was thus offered a choice between a) receiving from Lundbeck up-front an amount of anticipated damages that reflected what Arrow could have earned if it had entered the market without infringing any Lundbeck patents, on condition only that it did not enter the market; or b) rejecting the offer and accepting instead the commercial and litigation risks inherent in entering the market, with only a likelihood of earning a comparable amount of profits. Lundbeck's offer of payments thus served to induce Arrow to commit not to try to enter the United Kingdom citalopram market and Arrow accepted this outcome in exchange for the payment. Moreover, this happened for a fixed period in which the patent issues between the two parties remained *de facto* unexplored.

- (944) Arrow argued, in its reply to the Statement of Objections, that the Commission *"fails to take into account that the purpose of a cross-undertaking is to provide a mechanism for compensating a party which may later be found to have been wrongfully excluded from a market either because the patent was not infringed or because it was not valid."*¹⁷¹³ However, there is a fundamental difference between a cross-undertaking which is linked to an underlying litigation and which makes payment of damages to a generic undertaking dependent on a finding of non-infringement or invalidation of the patent by the court, and the payment which Lundbeck made to Arrow and which Arrow would, according to the agreement, keep even if such litigation was never pursued to a ruling or even if the litigation was pursued but the judgment went against Arrow. With a cross-undertaking linked to a positive litigation result for Arrow, the generic undertaking has every incentive to contest infringement and to prove the invalidity of the patent. With the up-front, irreversible payment made by Lundbeck, Arrow lost all such incentive.
- (945) For the entire period between 24 January 2002 and 20 October 2003, Lundbeck transferred to Arrow value of GBP 6.8 million, equivalent to around EUR 10.4 million.¹⁷¹⁴ In the absence of any other counter-performance by Arrow, all of this amount was a clear inducement to Arrow to give up its independent efforts to enter the United Kingdom market and to accept the commitment not to make, import or sell - or deal in any marketing authorisation regarding - any citalopram in the United Kingdom which Lundbeck would allege to be infringing.
- (946) The agreement provided in Article 2.2 that Lundbeck would pay the settlement amount of GBP 5 million for the first year in four instalments, the last instalment being paid on the last day of the agreement, 31 December 2002. The two extensions of the agreement (together amounting to GBP 1.8 million) provided even for monthly payments. This indicates that Lundbeck's payments were directly related to the desired result that Arrow effectively stayed out of the United Kingdom market with generic citalopram.

¹⁷¹² See also recital (400) above. Lundbeck's transfer of value covered only the profit Arrow expected to make and not the purchase cost of the tablets because Lundbeck did not pay for the 5 million tablets it took in escrow and had agreed to give these tablets back to Arrow at the end of the term.

¹⁷¹³ ID 6082, page 45.

¹⁷¹⁴ See recital (447) above.

- (947) Arrow's commitments, like those of Merck (GUK), allowed Lundbeck to avoid the possibility of generic entry in the United Kingdom as early as January 2002 and thereby to maintain complete control over the United Kingdom citalopram market. As has been analysed in recitals (198) to (201) above, the avoidance of generic entry Lundbeck achieved through the agreement with Arrow was worth a lot more to Lundbeck than the value Lundbeck transferred to Arrow.
- (948) The Commission notes that neither of the parties explained the value transfer by providing different, legitimate reasons.
- (949) The Commission concludes from the facts described in this section 12.4.6 that Lundbeck transferred considerable value to Arrow in exchange for Arrow's commitment under the agreement not to sell "*the said Citalopram*" or "*any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights*" in the United Kingdom for the term of the agreement.

12.4.7. Intentions of the parties

- (950) This section deals with the intentions of the parties regarding the aim of the agreement. Arrow's intentions relevant for the existence of potential competition have already been analysed in sections 12.4.3 and 12.4.4 above.
- (951) Lundbeck's intentions to delay generic entry have already been described in detail in Chapter 6 and have been summarised, in particular for the United Kingdom, in recitals (803) to (808) above. Those recitals apply here as well. In Lundbeck's overall strategy, time in the form of delay in generic entry was needed to prolong profits on citalopram in the United Kingdom and obtain a window of opportunity for the launch of Lundbeck's successor product escitalopram.
- (952) Little is known from contemporaneous documents about Arrow's intentions at the time it concluded the agreement with Lundbeck. Arrow can, however, have had no doubt that in signing the agreement it gave up, for the duration of the agreement, any possibility to enter the United Kingdom market with generic citalopram, whether from Cipla, Matrix, Ranbaxy, or any other API supplier, whether such products would actually infringe any Lundbeck patents or not. Arrow itself later indicated to the Commission that "*The test established by Article 1.1 of the Agreement is a subjective test of alleged infringement, not actual infringement.*"¹⁷¹⁵ Arrow therefore willingly accepted, in exchange for Lundbeck's payments, that it sufficed for Lundbeck to allege that a particular process infringed its patents in order for Arrow to be barred from using that process or selling the products resulting from such process. As already mentioned, Arrow in fact never even tried to seek Lundbeck's approval of any particular process or product.
- (953) Secondly, Arrow was, or should have been, aware that the payments Lundbeck made to Arrow were based on the profit Arrow could have made had it entered the United Kingdom market without infringing any Lundbeck patents. It was Arrow which explained to the Commission that the first payment of GBP 5 million represented "*a broad estimate of what Arrow would have received under a cross undertaking in damages in the event that the Lundbeck Process Patents were not infringed and/or were found to be invalid.*"¹⁷¹⁶ Thirdly, as for the link between Lundbeck's payments

¹⁷¹⁵ See recital (394) above.

¹⁷¹⁶ See recital (398) above.

and Arrow's commitment to stay out of the United Kingdom market with generic citalopram, this link was, in the absence of any other counter-performance by Arrow, obvious in the agreement itself and Arrow could not have been unaware of it. Finally, it was also Arrow itself which informed the Commission that, with respect to the legal proceedings, "*neither Lundbeck nor Arrow took any steps to progress the proceedings*".¹⁷¹⁷ Like Lundbeck, Arrow therefore consciously did not make any effort to resolve the underlying patent questions.

- (954) The Commission concludes from the facts described in this section 12.4.7 that both parties knew or should have known that their agreement was anti-competitive.

12.4.8. The agreement restricted competition to an appreciable degree in the United Kingdom

- (955) The Commission refers to sections 6.6 and 11.9 for its considerations on the appreciable degree to which the agreements in question restricted competition and to section 13.3 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 States¹⁷¹⁸, the Commission does not have to prove an appreciable restriction of competition, but that in any case each (set of) agreement(s) did restrict competition to an appreciable degree.¹⁷¹⁹
- (956) In the specific case of Arrow, the Commission notes that the agreement with Lundbeck covered the United Kingdom, where Lundbeck's market share at the time when it concluded the agreement with Arrow considerably exceeded 10%.¹⁷²⁰

12.4.9. Conclusion on restriction by object

- (957) The facts described and assessed in legal terms in sections 12.4.1 to 12.4.4 above show that at the time the undertakings Arrow and Lundbeck concluded their agreement regarding the United Kingdom of 24 January 2002, they were potential competitors in the United Kingdom market for citalopram. As analysed in section 12.4.5 above, under the agreement, Arrow accepted a number of commitments which ensured that Arrow would for the term of the agreement not compete with Lundbeck in the citalopram market in the United Kingdom, whether with citalopram from Tiefenbacher or any other citalopram that Lundbeck alleged to be infringing. As analysed in section 12.4.6 above, Lundbeck transferred considerable value to Arrow in exchange for Arrow's acceptance of these commitments. Section 12.4.7 has shown that this agreement formed part of Lundbeck's strategy to delay generic entry for citalopram in the United Kingdom and that Arrow knew or should have known that Lundbeck's transfer of value to it served to persuade Arrow to accept the commitments in question and thereby to eliminate the incentive for Arrow to continue its independent efforts to enter the citalopram market in the United Kingdom for the term of the agreement.

¹⁷¹⁷ See recital (410) above.

¹⁷¹⁸ See recital (724) above. For the effect on trade between Member States of each (set of) agreement(s), see chapter 13 below.

¹⁷¹⁹ See in particular section 6.6 above. The Commission notes, in this respect, that since each (set of) agreement(s) covered the United Kingdom, where Lundbeck succeeded through the agreements in preventing widespread generic competition from January 2002 to October 2002, each (set of) agreement(s) restricted competition to an appreciable degree in at least one of the markets covered by the agreement.

¹⁷²⁰ See recital (215) above.

- (958) Given that Arrow's acceptance of these limitations on its commercial autonomy was achieved not by the strength of Lundbeck's patents, but by the transfer of value from Lundbeck to Arrow, the Commission considers that these limitations constitute restrictions of competition within the meaning of Article 101(1) of the Treaty.
- (959) Moreover, since these limitations on Arrow's commercial autonomy, obtained by Lundbeck through the transfer of considerable value to Arrow, were by their very nature injurious to the proper functioning of normal competition and followed directly and necessarily from the clauses of the agreement itself, the Commission considers that they are restrictions of competition by object. Indeed, the provisions of the agreement considered together and in their context make it clear that it was an objective aim, a necessary consequence of the agreement to make it impossible, for the term of the agreement, for Arrow to sell Tiefenbacher citalopram tablets or to make, sell or import in the United Kingdom any other citalopram, whether API or medicines, which Lundbeck alleged to be infringing, in exchange for the considerable transfer of value from Lundbeck.
- (960) Arrow's commitment not to sell Tiefenbacher citalopram tablets or to make, sell or import in the United Kingdom any other citalopram, whether API or medicines, which Lundbeck alleged to be infringing existed irrespective of whether or not such citalopram would actually infringe Lundbeck's process patents. A mere allegation of infringement by Lundbeck sufficed for Arrow to be obliged not to make, import or sell such product. Lundbeck could not have obtained this complete exclusion of Arrow from the citalopram market in the United Kingdom through court enforcement of its process patents against the process used to produce the tablets Arrow had purchased, even if Lundbeck had been successful in these efforts, which was far from evident when the agreement was concluded.¹⁷²¹
- (961) Finally, it should be noted that there was no commitment from Lundbeck in the agreement that Lundbeck would refrain from infringement proceedings if Arrow entered the market with generic citalopram after expiry of the agreement. The agreement therefore essentially ensured that Arrow could not manufacture or sell generic citalopram during the term of the agreement, without any guarantee of market access thereafter.
- (962) The Commission concludes that the agreement examined in this section, including in particular the facts that:
- Lundbeck and Arrow were at the moment when they concluded their agreement at least potential competitors in the United Kingdom;
 - Lundbeck transferred significant value to Arrow in the agreement;
 - this transfer of value was linked to the acceptance by Arrow of the limitations on entry in the agreement, notably Arrow's commitment not to sell in the United Kingdom any generic citalopram which Lundbeck alleged to be infringing between 24 January 2002 and 20 October 2003;

¹⁷²¹ The commitment could therefore fall both within the scope of Lundbeck's patents and outside, as a mere subjective allegation of infringement sufficed for the commitment to take hold. As explained in recitals (659) and (660) above, the Commission also considers such commitments within the scope of the patent illegal if they are induced by a transfer of value from the originator undertaking.

- the transferred value corresponded roughly to the profits Arrow expected if it had successfully entered the market;
- Lundbeck could not have obtained those limitations on entry through enforcement of its process patents, the obligations on Arrow in the agreement going beyond the rights granted to holders of process patents; and
- the agreement contained no commitment from Lundbeck to refrain from infringement proceedings if Arrow entered the market with generic citalopram after expiry of the agreement,

constitutes a restriction of competition by object.

12.5. The agreement between Lundbeck and Arrow regarding Denmark restricted competition by object under Article 101(1) of the Treaty

12.5.1. Introduction

- (963) The general factual context for the legal assessment of the agreements dealt with in this Decision has been set out in chapters 4 to 6 above. The specific factual context for the legal assessment of the Arrow United Kingdom agreement has been set out in sections 3.2, 3.4 and 7.5 above. The general legal context for the assessment of the agreements dealt with in this Decision has been set out in chapters 8 to 11 above. The specific legal assessment of the Arrow United Kingdom agreement has been made in section 12.4. This assessment is also relevant for the Arrow Denmark agreement, which was linked to the Arrow United Kingdom agreement.¹⁷²² Moreover, many of the factors that made Arrow a potential competitor to Lundbeck in the United Kingdom market also made it a potential competitor to Lundbeck in Denmark.¹⁷²³ The current section will make a specific legal assessment of the Arrow Denmark agreement, examining its compliance with Article 101(1) of the Treaty, based in particular on the criteria identified in recital (661) and the other factors mentioned in recital (662) above. This assessment will be made in the manner indicated in recital (735) above, taking into account the actual content and objectives of the agreement, the legal and economic context of the agreement, the implementation of the agreement and the intentions of the parties.

12.5.2. The Danish agreement between Lundbeck and Arrow was an agreement between undertakings within the meaning of Article 101(1) of the Treaty

- (964) Article 101(1) of the Treaty prohibits "*agreements between undertakings*" that restrict competition. For the general legal assessment of these quoted terms, the Commission refers to section 9.3 above. An agreement within the meaning of Article 101(1) of the Treaty can be said to exist when there is a concurrence of wills between two parties regarding the future behaviour of one or both of them. An undertaking is any entity engaged in an economic activity, such as offering goods or services on a given market, regardless of its legal status and the way in which it is financed. In the

¹⁷²² The Danish agreement used in part the same or similar language as the United Kingdom agreement. Interpretations of such language in the United Kingdom agreement are therefore also relevant for the Danish agreement. The duration of the Danish agreement was also dependent on the United Kingdom consent injunction. See Article 1.1 of the Danish agreement and the last preamble of that agreement. Arrow stated in its reply to the Statement of Objections: "...it appears that the agreement was intended to try and reflect in Denmark, the position adopted between Lundbeck and Arrow in the United Kingdom Settlement Agreement." See ID 6082, page 50.

¹⁷²³ This pertains, for instance to Arrow's contract with Tiefenbacher.

present case, Lundbeck and Arrow were at the time of events economic entities that offered goods on given markets. They were therefore undertakings. As for the "Agreement" regarding Denmark these two undertakings concluded on 3 June 2002, this document, as signed by H. Lundbeck A/S and Arrow Group A/S (referred to in the agreement as Arrow), reflected a concurrence of wills between the undertakings Lundbeck and Arrow with respect to the commitments embodied in the document. It therefore qualifies as an agreement between undertakings within the meaning of Article 101(1) of the Treaty.

12.5.3. Lundbeck and Arrow were at least potential competitors at the time they concluded the agreement

- (965) For its general legal assessment of potential generic competition for citalopram in the relevant period, the Commission refers to section 9.4 above. By the time Arrow and Lundbeck entered into an "Agreement" on 3 June 2002 covering Denmark, Lundbeck's basic patent on the citalopram compound (which included the two original processes to produce the compound) had already expired in January 2002 in Denmark. This meant that the citalopram market in Denmark was open to generic competition, as generic citalopram medicine could henceforth be freely sold provided it met regulatory requirements as to quality, safety and efficacy, as confirmed by a marketing authorisation. Generic undertakings with a business plan to sell generic citalopram Denmark and a realistic prospect to obtain supplies of generic citalopram medicines and an accompanying marketing authorisation in the near future were potential competitors to Lundbeck and to each other.¹⁷²⁴
- (966) With respect to Arrow specifically, as mentioned in recital (878) above, from the start of its business in 2001 Arrow identified citalopram *"as a major product that it would market shortly after it began trading."* Denmark was the home market for Arrow's parent company Arrow Group A/S. This company had also concluded the contract of 22 May 2001 with Tiefenbacher, under which Arrow purchased copies of (future) marketing authorisations Tiefenbacher was applying for in a number of countries, including the United Kingdom.¹⁷²⁵ Tiefenbacher's marketing authorisations, including the one purchased by Arrow for Denmark, listed two alternative API suppliers, Cipla and Matrix.¹⁷²⁶ On 10 September 2001, Arrow ordered DM 2.8 million worth of citalopram tablets from Tiefenbacher. These tablets contained API from Cipla.¹⁷²⁷ A first shipment arrived in November 2001 and a second shipment in the second week of January 2002. The total number of tablets in the two shipments together (in strengths of 10, 20 and 40 mgs) was 9 222 000.¹⁷²⁸ Of these tablets, Arrow had given 5 032 348 in escrow to Lundbeck.¹⁷²⁹ Arrow therefore in principle still had more than 4 million Cipla citalopram tablets which it had agreed not to sell in the United Kingdom.¹⁷³⁰

¹⁷²⁴ See section 9.4 above.

¹⁷²⁵ See recital (375) above.

¹⁷²⁶ See recital (375) above.

¹⁷²⁷ See recital (379) above.

¹⁷²⁸ See recital (379) above.

¹⁷²⁹ See recital (412) above.

¹⁷³⁰ According to Article 3.1 of the Danish agreement, Lundbeck would *"...obtain delivery of Arrow's current stock of Citalopram tablets consisting of approximately 1 million tablets..."*. Lundbeck stated in reply to the Commission's request for information of 12 March 2010: *"Although this cannot be confirmed, Lundbeck believes that it obtained delivery of Arrow's entire stock of citalopram destined*

- (967) As mentioned in recital (454) above, on 8 May 2002, Tiefenbacher informed Arrow Scandinavia AB in Stockholm, Sweden (a holding company for Arrow Group's Scandinavian subsidiaries¹⁷³¹), that it had obtained a marketing authorisation in Denmark for the company Jacobsen Pharma A/S on 2 May 2002.¹⁷³² On 17 May 2002 Arrow Group A/S and Tiefenbacher agreed an appendix to their earlier contract of 22 May 2001.¹⁷³³ This appendix specified that Tiefenbacher agreed that Arrow could, instead of obtaining its own licence through the mutual recognition procedure, purchase a national licence granted to a third party in Denmark and Sweden based on Tiefenbacher's registration file (which covered citalopram sourced from Cipla or Matrix).¹⁷³⁴ This meant that Arrow could, in particular, buy the marketing authorisation obtained in Denmark by Jacobsen Pharma A/S. Arrow could then start selling in Denmark the Cipla tablets it still had. Arrow could also have ordered more tablets from Tiefenbacher, which could have been made with API from either Cipla or Matrix.
- (968) Arrow informed the Commission that in fact Arrow did not buy any national marketing authorisation under this provision in the appendix agreed with Tiefenbacher, including from Jacobson Pharma A/S.¹⁷³⁵ However, it is clear from the agreement that both parties believed at the time of the conclusion of the agreement that Arrow would obtain the marketing authorisation in Denmark of Jacobson Pharma A/S in the near future and would use this marketing authorisation to start importing and selling generic citalopram in Denmark. The preamble stated that *"Arrow is in the process of obtaining a licence from a third party to import bulk Citalopram not manufactured by Lundbeck or with the consent of Lundbeck"* and that *"Arrow intends to import bulk Citalopram into the Territory from Germany."*¹⁷³⁶ Following the conclusion of the agreement with Lundbeck, there was no longer any incentive for Arrow, at least for the duration of the agreement, to buy a marketing authorisation for Denmark, as the agreement prohibited Arrow from selling there.
- (969) The Commission concludes from the concrete realistic possibility Arrow had at the time of conclusion of the agreement with Lundbeck to enter the Danish market with Tiefenbacher citalopram in the near future that Arrow and Lundbeck were at least potential competitors at the time they concluded their agreement. Indeed, the very fact that Lundbeck agreed to transfer considerable value to Arrow if it accepted not to enter the Danish market for the term of the agreement shows that Lundbeck considered that Arrow's market entry was plausible and that Lundbeck perceived Arrow as a competitive threat to its position in that market.

12.5.4. *The possibility of infringement of Lundbeck's process patents did not prevent Arrow from being at least a potential competitor to Lundbeck*

- (970) With respect to the general patent situation for generic citalopram, the Commission refers to its general considerations in recitals (745) and (746) above. These general

for sale in Denmark." See ID 823, page 45. This could mean that Arrow's remaining 3 million Cipla tablets were destined for other markets, whether in the EEA or outside.

¹⁷³¹ ID 1325, page 9.

¹⁷³² ID 907, pages 95 to 97.

¹⁷³³ See recital (375) above.

¹⁷³⁴ ID 1329, pages 1 to 4.

¹⁷³⁵ ID 1325, pages 2, 3 and 5.

¹⁷³⁶ ID 8, page 254 and ID 823, page 45.

considerations, notably those regarding the fact that Lundbeck's process patents did not cover all possible processes to manufacture citalopram that met Danish regulatory requirements, the inherent difficulty of enforcing process patents and the distinct possibility that a court might hold the crystallisation patent invalid, also apply to Arrow in Denmark.

(971) As already mentioned in recital (885) above, under clause 6.1 of Arrow's agreement with Tiefenbacher, Arrow had the option upon written notice from time to time to:

- purchase the medicinal products in bulk exclusively from Tiefenbacher for five years after launch in each Member State;
- manufacture the medicinal products itself or through third parties with API purchased from Tiefenbacher (with a (lower) royalty percentage for Tiefenbacher); or
- manufacture the medicinal products itself or through third parties with API sourced from an Arrow affiliate (with a higher royalty percentage for Tiefenbacher).¹⁷³⁷

(972) In reply to the Commission's request for information of 9 March 2011, Arrow interpreted this contract with Tiefenbacher as follows: *"The contract did not contain an exclusive purchasing obligation (and indeed no obligation to purchase, only an option to do so)...Arrow Group did discuss a possible supply agreement with Tiefenbacher, but as far as it can ascertain this was never concluded."*¹⁷³⁸ *Under the terms of the contract, Arrow Group was expressly permitted to supply products sourced from third parties, subject to payment of a royalty to Tiefenbacher if it did so [x]% of gross sales if Arrow Group manufactured its own tablets with Tiefenbacher's API (which would have been sourced from either Cipla or Matrix...), or [y]% of gross sales if it manufactured its own tablets with API from a third party..."*¹⁷³⁹

(973) While Lundbeck could have invoked its crystallisation patent¹⁷⁴⁰ in Denmark against Arrow's intended sales of generic citalopram, there was at the time of conclusion of the agreement on 3 June 2002 no certainty for Lundbeck that the Danish courts would find the crystallisation patent valid and infringed or that they would grant an interim injunction.¹⁷⁴¹ Even if an interim injunction were granted, this could,

¹⁷³⁷ See Article 6.1 of the agreement, ID 619, page 4.

¹⁷³⁸ Clause 6.2 of the agreement of 22 May 2001 provided that Arrow and Tiefenbacher would sign a related Supply Agreement in the course of the duration of the current agreement. However, Arrow reported to the Commission that *"Arrow Group considered entering into a supply agreement with Tiefenbacher in Autumn 2002, but as far as it is aware this was not concluded as agreement could not be reached on its terms."* See ID 1297, page 24.

¹⁷³⁹ See recital (375) above.

¹⁷⁴⁰ The Danish film distillation patent had not yet been granted at the time of conclusion of the agreement. Later on, Lundbeck *"realized that it was possible for generic companies to design around the Film Distillation Patent"* and *"renounced enforcing that patent because it lent itself to invalidity claims."* See ID 5394, page 162.

¹⁷⁴¹ It is recalled that in retrospect, at least in the United Kingdom legal procedure between Lundbeck and Lagap, in which an inspection of Matrix's production process took place in November 2002, the judge stated that Lundbeck had to admit that the process inspected did not infringe Lundbeck's crystallisation patent. See recital (155). Moreover, in the same procedure, Lundbeck itself estimated the chance of the crystallisation patent being invalidated by the United Kingdom court at 60%. Lundbeck avoided a ruling by settling. See recital (156). Also, in the EPO, Lundbeck had to significantly narrow the claims of the crystallisation patent itself in an opposition and appeal procedure. See recital (166). In Denmark,

according to Lundbeck at the time, take up to six months.¹⁷⁴² It was only on 5 July 2002 that Lundbeck obtained its first interim injunction in Denmark, against the Cipla citalopram launched by the company Gea in Denmark in March 2002.¹⁷⁴³ The fact that even after Lundbeck had launched infringement action against Gea on 17 April 2002, Arrow nevertheless went ahead and agreed on 17 May 2002 with Tiefenbacher that Arrow could buy the Danish marketing authorisation which had been granted on 2 May 2002 to the Danish company Jacobsen Pharma A/S, shows that Arrow was a competitive threat to Lundbeck in Denmark, not only with Cipla citalopram but also potentially with citalopram from Matrix, the other API supplier of Tiefenbacher. It should be noted, in this context, that in September 2002 Ratiopharm launched generic citalopram from Matrix in Denmark, that Lundbeck started infringement proceedings against Ratiopharm on 18 November 2002, but that the court denied an injunction on 25 April 2003.¹⁷⁴⁴ In respect of Arrow, with which Lundbeck already had an agreement regarding the United Kingdom, Lundbeck apparently preferred the certainty of buying for USD 500 000 what it called a "consent injunction" for Denmark, over the uncertainty, cost and delay of seeking an injunction against Arrow through court action.

- (974) Apart from launching Tiefenbacher citalopram in Denmark, Arrow also had the possibility, once it had obtained the Danish marketing authorisation of Jacobson Pharma A/S, to apply for a variation to start using citalopram of another API producer. For instance, on 14 May 2002, before Arrow entered into the Danish agreement with Lundbeck, Ranbaxy had made Arrow a concrete price offer for the sale to Arrow of 500 to 1000 kgs of citalopram API. If Arrow had entered into an agreement with Ranbaxy, it could have started selling Ranbaxy citalopram in Denmark well before the end of 2002, given that Arrow could have obtained a type II variation to its marketing authorisation within three to four months.¹⁷⁴⁵
- (975) In sum, the facts analysed in this section 12.5.4 show that when Lundbeck and Arrow concluded their agreement regarding Denmark, there was a considerable likelihood that Arrow would in the near future have sought entry to the Danish market with Tiefenbacher citalopram product. Given the uncertainty at that point in time that a Danish court would hold Tiefenbacher's citalopram, whether of Cipla or Matrix, infringing and given the real possibility that Lundbeck's crystallisation patent might have been held invalid, Arrow had at that time also a realistic prospect of being able

however, Lundbeck turned out to be largely successful, at least in a first stage, in obtaining interim injunctions against generic suppliers of citalopram. See recitals (452), (453), (465), (467) and (468). Some of these were later lifted in appeal or settled after the generic companies in question had switched to citalopram produced with the Matrix II process. See also recital (185).

¹⁷⁴² With respect to Denmark, Lundbeck believed that *"Interim injunctions are granted within about 6 months"* (ID 5481, page 3) and that it might therefore not be able to prevent Arrow's market entry through an application for an interim injunction. See ID 5394, page 212.

¹⁷⁴³ See recital (452) above.

¹⁷⁴⁴ See recital (467) above. See also recital (468) above.

¹⁷⁴⁵ As Ranbaxy itself stated to Lundbeck (see recital (558) above), it was deemed possible to obtain a type II variation to an existing marketing authorisation within three to four months if the information submitted was correct and complete.

It is true, of course, that on 16 June 2002 Ranbaxy concluded an agreement with Lundbeck in which Ranbaxy agreed not to sell its citalopram to the EEA, but that was after Arrow had concluded its Danish agreement with Lundbeck on 3 June 2002. At the time when Arrow concluded its agreement with Lundbeck, therefore, Arrow had the option of switching to Ranbaxy citalopram.

to sell in the course of the term of the agreement with Lundbeck generic citalopram in Denmark without infringing any Lundbeck patents or by obtaining a court ruling finding any such patents to be invalid. At the latest, Arrow could, like Ratiopharm, have launched Matrix citalopram produced with Matrix's new and allegedly non-infringing process in September 2002, well within the term of Arrow's Danish agreement with Lundbeck (which lasted until 1 April 2003). Arrow could also in May 2002 have entered into a supply contract with Ranbaxy and have started selling Ranbaxy citalopram in Denmark before the end of 2002. Arrow was therefore at the time of conclusion of the agreement at least a potential competitor to Lundbeck in the Danish market.

12.5.5. Commitments accepted by Arrow in the Danish agreement with Lundbeck

- (976) In the agreement with Lundbeck, Arrow accepted several commitments that limited its freedom of action to enter the citalopram market in Denmark.

12.5.5.1. Arrow's commitment not to import or sell products containing citalopram which Lundbeck alleged to be infringing

- (977) Article 1.1 of the agreement provided:

"Arrow consents to cancel, cease and desist from any importation, manufacture, production, sale or other marketing of products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights in the Territory for the term of this Agreement, however only until a final, unappealable and enforceable, judicial decision in the Infringement Litigation, as defined above, has been rendered by the Courts in the UK. The obligation of Arrow under this clause 1.1 shall hereinafter be referred to as the "Consent Injunction"."

- (978) In reply to the Commission's request for information of 19 March 2010, Arrow confirmed to the Commission that *"The Lundbeck Agreements cover citalopram in any form, including both as an API and a medicine."*¹⁷⁴⁶
- (979) The Commission observes that the agreement left it entirely to the discretion of Lundbeck to conclude from an analysis of a sample of a product whether the process that had led to the product in question infringed Lundbeck's process patents. The agreement did not provide for any objective interpretation of the analysis of the samples in question, for instance by a third party, or for any possibility for Arrow to contest Lundbeck's purely subjective view that a particular production process infringed its patents.¹⁷⁴⁷ The mechanism, therefore, extended the scope of the agreement to any product that Lundbeck simply alleged to be infringing.
- (980) The Commission considers that in Article 1.1 Arrow committed itself for the term of the agreement not to import or sell any citalopram, whether API or medicines, which Lundbeck alleged to infringe its patents. This commitment covered both the citalopram tablets Arrow had in stock at that time and any other citalopram Arrow could buy from Tiefenbacher or other API suppliers, if Lundbeck alleged such products to be infringing.

¹⁷⁴⁶ ID 610, page 25.

¹⁷⁴⁷ It is recalled that in the Lagap litigation, Lundbeck had to admit that the inspected process was non-infringing, even though Lundbeck had previously demonstrated a *"firm and unshakeable confidence that it was impossible [...] to be operating a non-infringing process..."* See recital (155) above.

Arguments of the parties

- (981) Lundbeck claimed, in its reply to the Statement of Objections, that Article 1.1 of the Danish agreement covered only the Cipla tablets Arrow had in stock at the time.¹⁷⁴⁸ Arrow, for its part, simply stated in its reply to the Statement of Objections with respect to the Danish agreement as a whole that *"...the arguments raised above in relation to the UK Settlement Agreement apply equally to the Danish Settlement Agreement."*¹⁷⁴⁹
- (982) According to the parties, therefore, the term *"products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights"* covered the citalopram tablets Arrow had in stock at the moment of conclusion of the agreement. Article 3.1 of the agreement provided that Arrow would deliver its *"...current stock of Citalopram tablets consisting of approximately 1 million tablets..."* to Lundbeck.
- (983) The Commission does not, however, agree with Lundbeck's statement that, *"the parties obviously intended to and did limit the scope of the Arrow Denmark Agreement only to Arrow's infringing citalopram that already existed at the time, as described in the preamble to the Agreement."*¹⁷⁵⁰
- (984) The preamble to the Danish agreement provided:
- "WHEREAS, Arrow is in the process of obtaining a licence from a third party to import bulk Citalopram not manufactured by Lundbeck or with the consent of Lundbeck into the Territory;*
- WHEREAS, Arrow intends to import bulk Citalopram into the Territory from Germany;*
- WHEREAS, Lundbeck has performed laboratory analyses of the bulk Citalopram to be imported by Arrow;*
- WHEREAS, the results of these analyses give Lundbeck substantial reason to believe that the bulk Citalopram infringes Lundbeck's above mentioned intellectual property rights."*
- (985) The Commission observes, firstly, that the term *"products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights"* is not defined or limited in scope by any wording in the agreement. There is therefore no apparent reason why these words would not be interpreted based on the plain meaning of the words. That plain meaning is that any product containing citalopram which Lundbeck alleges to be infringing is covered by Article 1.1.
- (986) Secondly, the preamble, on which Lundbeck based itself to suggest a narrower interpretation of Article 1.1, is not as specific as Lundbeck might hope. There is reference to *"a licence from a third party to import bulk Citalopram"* thereby referring to the Tiefenbacher marketing authorisation for Denmark which Arrow was in the process of acquiring from Jacobsen Pharma A/S and which would have allowed Arrow to import and sell Tiefenbacher citalopram, whether produced with Cipla API or Matrix API, now and in the future. As for the laboratory analyses of Lundbeck, these could pertain both to Cipla API as Matrix API, as Lundbeck had

¹⁷⁴⁸ ID 5394, page 210.

¹⁷⁴⁹ ID 6082, page 50.

¹⁷⁵⁰ ID 5394, page 215.

analysed both (that is, the Cipla I and Matrix I processes). This recital may therefore be understood as saying that Lundbeck has analysed Tiefenbacher's citalopram, both made with Cipla API and with Matrix API, and considered that both production methods (at that time) infringed its process patents. Taken together, the part of the preamble quoted in recital (984) above therefore generally refers to any citalopram Arrow could import under Tiefenbacher's licence, not just to the citalopram Arrow had in stock.

- (987) One cannot therefore conclude from an introductory preamble describing background, (namely that the dispute was caused by the intended sale by a generic undertaking of a particular product produced with a particular production process), that differently drafted operational obligations which the generic undertaking accepted in the agreement in exchange for a significant transfer of value are also necessarily limited to that particular product produced with that particular production process. Given that Lundbeck's perspective at the time was, as its representatives told Merck (GUK), that Lundbeck *"do not want a generic on the market. However they could compensate us for the profit we would have made etc"*¹⁷⁵¹, an obligation not to make, import or sell any generic citalopram whatsoever in the operational provisions of the different agreements fitted perfectly with that objective. From a commercial perspective, the damage to Lundbeck's incumbent market position was as great from non-infringing generic citalopram as it was from infringing citalopram, or even greater if Lundbeck could in the case of infringing citalopram avoid decreases in price or reimbursement levels and obtain damages.
- (988) The so-called Consent Injunction which Arrow accepted applied, according to the terms of Article 1.1 *"for the term of this Agreement, however only until a final, unappealable and enforceable, judicial decision in the Infringement Litigation, as defined above, has been rendered by the Courts in the UK"*.¹⁷⁵² Since the *"Infringement Litigation"* was defined in the preamble as the *"voluntary injunction against Arrow"* in the United Kingdom proceedings, which applied *"until further order"*, it was highly unlikely that any *"final and unappealable court decision"* would be issued on this voluntary consent order before 1 April 2003.¹⁷⁵³ The same applied to the main infringement proceedings, given that these proceedings were by June 2002 no longer being pursued on substance either by Lundbeck or by Arrow.¹⁷⁵⁴ The agreement was therefore in reality not an interim agreement to preserve the status quo between the parties while awaiting resolution by the courts of the legal issues between them, but an agreement to keep Arrow out of the generic market in Denmark for the period between 3 June 2002 and 1 April 2003.
- (989) This conclusion is reinforced by the fact that the agreement did not refer to any on-going patent litigation in Denmark, whether between the parties or between Lundbeck and a third party (such as Gea)¹⁷⁵⁵, but to the consent injunction between Lundbeck and Arrow in the United Kingdom. Even if a ruling in the main proceeding, in which Lundbeck had claimed infringement of its film distillation

¹⁷⁵¹ See recital (255) above.

¹⁷⁵² See recital (457) above.

¹⁷⁵³ Certainly the parties did not interpret the Tomlin order by the United Kingdom court of 30 January 2003, confirming the previous consent order and staying the main infringement proceedings, as a court decision that would end the Danish agreement.

¹⁷⁵⁴ See recitals (410) and (430) above.

¹⁷⁵⁵ See recital (452) above.

patent, had been given by the United Kingdom Patent Court, such a ruling could have been influential in Danish courts, but it would not have been decisive as such for the outcome of any legal procedure regarding the film distillation patent in Denmark.¹⁷⁵⁶ Such ruling would also have had no relevance for any claim by Lundbeck in Denmark of infringement by Arrow of the crystallisation patent.

- (990) The provisions of Article 4.2 of the agreement¹⁷⁵⁷ obliged Lundbeck to pursue generic entry by any other companies in Denmark based on Lundbeck's patents there. If Lundbeck were unsuccessful in such litigation, Arrow had the right to annul the agreement, to repay to Lundbeck that portion of the compensation for the Consent Injunction which applied to the period after generic entry and to buy back its stock of tablets at the same cost price as for which it had sold them to Lundbeck. This provision indicates that Arrow was willing to stay out of the Danish citalopram market in exchange for Lundbeck's compensation as long as no other generic undertaking successfully entered the Danish market. If, however, Lundbeck allowed generic entry to take place or if it were to lose in court against any attempted generic sales in Denmark, Arrow wanted a possibility to be released of its obligations under the agreement, so that it too would be free to sell generic citalopram in Denmark. This provision operated independently of the question which API supplier had produced the citalopram which the court would stop or allow onto the market. If, for instance, a Danish court would find Cipla citalopram in infringement of Lundbeck's patents, Arrow would still be entitled to further payments, even if it also had intended to sell Cipla tablets in Denmark. *Vice versa*, if a Danish court found for instance that Matrix citalopram did not infringe Lundbeck's patents and could be freely sold on the Danish market, Arrow could terminate the agreement with Lundbeck, even if it were to going to sell Cipla citalopram. In that respect Article 4.2 aimed not at any clarification of the legal question whether Arrow's citalopram was infringing, but simply at determining whether generic entry (with whatever citalopram) was successful in Denmark or not. The prospect of Lundbeck losing infringement litigation in Denmark may also explain why the agreement was not renewed after 1 April 2003. On 25 April 2003, a Danish court denied Lundbeck's request for an interim injunction against the generic undertaking Ratiopharm, which was supplied by Tiefenbacher with Matrix citalopram.¹⁷⁵⁸ Lundbeck later explained to the Commission: *"Because generic versions of citalopram had entered the market by the end of the agreement with Arrow, Lundbeck did not seek to extend the agreement with Arrow beyond this date."*¹⁷⁵⁹

Conclusion

- (991) The conclusion from this section 12.5.5.1 is that Arrow's commitment in Article 1.1 of the agreement with Lundbeck not to make, sell or import *"products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights"* in Denmark for the term of the agreement meant that Arrow was not allowed to make, sell or import any generic citalopram, whether API or medicines, which Lundbeck alleged to infringe its process patents, irrespective of the API supplier and irrespective of whether the manufacturing process used actually infringed any

¹⁷⁵⁶ This patent was granted in Denmark on 29 June 2002 as patent DK 2001 00386. Source: Espacenet.

¹⁷⁵⁷ See recital (463) above.

¹⁷⁵⁸ See recital (185) above.

¹⁷⁵⁹ See recital (473) above.

Lundbeck patents or not, a result Lundbeck could not have obtained by launching infringement proceedings against Arrow in Denmark. If instead of concluding the Danish agreement with Arrow, Lundbeck had pursued infringement litigation against Arrow in Denmark, Lundbeck could, if it had been successful in proving infringement and if Arrow's counter-claim of patent invalidity had failed, only have prevented Arrow from marketing the Cipla citalopram Arrow had purchased. Arrow would thus have remained free to import and sell citalopram from Cipla if Cipla had in the meantime switched to another, non-infringing production method. Arrow would also have been free to import and sell citalopram from Matrix or any other producer. Arrow would likewise have been free to produce generic citalopram itself, through its subsidiary Resolution Chemicals.

12.5.5.2.Arrow's commitment not to dispose of its licences and marketing authorisations

(992) Article 1.2 of the agreement provided:

"During the term of this Agreement, Arrow shall maintain all licenses and marketing authorisations and may not dispose of such licenses or marketing authorisations neither as sale, license or in any other way."

(993) This commitment prohibited Arrow from out-licensing or selling its Danish marketing authorisation for Tiefenbacher citalopram, which it expected to obtain soon, to any third party. This ensured Lundbeck that Arrow's Danish marketing authorisation for Tiefenbacher citalopram, once obtained, would not be used by any other undertaking to sell Tiefenbacher's citalopram in Denmark.¹⁷⁶⁰

12.5.5.3.Arrow's commitment to deliver its current stock of citalopram tablets to Lundbeck

(994) Article 3.1 of the agreement provided:

"On payment of compensation as provided in clause 2 Lundbeck shall obtain delivery of Arrow's current stock of Citalopram tablets consisting of approximately 1 million tablets which shall comply with the marketing authorisation granted by the Danish authorities, at cost price being USD 147,000 plus applicable VAT or other taxes..."

(995) The sale of Arrow's current stock of Cipla tablets to Lundbeck served as a safeguard from Lundbeck that Arrow would not sell these tablets in other markets in the EEA or to another generic undertaking for sale in Denmark or elsewhere. Lundbeck itself could not sell these tablets as the agreement did not provide for Arrow to transfer its marketing authorisation to Lundbeck. This indicates that Lundbeck had no intention to sell the tablets in question itself. Instead it initially stored and, after expiry of the agreement, destroyed them.¹⁷⁶¹

12.5.6. Lundbeck transferred considerable value to Arrow in exchange for Arrow's commitments under the agreement

(996) The wording in Article 2.1 of the agreement that *"Lundbeck shall grant Arrow a compensation for the Consent Injunction under clause 1 of USD 0.5 million (USD*

¹⁷⁶⁰ It is recalled that Arrow, following the conclusion of the agreement with Lundbeck, did not obtain the Danish marketing authorisation of Jacobsen Pharma A/S.

¹⁷⁶¹ See recital (471) above.

500,000.00)"¹⁷⁶² shows a clear link between Lundbeck's payment of USD 0.5 million and Arrow's commitment not to sell for the term of the agreement any generic citalopram in Denmark that Lundbeck would allege to be infringing. In the absence of any other counter-performance than Arrow's commitment in Article 1.2 not to sell or license any marketing authorisations or licences in its possession, which served to complement the so-called Consent Injunction in Article 1.1, Lundbeck's payment of USD 0.5 million was a clear inducement to Arrow to give up its independent efforts to enter the Danish market and to accept the commitment not to enter the Danish market with generic citalopram for the term of the agreement, a result that infringement litigation in Denmark against the Cipla product Arrow had purchased could not have procured.

- (997) It follows, moreover, from Article 2.2 of the agreement¹⁷⁶³, saying that the amount of USD 0.5 million constituted full and final compensation for any and all losses sustained by Arrow due to the Consent Injunction, that this amount corresponded to the profit Arrow would have expected to make in Denmark in the period covered by the agreement, if Arrow were to have entered that market without infringing any Lundbeck patents. Arrow was thus offered a choice between a) receiving from Lundbeck up-front an amount of anticipated damages that reflected what Arrow could have earned if it had entered the Danish market without infringing any Lundbeck patents, on condition only that it did not enter that market; or b) rejecting the offer and accepting instead the commercial and litigation risks inherent in competing and entering the Danish market, with only a possibility of earning a comparable amount of profits. Lundbeck's offer thus served to induce Arrow to commit not to try to enter the Danish citalopram market and Arrow accepted this commitment in exchange for the payment. Moreover, this happened not just while the two parties were awaiting a ruling on the patent issues between them, but in reality for a fixed period in which the patent issues between the two parties in Denmark (and the United Kingdom) remained unexplored.
- (998) Article 3.1 of the agreement provided that Lundbeck purchased Arrow's current stock of around 1 million tablets "*at cost price being USD 147,000...*".¹⁷⁶⁴ Article 4.2 of the agreement provided that Arrow could buy these tablets back at the same price if another generic undertaking successfully entered the Danish market.¹⁷⁶⁵ This provision was not applied during the operation of the agreement and afterwards Lundbeck destroyed the tablets.¹⁷⁶⁶ Lundbeck did not, in any case, have a marketing authorisation to sell these tablets in Denmark or elsewhere. The only value possession of these tablets therefore had for Lundbeck was that they could thus not be sold by Arrow or any other generic undertaking, whether in Denmark or elsewhere. As Lundbeck paid Arrow the amount of USD 147 000 not for any benefit the tablets would have in themselves for Lundbeck, but merely to exclude the possible marketing of the tablets concerned by a generic undertaking, this payment should, like the other payment to Arrow of USD 500 000, be considered part of Lundbeck's total transfer of value to Arrow in exchange for Arrow's commitment not to import, make or sell - or sell or license any marketing authorisation or licence

¹⁷⁶² See recital (459) above.

¹⁷⁶³ See recital (460) above.

¹⁷⁶⁴ See recital (461) above.

¹⁷⁶⁵ See recital (463) above.

¹⁷⁶⁶ See recital (471) above.

regarding - any citalopram in Denmark for the duration of the agreement. In its Business Development document with the title "Generic citalopram update 04 09 2002", Lundbeck registered both payments to Arrow together as "*Cost*" to gain "*Time*".¹⁷⁶⁷

- (999) The Commission concludes from the facts described in this section 12.5.6 that Lundbeck transferred considerable value to Arrow in exchange for Arrow's commitment under the agreement not to import or sell in Denmark during the term of the agreement products containing Citalopram which Lundbeck alleged to be infringing.

12.5.7. Intentions of the parties

- (1000) This section deals with the intentions of the parties regarding the aim of the agreement. Arrow's intentions relevant for the existence of potential competition have already been analysed in sections 12.5.3 and 12.5.4 above.
- (1001) Lundbeck's intentions to delay generic entry have already been described in detail in Chapter 6 and have been summarised, in particular for the United Kingdom, in recitals (803) to (808) above. Those recitals apply here as well. In Lundbeck's overall strategy, time in the form of delay in generic entry was needed to prolong profits on citalopram in Denmark and obtain a window of opportunity for the launch of Lundbeck's successor product escitalopram.
- (1002) Little is known from contemporaneous documents about Arrow's intentions at the time it concluded the agreement regarding Denmark with Lundbeck. Arrow can, however, have had no doubt that in signing the agreement it gave up, for the duration of the agreement, any possibility to enter the Danish market with generic citalopram, whether from Cipla, Matrix, its own subsidiary Resolution Chemicals, or any other API supplier, whether such products would actually infringe any Lundbeck patents or not. With respect to the United Kingdom agreement, Arrow itself later indicated to the Commission that "*The test established by Article 1.1 of the Agreement is a subjective test of alleged infringement, not actual infringement.*"¹⁷⁶⁸ This test of alleged infringement was even made lighter in the subsequent Danish agreement, in that there was no sampling analysis mechanism whatsoever anymore in the Danish agreement. Arrow therefore willingly accepted in the Danish agreement, in exchange for Lundbeck's payments, that it sufficed for Lundbeck to just say that it believed that a particular process infringed its patents in order for Arrow to be barred from using that process or selling the products resulting from such process in Denmark. As already mentioned, Arrow in fact never even tried to seek Lundbeck's approval of any particular process or product.
- (1003) Secondly, Arrow was, or should have been, aware that the payments Lundbeck made to Arrow were based on the profit Arrow could have made had it entered the Danish market. As in the agreement regarding the United Kingdom, Lundbeck's compensation for the Consent Injunction served, according to Article 2.2 of the Danish agreement, as full and final compensation for any and all losses sustained by Arrow for not having entered the Danish market.

¹⁷⁶⁷ See recital (286) above.

¹⁷⁶⁸ See recital (394) above.

- (1004) Thirdly, as for the link between Lundbeck's payments and Arrow's commitment to stay out of the Danish market with generic citalopram, this link was, in the absence of any other counter-performance by Arrow, obvious in the agreement and Arrow could not have been unaware of it.
- (1005) The Commission concludes from the facts described in this section 12.5.7 that both parties knew or should have known that their agreement was anti-competitive.

12.5.8. The agreement restricted competition to an appreciable degree in Denmark

- (1006) The Commission refers to sections 6.6 and 11.9 for its considerations on the appreciable degree to which the agreements in question restricted competition and to section 13.3 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 States¹⁷⁶⁹, the Commission does not have to prove an appreciable restriction of competition, but that in any case each (set of) agreement(s) did restrict competition to an appreciable degree.¹⁷⁷⁰
- (1007) In the specific case of Arrow, the Commission notes that the agreement with Lundbeck covered Denmark, where Lundbeck's market share at the time when it concluded the agreement with Arrow considerably exceeded 10%.¹⁷⁷¹

12.5.9. Conclusion on restriction by object

- (1008) The facts described and assessed in legal terms in sections 12.5.1 to 12.5.4 above show that at the time the undertakings Arrow and Lundbeck concluded their agreement regarding Denmark of 3 June 2002, they were potential competitors in the Danish market for citalopram. As analysed in section 12.5.5 above, under the agreement, Arrow accepted a number of commitments which ensured that Arrow would for the term of the agreement not compete with Lundbeck in the citalopram market in Denmark, whether with citalopram from Tiefenbacher or any other citalopram that Lundbeck alleged to be infringing. As analysed in section 12.5.6 above, Lundbeck transferred considerable value to Arrow in exchange for Arrow's acceptance of these commitments. Section 12.5.7 has shown that this agreement formed part of Lundbeck's strategy to delay generic entry for citalopram and that Arrow knew or should have known that Lundbeck's transfer of value to it served to persuade Arrow to accept the commitments in question and thereby to eliminate the incentive for Arrow to continue its independent efforts to enter the citalopram market in Denmark for the term of the agreement.
- (1009) Given that Arrow's acceptance of these limitations on its commercial autonomy was achieved not by the strength of Lundbeck's patents, but by the transfer of value from Lundbeck to Arrow, the Commission considers that these limitations constitute restrictions of competition within the meaning of Article 101(1) of the Treaty.

¹⁷⁶⁹ See recital (724) above. For the effect on trade between Member States of each (set of) agreement(s), see chapter 13 below.

¹⁷⁷⁰ See in particular section 6.6 above. The Commission notes, in this respect, that since each (set of) agreement(s) covered the United Kingdom, where Lundbeck succeeded through the agreements in preventing widespread generic competition from January 2002 to October 2002, each (set of) agreement(s) restricted competition to an appreciable degree in at least one of the markets covered by the agreement.

¹⁷⁷¹ See recital (215) above.

- (1010) Moreover, since these limitations on Arrow's commercial autonomy, obtained by Lundbeck through the transfer of considerable value to Arrow, were by their very nature injurious to the proper functioning of normal competition and followed directly and necessarily from the clauses of the agreement itself, the Commission considers that they are restrictions of competition by object. Indeed, the provisions of the agreement considered together and in their context make it clear that it was an objective aim, a necessary consequence of the agreement to make it impossible, for the term of the agreement, for Arrow to sell Tiefenbacher citalopram tablets or to make, sell or import in Denmark any other citalopram, whether API or medicines, which Lundbeck alleged to be infringing, in exchange for the considerable transfer of value from Lundbeck.
- (1011) Arrow's commitment not to sell Tiefenbacher citalopram tablets or to make, sell or import in Denmark any other citalopram, whether API or medicines, which Lundbeck alleged to be infringing existed irrespective of whether or not such citalopram would actually infringe Lundbeck's process patents. A mere allegation of infringement by Lundbeck sufficed for Arrow to be obliged not to make, import or sell such product. Lundbeck could not have obtained this complete exclusion of Arrow from the citalopram market in Denmark through court enforcement of its process patents against the process used to produce the tablets Arrow had purchased, even if Lundbeck had been successful in these efforts, which was far from evident when the agreement was concluded.¹⁷⁷²
- (1012) Finally, it should be noted that there was no commitment from Lundbeck in the agreement that Lundbeck would refrain from infringement proceedings if Arrow entered the market with generic citalopram after expiry of the agreement. The agreement therefore essentially ensured that Arrow could not manufacture or sell generic citalopram during the term of the agreement, without any guarantee of market access thereafter.
- (1013) The Commission concludes that the agreement examined in this section, including in particular the facts that:
- Lundbeck and Arrow were at the moment when they concluded their agreement at least potential competitors in Denmark;
 - the existence of a significant transfer of value from Lundbeck to Arrow in the agreement;
 - the link between that transfer of value and the acceptance by Arrow of the limitations on entry in the agreement, notably Arrow's commitment not to sell in Denmark any generic citalopram which Lundbeck alleged to be infringing between 3 June 2002 and 1 April 2003;
 - the transferred value corresponded roughly to the profits Arrow expected if it had successfully entered the market;

¹⁷⁷²

The commitment could therefore fall both within the scope of Lundbeck's patents and outside, as a mere subjective allegation of infringement sufficed for the commitment to take hold. As explained in recitals (659) and (660) above, the Commission also considers such commitments within the scope of the patent illegal if they are induced by a transfer of value from the originator undertaking.

- Lundbeck could not have obtained those limitations on entry through enforcement of its process patents, the obligations on Arrow in the agreement going beyond the rights granted to holders of process patents; and
- the agreement contained no commitment from Lundbeck to refrain from infringement proceedings if Arrow entered the market with generic citalopram after expiry of the agreement,

constitutes a restriction of competition by object.

12.6. The agreement between Lundbeck and Alpharma regarding the EEA restricted competition by object under Article 101(1) of the Treaty

12.6.1. Introduction

- (1014) The general factual context for the legal assessment of the agreements dealt with in this Decision has been set out in chapters 4 to 6 above. The specific factual context for the legal assessment of the Alpharma agreement has been set out in sections 3.2, 3.5 and 7.6 above. The general legal context for the assessment of the agreements dealt with in this Decision has been set out in chapters 8 to 11 above. The current section will make a specific legal assessment of the Alpharma agreement, examining its compliance with Article 101(1) of the Treaty, based in particular on the criteria identified in recital (661) and the other factors mentioned in recital (662) above. This assessment will be made in the manner indicated in recital (735) above, taking into account the actual content and objectives of the agreement, the legal and economic context of the agreement, the implementation of the agreement and the intentions of the parties.

12.6.2. The agreement between Lundbeck and Alpharma was an agreement between undertakings within the meaning of Article 101(1) of the Treaty

- (1015) Article 101(1) of the Treaty prohibits "*agreements between undertakings*" that restrict competition. For the general legal assessment of these quoted terms, the Commission refers to section 9.3 above. An agreement within the meaning of Article 101(1) of the Treaty can be said to exist when there is a concurrence of wills between two parties regarding the future behaviour of one or both of them. An undertaking is any entity engaged in an economic activity, such as offering goods or services on a given market, regardless of its legal status and the way in which it is financed. In the present case, Lundbeck and Alpharma were at the time of events economic entities that offered goods on given markets. They were therefore undertakings. As for the "*Settlement Agreement*" these two undertakings concluded on 22 February 2002, this document, as signed by H. Lundbeck A/S and Alpharma ApS, reflected a concurrence of wills between these two undertakings with respect to the commitments embodied in the document. It therefore qualifies as an agreement between undertakings within the meaning of Article 101(1) of the Treaty.

12.6.3. Lundbeck and Alpharma were at least potential competitors at the time they concluded the agreement

- (1016) For its general legal assessment of potential generic competition for citalopram in the relevant period, the Commission refers to section 9.4 above. By the time Alpharma and Lundbeck entered into a "*Settlement Agreement*" on 22 February 2002 covering all Union countries, Norway and a third country, Lundbeck's basic patent on the citalopram compound (which included the two original processes to produce the compound) had lapsed by January 2002 in most Contracting Parties of the EEA Agreement. This meant that citalopram markets in those Contracting Parties of the

EEA Agreement were open to generic competition, as generic citalopram medicine could henceforth be freely sold provided it met regulatory requirements as to quality, safety and efficacy, as confirmed by a marketing authorisation. Generic undertakings with a business plan to sell generic citalopram in markets in the EEA and a realistic prospect to obtain supplies of generic citalopram medicines and an accompanying marketing authorisation in the near future were potential competitors to Lundbeck and to each other.¹⁷⁷³

- (1017) At the time of the conclusion of the agreement, Alpharma had a supply contract dated 25 June 2001 with Tiefenbacher for generic citalopram made with either Cipla or Matrix API.¹⁷⁷⁴ Alpharma explained to the Commission that *"Alpharma AS was not involved in the selection of the API supplier as this was dealt with by Tiefenbacher as the applicant for the marketing authorisation and Alpharma simply purchased the finished dose form of the product from Tiefenbacher."*¹⁷⁷⁵ It is apparent from the facts that Cipla was the API supplier of the citalopram products purchased by Alpharma up to the conclusion of the agreement with Lundbeck.¹⁷⁷⁶ This supply agreement and the earlier contract with Tiefenbacher of 31 July 2000 allowed Alpharma to obtain from Tiefenbacher marketing authorisations and supplies of citalopram product for sales throughout the EEA.¹⁷⁷⁷ For a period of three years after launch in the United Kingdom, Alpharma would buy the product as tablets in bulk from Omega Farma and for an additional two years, Alpharma would buy the API exclusively from Tiefenbacher. Alpharma had at the time of conclusion of the agreement with Lundbeck 9.4 million citalopram tablets in stock and had ordered 16 million more.¹⁷⁷⁸ Alpharma had already obtained marketing authorisations in the Netherlands, Finland, Denmark and Sweden.¹⁷⁷⁹ In the United Kingdom, both Lundbeck and Alpharma expected Alpharma to receive a marketing authorisation any day. On 9 January 2002 Lundbeck reported that *"Alpharma...have verbal confirmation of a citalopram licence for all strengths."*¹⁷⁸⁰ Alpharma had already published sales prices for its citalopram in the United Kingdom.¹⁷⁸¹ On 19 February 2002, three days before concluding the agreement with Lundbeck, the [employee function]* of Alpharma ApS stated in an internal e-mail: *"Currently we*

¹⁷⁷³ See section 9.4 above.

¹⁷⁷⁴ See recital (480) above.

¹⁷⁷⁵ See footnote 895 above.

¹⁷⁷⁶ See footnote 895 above. See also recitals (480) and (518) above. It is not excluded that part of the tablets on order and supplied later in the course of the operation of the agreement with Lundbeck were made with API from Matrix, using the new Matrix process including the washing step (the so-called Matrix II process). See the reference to *"Matrix new"* in ID 681, page 53.

¹⁷⁷⁷ See recitals (476) and (480) above.

¹⁷⁷⁸ See recital (527) above.

¹⁷⁷⁹ See recital (516) above.

¹⁷⁸⁰ See recital (491). For other EEA countries, see recital (490).

¹⁷⁸¹ See recitals (486), (489), (492), (493) and (529) above. In its reply to the Statement of Objections Lundbeck states: *"Lundbeck's belief that Alpharma would imminently enter the UK market was corroborated by the list of prices published by Alpharma."* See ID 5394, page 227. In retrospect, Alpharma received its United Kingdom marketing authorisation only on 26 July 2002, due to Lundbeck's appeal against the Dutch marketing authorisation which served as the reference for the United Kingdom marketing authorisation. See recital (168) above.

Following the conclusion of the agreement with Lundbeck, and during its operation until 30 June 2003, Alpharma obtained additional marketing authorisations in Norway, Germany, Austria and the United Kingdom. See recital (516) above.

plan to launch Citalopram in UK, NL DE, DK, NO, SF, FI within the next 2-6 weeks."¹⁷⁸²

- (1018) The Commission concludes from these concrete realistic possibilities AlphaPharma had of entering one or more Contracting Parties of the EEA Agreement with generic citalopram in the near future that AlphaPharma and Lundbeck were at least potential competitors at the time they concluded their agreement. Indeed, the very fact that Lundbeck agreed to transfer considerable value to AlphaPharma if it accepted not to enter EEA markets for the term of the agreement shows that Lundbeck considered that AlphaPharma's market entry in one or more EEA markets was plausible and that Lundbeck perceived AlphaPharma as a competitive threat to its position in those markets.

12.6.4. The possibility of infringement of Lundbeck's process patents did not prevent AlphaPharma from being at least a potential competitor to Lundbeck

Introduction

- (1019) This section responds to arguments raised by Lundbeck¹⁷⁸³ and AlphaPharma¹⁷⁸⁴ claiming that there could be no potential competition between Lundbeck and AlphaPharma when they concluded their agreement because both parties considered at that time that the citalopram product AlphaPharma had purchased infringed Lundbeck's crystallisation patent. This section will show that despite AlphaPharma's concerns that Lundbeck could claim its process patents were infringed, AlphaPharma had real concrete possibilities of entering one or more EEA markets in the near future. If Lundbeck had challenged such market entry with patent infringement litigation, evidence shows that even Lundbeck was uncertain of the outcome.
- (1020) With respect to the patent situation in the EEA for generic citalopram, the Commission refers to its general considerations in recitals (745) and (746) above. These general considerations, notably those regarding the fact that Lundbeck's process patents did not cover all possible processes to manufacture citalopram that met regulatory requirements in the EEA, the inherent difficulty of enforcing process patents and the distinct possibility that a court might hold the crystallisation patent invalid, also apply to other Contracting Parties of the EEA Agreement than the United Kingdom.

The Commission's comments on the parties' assessment of the patent situation at the time of conclusion of the agreement

- (1021) With respect to AlphaPharma specifically, the agreement between Lundbeck and AlphaPharma claimed infringement of two of Lundbeck's patents, the crystallisation patent and the film distillation patent. Based on the information in Appendix A to the agreement, at that point in time, these two patents had been granted as patents only in the United Kingdom, Belgium and Denmark. They had been granted as utility models (that is to say without examination) in Austria, Germany and the Netherlands. Lundbeck had made patent applications for these two processes at the

¹⁷⁸² See recital (518) above. For an analysis of the patent situation as described in this document, see section 12.6.4 below.

¹⁷⁸³ ID 5394, pages 162 to 190.

¹⁷⁸⁴ ID 6056, pages 20 to 40.

EPO as well as at several other national patent offices in the EEA.¹⁷⁸⁵ These patent applications were under examination.

- (1022) In its reply to the Statement of Objections, Lundbeck informed the Commission that between June 2001 and January 2002, it performed several analyses of citalopram produced by Cipla and Matrix and that, based on these analyses Lundbeck believed the processes used to produce those products to be in infringement of Lundbeck's crystallisation patent (application).¹⁷⁸⁶ Lundbeck had, on 31 January 2002, one day after the crystallisation patent had been granted in the United Kingdom, initiated litigation in the United Kingdom against Alpharma and its supplier Tiefenbacher for alleged infringement of Lundbeck's patents GB 2357762 (the crystallisation patent) and GB 2356199 (production of citalopram in pure form, by cyanide exchange; the film distillation patent).¹⁷⁸⁷ At that time, although it had as yet been unable to acquire any citalopram from Alpharma, Lundbeck (correctly) believed Alpharma's citalopram stock to have come from Cipla.¹⁷⁸⁸
- (1023) With respect to patent GB 2356199, the so-called film distillation patent, Tiefenbacher was convinced at the time that Cipla did not use the process described in this patent.¹⁷⁸⁹ Alpharma also believed that this patent was *"not likely to cause problems."*¹⁷⁹⁰ Lundbeck admitted, in its reply to the Statement of Objections, that it *"renounced enforcing that patent because it lent itself to invalidity claims and, most importantly, because Lundbeck had realized that it was possible for generic companies to design around the Film Distillation Patent."*¹⁷⁹¹
- (1024) Clearly more problematic for the API producer Cipla was patent GB 2357762, the crystallisation patent. Due to various chemical analyses Lundbeck had already made of Cipla's citalopram¹⁷⁹² and being in possession of part of Cipla's DMF, which stated that *"Crude citalopram is crystallised to get pure citalopram"*¹⁷⁹³, Lundbeck may well have thought at the time that Cipla's production process infringed its

¹⁷⁸⁵ See Appendix A1 and Appendix A2 to the agreement, ID 8, pages 270 and 271

¹⁷⁸⁶ See recital (481) above.

¹⁷⁸⁷ See recital (510) above.

¹⁷⁸⁸ In its reply to the Statement of Objections, Lundbeck stated: *"Arrow and Alpharma exclusively used Cipla's API during the operation of the Agreements. At that time, however, Lundbeck could not be entirely certain that they did not also use Matrix's API."* See ID 5394, page 170. This having been said, Lundbeck argues in its reply to the Statement of Objections that Lundbeck had as of June 2001 also analysed Matrix's citalopram (produced with the Matrix I process) and believed this citalopram to be infringing of the crystallisation patent (application) as well. See ID 5394, pages 170-171.

¹⁷⁸⁹ See recital (382) above.

¹⁷⁹⁰ See recital (506) above.

¹⁷⁹¹ See ID 5394, page 162. It should be noted that at the start of the United Kingdom infringement proceedings against Alpharma, Lundbeck's head of chemistry had confidently stated that Cipla's material had "fingerprints" "consistent to the best of my own knowledge **only** with purification using the processes disclosed in United Kingdom Patents **2 356 199 B** and **2 357 762 B**" (emphasis added). See recital (511) above. Later on, however, Lundbeck *"realized that it was possible for generic companies to design around the Film Distillation Patent."* See ID 5394, page 162. Lundbeck showed a similar initial self-confidence in the United Kingdom Lagap proceedings, where the United Kingdom judge observed with respect to patent GB 2357762: *"Lundbeck and [an independent expert on whose views Lundbeck had relied] now had to admit, having examined the process in operation in India, that their firm and unshakeable confidence that it was impossible for Lagap and its suppliers to be operating a non-infringing process was unfounded. The process that they had seen was indeed a non-infringing process..."*. See recital (155) above.

¹⁷⁹² See footnote 923 above.

¹⁷⁹³ See recital (486) above.

crystallisation patent.¹⁷⁹⁴ While Cipla and Tiefenbacher appeared to believe at that time that there were arguments to claim non-infringement¹⁷⁹⁵, Tiefenbacher was also reported at the time by another generic company as having admitted that the Cipla product was infringing.¹⁷⁹⁶ Alpharma, from its side, considered three days before concluding the agreement with Lundbeck, that *"The product produced by Cipla (API) – Omega (tablets) – Tiefenbacher is, to the best of all knowledge, infringing on the Lundbeck patent."*¹⁷⁹⁷

- (1025) With respect to validity, however, Cipla and Tiefenbacher considered at that time that, as Cipla's production method was based on Lundbeck's original production processes, on which patent protection had expired, Lundbeck's crystallisation patent was either likely invalid in its entirety, because the alleged invention was fully covered by prior art and therefore not novel¹⁷⁹⁸, or would at least have to be significantly narrowed because it was overly broad.¹⁷⁹⁹ In the latter case, Cipla appeared to believe its process might not infringe a more narrowly defined process patent, given that according to Cipla the crystallisation process it used showed certain differences with the process as described by Lundbeck in its patent.¹⁸⁰⁰

¹⁷⁹⁴ But see footnote 1791 above. Cipla's inspection process was, contrary to that of Matrix, not actually inspected in the time period covered by this Decision. Lundbeck's deductions from chemical analyses of finished products about what process 'must' have been used to produce that product were heavily criticised by an expert acting on behalf of Lagap in the United Kingdom Lagap proceedings: *"Some of [Lundbeck's allegations], in particular those concerning so called 'fingerprints' for purification methods, are highly flawed..."*. See recital (156) above.

¹⁷⁹⁵ For Cipla's analysis in January and February 2002, see recitals (510) and (505) above. For Tiefenbacher's analysis in February 2002, see recital (505) above. Lundbeck argued, in its reply to the Statement of Objections, that, in practice, generic companies did not bother to challenge Lundbeck's claim of infringement by Cipla before the court, referring to proceedings in the Netherlands. See ID 5394, page 169. However, those proceedings show that non-infringement was in fact argued before the court by Tiefenbacher and endorsed by the generic companies in question. See ID 5450, page 6. Lundbeck also points out that Tiefenbacher stated to the Commission that *"Lundbeck obtained copies of the DMF of Cipla and Matrix, which were included in MA application as substitutes for VIS. It can be assumed that the first batches indeed were produced by base crystallization."* See ID 5394, page 182 and ID 280, page 5. However, that is an *ex post facto* statement of Tiefenbacher, based on hindsight. What matters to determine whether potential competition existed is the *ex-ante* perspective at the time of events.

¹⁷⁹⁶ See recital (497) above. It is clear from recital (505) above that Tiefenbacher was especially concerned about the product claims in Lundbeck's crystallisation patent. These claims were later withdrawn and or invalidated before the EPO and the Dutch patent office, but were accepted, apparently, by the United Kingdom patent office in granting the patent as requested. This made the United Kingdom crystallisation patent particularly vulnerable to at least partial invalidation by the United Kingdom courts. See recital (151) above.

¹⁷⁹⁷ See recital (518) above. The preamble of Alpharma's agreement with Lundbeck stated that Lundbeck had *"substantial reason to believe that the production methods used to produce Alpharma's products infringe Lundbeck's intellectual property rights"* and that *"Alpharma...has acknowledged that the findings by Lundbeck are correct and has undertaken to refrain from marketing such products."* The belief of parties that infringement may exist or even exists should not be confused with the objective existence of infringement. Only a court can establish the latter. In their replies to the Statement of Objections, Lundbeck and Alpharma, for instance, constantly refer to *"infringing citalopram"*, whereas in fact they should properly refer to *"citalopram believed to be infringing"*.

¹⁷⁹⁸ See recitals (76) and (149) above.

¹⁷⁹⁹ See recital (151) above.

¹⁸⁰⁰ See recitals (482), (487), (505), (508) and (510) above. It is recalled that initially Lundbeck had patented both the crystallisation purification process and the crystalline free base itself. The latter patent was revoked by the EPO in 2007, see recital (151) above. The former patent was significantly narrowed in 2009 following opposition and appeal at the EPO, see recital (166) above.

Moreover, Lundbeck's crystallisation patent was at that time considered, by Lundbeck's "enemies", as "high school chemistry".¹⁸⁰¹

(1026) Alpharma shared this basic assessment of the vulnerability of Lundbeck's crystallisation patent. On 24 January 2002, the [employee function]* at Alpharma ApS stated: *"It might very well be that we can seek the Lundbeck [crystallisation] patent application invalidated without specific knowledge of the Cipla API process. Tiefenbacher strongly believe that they can invalidate the utility models and other applications related to that family. I too believe that."*¹⁸⁰² One day later, the same person wrote: *"My personal opinion, regarding the patent in question [that is to say Lundbeck's crystallisation patent], is that we shall go ahead and market our product. The patent is not likely to pass scrutiny on novelty and inventive step. I expect that they will end up, either with no patent or a very limited and narrow patent, which should not cause us problems. We do however need the supportive opinions of [external lawyers]. If they coincide, then I would recommend a "go ahead". We might loose and have to pay a limited damage fee, but not entering the market, could also lead to a significant loss."*¹⁸⁰³

(1027) On 19 February 2002, three days before concluding the agreement with Lundbeck, the [employee function]* of Alpharma ApS wrote:

"Currently we plan to launch Citalopram in UK, NL, DE, DK, NO, SE, FI within the next 2 – 6 weeks. However, the legal situation is complicated by the infringement of a key Lundbeck patent.

It is basically one family of patents, which Lundbeck currently are using in their defence of Cipramil. The name of the family is "Crystalline base of Citalopram", and it is present in one or more forms, in all HPI countries. The patent is already approved/granted in several countries in record time...

The product produced by Cipla (API) – Omega (tablets) – Tiefenbacher is, to the best of all knowledge, infringing on the Lundbeck patent. This is the product currently on stock in most of our affiliates. (Stocking would be considered infringement).

Lundbeck has applied for Preliminary Injunction in NL and UK, and is likely to do so in all countries where they get the patent approved (a prerequisite for injunction).

¹⁸⁰¹ See recital (149) above.

¹⁸⁰² See recital (506) above.

¹⁸⁰³ See recital (508) above. Section 7.6 as a whole and this document in particular show that the risk of infringing Lundbeck's crystallisation patent did not come as a sudden shock in the last days before concluding the agreement with Lundbeck, causing Alpharma to "completely rethink its strategy", as Alpharma argued in its reply to the Statement of Objections (ID 6056, page 20). Ever since Lundbeck's warning letter of 11 January 2001, Alpharma had been aware of this patent. Concern in Alpharma over possible infringement of this patent had gradually grown over time. See recitals (477), (482), (487), (492), (494), (496) to (502) and (504) to (506). But even after Alpharma had heard from another generic company that Tiefenbacher had said that the Cipla product was infringing (see recital (497)), the [employee function]* at Alpharma ApS believed that, subject to the supportive opinion of external counsel, "we shall go ahead and market our product." (recital (508)). Alpharma's belief that its Cipla product could be infringing Lundbeck's crystallisation patent was fully taken into account in the considerations of the [employee function]* of Alpharma's ApS three days before concluding the agreement with Lundbeck. That document shows clearly, in the view of the Commission, that Alpharma would not have given up its independent efforts to enter citalopram markets in the EEA if Lundbeck had not made it a more lucrative offer. See recital (1027) below.

We are currently establishing defence in UK and NL. An injunction hearing is set for 26 March in London high court, and we have to submit our defence by 4 March. Our defence will be to convince the court that the Lundbeck patent is foreseeable and therefore none inventive. It is likely that we can avoid an injunction, and we have a reasonable case to win a case of invalidation of the Lundbeck patent.

It can be lengthy and probably costly, but we should be able to get a substantial part back in damage fee, if we win! On the other hand Lundbeck can claim substantial damage compensation if they win!!

The second API supplier Matrix is, also to the best of all knowledge, using a none infringing process and this API could be used without the risk of infringement. It would mean a lot of scrapping and launch delay of roughly 3-4 month.

If we halt all launch activities now, to clarify the legal situation and launch later in the spring/summer with the non-infringing API from Matrix, we will have lost the competitive (time) advantage we have by launching the next 2 – 6 weeks and we have scrappings of USD 2 million. This will significantly influence the business case which has an NPV of USD 10 million.

Our recommendation is to pursue a deal with Lundbeck if a reasonable settlement can be achieved serving our legal and commercial interests.”¹⁸⁰⁴

The Commission's assessment of Alpharma's possibilities of entering one or more EEA markets

- (1028) It is apparent from the document quoted in recital (1027) above that just days before concluding an agreement with Lundbeck, Alpharma was all prepared for launching Cipla citalopram products in initially seven EEA markets within the next 2 to 6 weeks. In the United Kingdom, Alpharma expected to receive a marketing authorisation any day and had already published prices for citalopram, thereby announcing its intention to enter the market. While Alpharma believed that Cipla's product was to the best of all knowledge infringing Lundbeck's crystallisation patent, it considered that it was likely that an injunction could be avoided and that it had a reasonable chance of invalidating Lundbeck's crystallisation patent.¹⁸⁰⁵ Alpharma also considered that if it were to postpone its launch activities, it would suffer

¹⁸⁰⁴ See recital (518) above.

¹⁸⁰⁵ It is recalled that in the United Kingdom legal procedure between Lundbeck and Lagap, Lundbeck itself estimated the chance of the crystallisation patent being invalidated by the United Kingdom court at 60%. Lundbeck avoided a ruling by settling. See recital (156). In its reply to the Statement of Objections, Alpharma argued that all of its preparations to enter the market were "irrelevant", because they "took place before Alpharma realized that its products infringed Lundbeck's patents." See ID 6056, page 27. The facts as described in section 7.6 and in this section show, however, that there was nothing sudden about Alpharma's growing awareness of the risk of infringing Lundbeck's crystallisation patent. This awareness started in January 2001 with Lundbeck's warning letter and gradually grew over time to the assessment made three days before concluding the agreement with Lundbeck (see recital (1027)). This assessment, however, does not say that, absent an agreement with Lundbeck, Alpharma could not or should not pursue its efforts to enter citalopram markets in the EEA because of the risk of infringement. It just recommends to strike a deal with Lundbeck if the conditions thereof are more attractive than the other options identified, notably the option of launching Cipla citalopram (with the possibility that an injunction could be avoided and Lundbeck's patent invalidated) or the option of switching to non-infringing Matrix product. These options were concrete possibilities for Alpharma to enter the market and compete with Lundbeck. They were therefore important elements of potential competition.

immediate losses of USD 2 million for stock already bought¹⁸⁰⁶ and lose out on estimated profits of USD 10 million.

- (1029) That it was indeed Alpharma's intention to enter EEA markets was recognised by the preamble of the agreement which stated that *"Alpharma has manufactured, produced and/or purchased pharmaceutical products containing Citalopram with the intention of marketing such products in the Territory [defined in the agreement as "all EU countries, Norway and [third country]"]"*.
- (1030) It should be recalled that at this point in time, Lundbeck's patent applications for the crystallisation and film distillation processes had not been granted yet by the EPO and the patent offices of a number of other Contracting Parties of the EEA Agreement and that there was no certainty that they would be granted at all or in their entirety.¹⁸⁰⁷
- (1031) Moreover, given that infringements of process patents tend to be difficult to prove¹⁸⁰⁸ and that the [employee function]* at Alpharma ApS considered on 25 January 2002, less than a month before concluding the agreement with Lundbeck, that *"The [crystallisation] patent is not likely to pass scrutiny on novelty and inventive step. I expect that they will end up, either with no patent or a very limited and narrow patent, which should not cause us problems"*¹⁸⁰⁹, Alpharma thought, at the time of conclusion of the agreement, that it had a realistic chance that it would have been able to sell Cipla citalopram in the United Kingdom and other EEA markets and that a court would have found Alpharma's product non infringing or Lundbeck's patent invalid.¹⁸¹⁰ Had it not been for the agreement with Lundbeck, Alpharma might therefore well have launched the Cipla citalopram it had in stock in one or more of the seven EEA markets initially targeted for launch.¹⁸¹¹ In doing so, Alpharma could, like Lagap eight months later, have initially limited its sales volume so as to reduce its exposure to possible damage claims from Lundbeck. Or, as part of the competitive process, Alpharma could have tried to clear the way first by seeking a declaration of non-infringement or the invalidity of Lundbeck's crystallisation patent.¹⁸¹²

¹⁸⁰⁶ At the time of conclusion of the agreement with Lundbeck, Alpharma had 9.4 million citalopram Cipla tablets in stock and 16 million more on order, for a total purchase value of EUR 3.7 million. See recital (528) above.

¹⁸⁰⁷ See recital (1021) above.

¹⁸⁰⁸ In its reply to the Statement of Objections, Lundbeck stated that, in practice, proof of infringement of a process patent is *"very difficult"* (ID 5394, page 29, see also page 183). The preamble of the agreement between Lundbeck and Alpharma also recognised that the outcome of legal proceedings *"cannot be predicted with absolute certainty."*

¹⁸⁰⁹ See recital (508) above.

¹⁸¹⁰ It is recalled that Lundbeck itself later estimated the chance that its crystallisation patent would be held invalid by a United Kingdom judge at 60%. See recital (157) above.

¹⁸¹¹ In its reply to the Statement of Objections, Alpharma stated that *"Alpharma may well not have entered the market in the absence of the Settlement Agreement."* See ID 6056, page 32. The Commission does not disagree with this statement. But likewise, Alpharma may well have entered. It is this realistic possibility that Alpharma would have entered that constitutes an important element of potential competition.

¹⁸¹² Regarding a *"declaration of non-infringement"* in the United Kingdom, the United Kingdom High Court of Justice stated in the Paroxetine case that *"since there are certain difficulties with the latter (for example onus of proof goes the other way round), [the generic undertaking] could simply have said to the patentees, 'We intend (we are not saying when but it is a settled intention) to launch our product within the next five years. If you intend to sue us, sue us now'."* See footnote 312 above.

- (1032) That bringing invalidity actions against the crystallisation patent was not a theoretical option, but actually realistically considered, even - and in particular - after Lundbeck's letter of 22 January 2002 warning of patent infringement¹⁸¹³, is shown by the statement of [employee function]* at Alpharma ApS of 25 January 2002 quoted in recital (1031) above, by the fact that the same person considered on 24 January 2002 that *"It might very well be that we can seek the Lundbeck patent application invalidated without specific knowledge of the Cipla API process. Tiefenbacher strongly believe that they can invalidate the utility models and other applications related to that family. I too believe that"*¹⁸¹⁴, as well as by the fact that on 23 January 2002 Alpharma intended to challenge Lundbeck's crystallisation utility model in the Netherlands.¹⁸¹⁵ With respect to the United Kingdom, the [employee function]* Alpharma ApS stated on 19 February 2002: *"We are currently establishing defence in UK and NL... Our defence will be to convince the court that the Lundbeck patent is foreseeable and therefore none inventive. It is likely that we can avoid an injunction, and we have a reasonable case to win a case of invalidation of the Lundbeck patent."*¹⁸¹⁶
- (1033) Alternatively or in parallel, Alpharma could have asked Cipla to modify its process to reduce or eliminate the risk of infringing Lundbeck's crystallisation patent.¹⁸¹⁷ Based on the widespread practice in the generic industry that API producers invent around process patent obstacles, Alpharma could have expected or requested that Cipla would do the same, once it had been disappointed in its expectation that Lundbeck's crystallisation patent application would not be granted. Indeed, according to Tiefenbacher, after Lundbeck's patent had been granted, Cipla succeeded in creating a new *"patent free"* purification method based on absorption of silica (the so-called Cipla II process), which was ready for filing as a type I variation on 24 September 2002.¹⁸¹⁸
- (1034) Moreover, under the contract with Tiefenbacher, Alpharma also had the option of switching to Matrix citalopram. As the [employee function]* of Alpharma ApS said, just three days before the agreement with Lundbeck was concluded: *"The second API supplier Matrix is, also to the best of all knowledge, using a none infringing process and this API could be used without the risk of infringement. It would mean a lot of scrapping and launch delay of roughly 3-4 month."*¹⁸¹⁹ In Alpharma's own assessment at the time, therefore, Alpharma could have launched with non-infringing

¹⁸¹³ See recital (496) above.

¹⁸¹⁴ See recital (1026) above.

¹⁸¹⁵ See for instance recitals (498), (500), (502) above.

¹⁸¹⁶ See recital (518) above.

¹⁸¹⁷ In its reply to the Statement of Objections, Lundbeck stated that *"...the difficulty in enforcing a particular process patent, as opposed to a product patent, lies in the potentially endless alternatives to that process, which means that the originator will have to investigate every single claim of a generic that it has now produced the same product by means of a non-infringing process. And by fudging slightly with a given process, the generic can at least initially claim it now has a new, non-infringing process..."*

¹⁸¹⁸ ID 1713, page 1. In its settlement with the generic company Neolab, which had launched Cipla citalopram in the United Kingdom in October 2002, Lundbeck paid Neolab a considerable sum in damages based on Lundbeck's assessment that it had a 90% chance of losing infringement litigation against the Cipla II process, either because it would not be found infringing or because the crystallisation patent would have been found invalid. See ID 845, page 99. See also recital (164) above.

¹⁸¹⁹ See recital (1027) above.

Matrix citalopram in June 2002, four months before Lagap actually became the first generic company in the United Kingdom to do so. In the Lagap litigation, Lundbeck had to admit that the Matrix production process it had inspected in India was non-infringing.

(1035) Under these circumstances, there would, in the view of the Commission, have been a real concrete possibility that, if Lundbeck had not made its lucrative offer of USD 12 million to Alpharma, Alpharma would have continued its independent efforts to enter markets in the EEA in the coming months with the Cipla citalopram products it had in stock and had ordered or would have switched to Matrix product as soon as this was possible. In this respect, the words "*Our recommendation is to pursue a deal with Lundbeck if a reasonable settlement can be achieved serving our legal and commercial interests* (emphasis added)" in Alpharma's assessment of 19 February 2002 are revealing. They show that Alpharma's acceptance of an agreement with Lundbeck not to sell its Cipla citalopram in the market was **subject to** "*a reasonable settlement...serving our ...commercial interests.*" In the absence of an agreement with Lundbeck, the alternatives which Alpharma seriously considered following in this document were:

- continuing preparations for launch in seven Contracting Parties of the EEA Agreement within the next two to six weeks and as a consequence facing possible patent litigation with Lundbeck, in which case Alpharma would claim invalidity of the crystallisation patent¹⁸²⁰; or
- halting the current launch activities, clarifying the legal situation and launching later in the spring/summer with non-infringing Matrix citalopram (see recital (1034) above).

Importantly, the option of ceasing all efforts to enter the market because of the alleged strength of Lundbeck's patents did not figure as an option that was considered.¹⁸²¹

(1036) In its reply to the Statement of Objections Alpharma argued that "*The possibility that Alpharma could have convinced a court to declare the patents to be invalid is irrelevant to the assessment of whether Alpharma was a potential competitor*

¹⁸²⁰ In its reply to the Commission's Letter of Facts of 12 April 2013, Alpharma stated that the document quoted in recital (1027) above "*definitely proves that Alpharma was still uncertain whether it would sell its infringing citalopram if it could not reach a settlement.*" See ID 6782, page 17. The Commission considers that even if Alpharma "*was still uncertain*" whether it would enter EEA markets with its citalopram product this clearly shows the existence of at least potential competition.

¹⁸²¹ In its reply to the Statement of Objections, Alpharma claimed, quoting Actavis, that Alpharma was risk averse from a patent perspective. See ID 6056, page 32. The contemporaneous document quoted in recital (1027) shows that Alpharma did not consider any option of relinquishing its efforts to enter markets in the EEA with generic citalopram. To the extent that Alpharma may have been risk averse, it might have preferred to launch its Cipla citalopram in small quantities only (to avoid high damage claims from Lundbeck), as Lagap later did, or it might have preferred to switch to Matrix citalopram, which it considered to be non-infringing. In any case, as the General Court found in Case T-461/07, *Visa Europe Ltd and Visa International Service v European Commission*: "*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 pressure represented by the likelihood that a new competitor will enter the market if the market becomes more attractive.*" See recital (611) above.

because it is a well-established principle that Lundbeck's patents must be presumed to be valid for the purposes of this assessment."¹⁸²² In reply to this argument the Commission refers to recital (78) above. The assumption of validity of the patent does not bar legal action in court to challenge the validity of the patent. The Commission's assessment is based on evidence in the file that shows that Alpharma considered claiming invalidity of Lundbeck's patents. Indeed, as the European 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.*"¹⁸²³ Such actions, if they have a realistic chance of succeeding, are an essential part of the competitive process between generic companies seeking market entry for compounds that are no longer patent-protected and originator companies that invoke process patents against such market entry.¹⁸²⁴

- (1037) In its reply to the Statement of Objections, Lundbeck advanced several other arguments: Lundbeck argued that since Alpharma only obtained a marketing authorisation in the United Kingdom on 26 July 2002, it could not be a potential or actual competitor to Lundbeck in that market before.¹⁸²⁵ According to Lundbeck, the same would apply to other EEA markets where Alpharma only obtained a marketing authorisation after the agreement with Lundbeck had ended.¹⁸²⁶ In the same reply Lundbeck also argued, based on information relating to Arrow (not Alpharma), that "*In the UK, however, the sale of citalopram purified via the Matrix's additional washing step was not fully authorized before June 4, 2003.*"¹⁸²⁷ Thirdly, Lundbeck argued in its reply to the Statement of Objections that "*The free base crystallization could not have been removed from the [Matrix] production process via a Type I variation.*"¹⁸²⁸ Alpharma made similar arguments in its reply to the Statement of

¹⁸²² ID 6056, page 8.

¹⁸²³ Case 193/83, *Windsurfing International v Commission*, [1986] ECR 611, paragraph 92.

¹⁸²⁴ See sections 4.1 and 9.1 above.

¹⁸²⁵ ID 5394, pages 227-228.

¹⁸²⁶ ID 5394, page 228. This argument disregards the fact that once Alpharma had agreed not to enter EEA markets with citalopram until 30 June 2003, Alpharma lost the incentive to obtain marketing authorisations throughout the EEA as quickly as possible. What matters, therefore, is the likelihood, just before it concluded the agreement with Lundbeck, that Alpharma could have obtained such marketing authorisations before 30 June 2003. See also recital (1038) below.

¹⁸²⁷ ID 5394, page 164.

¹⁸²⁸ ID 5394, page 173. Lundbeck implies that Matrix must still have been crystallizing even after introducing the washing step. This argument pre-supposes a) that Matrix was originally crystallising; b) that this crystallising was an infringement of Lundbeck's crystallisation process patent; c) that this patent and all of its claims were valid in their entirety; and d) that Matrix's washing method did not replace crystallisation but was added to it. In February 2002, none of these elements had been proven or even raised yet. Indeed, not all of these elements were proven by Lundbeck afterwards. The most Lundbeck achieved was a district court ruling in Denmark in November 2002, which ordered an interim injunction against Matrix citalopram based on the opinion of the judge that, waiving for the time being the question of possible invalidity of Lundbeck's crystallisation patent, it was "*probable*" because of expert witness testimony (no inspection was undertaken of Matrix's process) that Matrix was infringing that patent even after having introduced the washing step. In the Danish district judge's view, "*it has been rendered probable to the Court's satisfaction that the cyanation process of 5-bromo-citalopram cannot be carried out [by Matrix] on a large scale in such a way that the residues of 5-bromo-citalopram each time are brought to the interval of 0.2-0.3%.*" See ID 5394 pages 173 and 175 and ID 392, pages 183 to 225. However, one year later in the United Kingdom Lagap litigation, after the Matrix process had actually been inspected, Lundbeck's counsel declared about the same Matrix II

Objections, in particular with respect to what it called 'non-infringing' citalopram.¹⁸²⁹ Alpharma also argued that the fact that Alpharma did not immediately enter all EEA markets after expiry of the agreement with Lundbeck was evidence that Alpharma was not a potential competitor when it concluded the agreement with Lundbeck.¹⁸³⁰

- (1038) This line of argumentation is *ex post facto*. What matters to determine whether potential competition existed at the time Alpharma concluded the agreement with Lundbeck is whether Alpharma had real concrete possibilities of entering the market and competing with Lundbeck based on the circumstances at that point in time. As mentioned in recitals (1032) and (1035) above, contemporaneous documents show that just days before concluding the agreement with Lundbeck, Alpharma seriously considered to either launch the Cipla citalopram it had and face Lundbeck's patent challenge, considering that "*It is likely that we can avoid an injunction, and we have a reasonable case to win a case of invalidation of the Lundbeck patent*" or to switch to Matrix citalopram, which it considered to be "*using a none infringing process*", and launch that three to four months later, if Lundbeck would not make it a more lucrative offer. If Alpharma had followed either of these two options, there would have been a real concrete possibility that it would have been able to sell generic citalopram in EEA markets in the course of the agreement with Lundbeck and that a court would have found Alpharma's product non infringing or Lundbeck's patent invalid. Market entry by Alpharma in EEA markets during the term of the agreement with Lundbeck, whether with Cipla citalopram or Matrix citalopram, was therefore clearly an economically viable strategy for Alpharma. The decisive reason why Alpharma did not implement this strategy was not Lundbeck's process patents, of which Alpharma had been well aware for a long time and which it was willing to either challenge as invalid or avoid by using a non-infringing process, but the fact that Lundbeck made it a more lucrative offer of payment if it stayed out of the market.

process: "*I do accept that it can be run economically. It does depend on how you do the cyanation. They [Matrix] do the cyanation more efficiently than we have believed that they could do it.*" See recital (158) above.

It should be noted that some of the key arguments Lundbeck has raised with the Commission to claim that "*Matrix's products that were available on the marketplace in fact were not produced via the additional washing step*", notably the bromo-chloro impurities ratio, the dimer impurities and the alleged insufficient capacity of Matrix's new process (see ID 5394, pages 177 and 178) were arguments that Lundbeck had already withdrawn in the Lagap litigation in 2003. See recital (158) above. Lundbeck did not explain this inconsistency.

¹⁸²⁹ ID 6056, pages 34 to 40.

¹⁸³⁰ ID 6056, page 37. In respect of this particular argument, the Commission observes that the General Court has stated in Case T-461/07, *Visa Europe and Visa International Service v Commission*, judgment of 14 April 2011, paragraph 178: "*Moreover, as regards the fact that Morgan Stanley took no steps to enter the acquiring market following its admission to membership, it must be recalled that that admission was granted to it more than six years after its application for that purpose. Accordingly, that fact gives no guidance as to what Morgan Stanley might have intended or how Morgan Stanley might have acted if Visa membership had been granted to it at an earlier date.*" A similar logic applies in this case. The fact that certain generic companies may no longer have been interested or less interested in entering the generic citalopram market in the EEA after the expiry of their agreement with Lundbeck says nothing about their interest in entering at the point in time just before they concluded their agreement with Lundbeck.

Conclusion

- (1039) In sum, the facts analysed in this section 12.6.4 show that, after Lundbeck's patent on the compound and the two original production processes had expired, Alpharma, despite concerns over Lundbeck's process patents, had real concrete possibilities of entering one or more EEA markets in the near future. If Lundbeck had challenged such market entry with patent infringement litigation, evidence shows that even Lundbeck was uncertain of the outcome. The Commission therefore concludes that Lundbeck's process patents did not prevent Alpharma from being a potential competitor to Lundbeck at the time they concluded their agreement.

12.6.5. Commitments accepted by Alpharma in the agreement with Lundbeck

- (1040) In the agreement with Lundbeck, Alpharma accepted several commitments that limited its freedom of action to enter citalopram markets in the EEA.

12.6.5.1. Alpharma's commitment not to sell "pharmaceutical products containing Citalopram"

- (1041) In Article 1.1 of the agreement, Alpharma accepted, "[s]ubject to the terms and conditions of this Agreement"¹⁸³¹, to refrain from "any importation, manufacture, production, marketing or sale of pharmaceutical products containing Citalopram" in the Union and Norway during the operation of the agreement until 30 June 2003.¹⁸³²
- (1042) Article 1.1 of the agreement, rather than prohibiting Alpharma from selling during the term of the agreement citalopram produced with a specified process from a specified API supplier, sweepingly covered "any" sales of "pharmaceutical products containing Citalopram", without any restriction as to the scope of this term. The term "pharmaceutical products containing Citalopram" is not defined anywhere in the agreement. The meaning of these words is clear: "pharmaceutical products containing Citalopram" means all pharmaceutical products containing citalopram, irrespective of the API supplier and irrespective of whether such products would or would not utilise processes protected by any patents of Lundbeck.¹⁸³³ The prohibition of "any" sale confirms that no citalopram products whatsoever were to be sold by Alpharma in the EEA until 30 June 2003. In exchange for the transfer of value Lundbeck made in instalments to Alpharma in the course of operation of the agreement, the last instalment being made on the date of expiry of the agreement, Alpharma complied with this obligation and did not sell any citalopram whatsoever in the EEA until after the agreement with Lundbeck had expired. It was only in August 2003, following expiry of the agreement with Lundbeck that Alpharma started to sell citalopram – from Matrix – in the EEA, beginning with Germany.
- (1043) Article 1.2 of the agreement provided Lundbeck with the means to enforce this all-encompassing obligation on Alpharma not to sell any citalopram products whatsoever. As will be further analysed in section 12.6.5.2 below, this provision

¹⁸³¹ Notably Article 1.3 providing for a considerable transfer of value from Lundbeck, see further section 12.6.6 below.

¹⁸³² See recital (523) above.

¹⁸³³ By comparison, the EEA agreement with Merck (GUK) used identical language in obliging Merck (GUK) not to sell "pharmaceutical products containing Citalopram". In a contemporaneous document, Merck (GUK) interpreted this as meaning: *we have an agreement with Lundbeck not to sell in Europe until sometime around the end of October this year...We agreed not to sell citalopram in our EU markets for 1 year.*" See recital (367) above.

obliged Alpharma "at the request of Lundbeck" to "voluntarily submit to an interim injunction by any competent court in any applicable country in the Territory" and to "sign any document necessary to obtain such injunctions." It would, therefore, not have been difficult for Lundbeck to present any intended sale by Alpharma of any citalopram whatsoever, including potentially non-infringing citalopram, in EEA markets to the competent courts as an admitted infringement of Lundbeck's process patents, justifying an immediate interim injunction, unless of course Alpharma decided to breach the agreement by not agreeing to such a consent order and defending itself in court against Lundbeck's infringement allegations, in which case Lundbeck could, under Article 4.2 of the agreement, have stopped the instalments of the transfer of value, terminated the agreement and sued Alpharma for damages for breach of contract.¹⁸³⁴ This article is further analysed below at section 12.6.5.2.

Arguments of the parties

- (1044) Alpharma¹⁸³⁵ and Lundbeck¹⁸³⁶ argued in their replies to the Statement of Objections that the obligation on Alpharma in Article 1.1 not to sell "*pharmaceutical products containing Citalopram*" had to be interpreted in the light of all the provisions of the agreement, including notably the preamble and Appendix A. On this basis both parties argued that only "*infringing*" citalopram was covered.¹⁸³⁷
- (1045) Before analysing this notion of "*infringing*" citalopram, the Commission will first examine whether the preamble and Appendix A of the agreement lead to the conclusion that the term "*pharmaceutical products containing Citalopram*" in Article 1.1 was intended to mean something more limited in scope than all citalopram products.
- (1046) The preamble of the agreement¹⁸³⁸ stated in full:
- WHEREAS, Lundbeck owns intellectual property rights including, in particular, patent rights relating to the manufacture and production of the active chemical substance Citalopram, including the patents set out in Appendix A hereto;*¹⁸³⁹
- WHEREAS, Lundbeck manufactures, produces, markets and sells pharmaceutical products containing Citalopram in all EU countries, Norway and Switzerland (the "Territory");*
- WHEREAS, Alpharma has manufactured, produced and/or purchased pharmaceutical products containing Citalopram with the intention of marketing such products in the Territory;*
- WHEREAS, Alpharma's manufacture, production and/or purchase of pharmaceutical products containing Citalopram have taken place without the consent of Lundbeck;*

¹⁸³⁴ See recital (548) above.

¹⁸³⁵ ID 6056, page 15.

¹⁸³⁶ ID 5394, page 229.

¹⁸³⁷ ID 6056, page 7.

¹⁸³⁸ See recital (522) above.

¹⁸³⁹ Appendix A to the agreement listed for the different EEA Contracting Parties the national equivalents (whether in terms of patents already granted or patent applications made) of Lundbeck's crystallisation patent and film distillation patent.

WHEREAS, Lundbeck has performed laboratory analyses of the pharmaceutical products containing Citalopram manufactured, produced and/or purchased by Alpharma;

WHEREAS, the results of these laboratory analyses give Lundbeck substantial reason to believe that the production methods used to produce Alpharma's products infringe Lundbeck's intellectual property rights;

WHEREAS, on 31 January 2002 Lundbeck filed a patent infringement lawsuit in the United Kingdom High Court of Justice Chancery Division seeking an injunction against Alpharma's sale of products containing Citalopram for infringing Lundbeck's intellectual property rights;

WHEREAS, Alpharma has had no intention to infringe Lundbeck's intellectual property rights, but has acknowledged that the findings by Lundbeck are correct and has undertaken to refrain from marketing of such products; and

WHEREAS, Lundbeck has agreed to compensate Alpharma in order for Lundbeck to avoid a costly and time-consuming patent litigation, the outcome of which cannot be predicted with absolute certainty;"

WHEREAS, in order to settle the dispute Lundbeck has furthermore agreed to purchase all of Alpharma's stock of products containing Citalopram and to compensate Alpharma for such products."

- (1047) In the view of the Commission, the preamble and Appendix A do not allow for any decisive argument that the obligation in Article 1.1 not to sell "*any*" "*pharmaceutical products containing Citalopram*" should be interpreted to mean something less than all products containing citalopram. While the preamble, including the reference to Appendix A, clearly indicated the origin and immediate cause of the patent dispute between Lundbeck and Alpharma, namely that Alpharma intended to sell in the EEA specific citalopram products it had purchased from Tiefenbacher and which Lundbeck, based on analyses of Cipla and Matrix citalopram, believed to be infringing, the preamble did not define the term "*pharmaceutical products containing Citalopram*". Nor is it evident from the preamble that with this term parties intended to refer only to the products Alpharma had purchased. The Commission observes, in this respect, that when the preamble introduced for the first time the term "*pharmaceutical products containing Citalopram*", it referred to Lundbeck's manufacture of such products. Clearly, here the term "*pharmaceutical products containing Citalopram*" cannot mean the specific products Alpharma had purchased. Alpharma's undertaking "*to refrain from marketing of such products*" could therefore refer both to the specific products it had purchased and to citalopram products in general. The same applies for the words "*such products*" in the third 'Whereas'.
- (1048) Even if in the preamble Alpharma expressed only its intention to refrain from marketing the specific citalopram products it had purchased from Tiefenbacher, it still does not follow that also the operational obligation on Alpharma in Article 1.1 not to sell "*any*" "*pharmaceutical products containing Citalopram*" should be limited to the specific products it had purchased. If the parties had wanted the obligation in Article 1.1 to have the same scope, they could simply have included in Article 1.1 a cease and desist obligation with respect to the "*the pharmaceutical products containing Citalopram purchased by Alpharma*". Alternatively they could have identified the API supplier of the product Alpharma had purchased and limited the obligation not to sell to production methods of this API supplier that utilised

processes covered by Lundbeck's process patents. But parties did not do that. Instead they agreed that Alpharma would simply not sell "any" "pharmaceutical products containing Citalopram".

- (1049) One cannot conclude from the preamble to this agreement, which describes, by way of background, the patent dispute caused by the intended sale by Alpharma of a particular product produced with a particular process, that differently drafted operational obligations which the generic undertaking accepted in the agreement in exchange for a significant transfer of value are also necessarily limited to that particular product produced with that particular production process.
- (1050) The Commission observes, in this respect, that the last sentence of Article 1.1 stated: *"This Article 1.1 shall not apply to any product containing escitalopram."* If parties felt it necessary to specify that the obligations in Article 1.1 did not extend to escitalopram, which is a different product than citalopram, then it is difficult to understand why, if they really did not want all citalopram products to be covered by Article 1.1, they would not have specified this also and, indeed, all the more.
- (1051) That Alpharma knew very well that in exchange for Lundbeck's transfer of value it would not be able to sell any citalopram in the EEA for the term of the agreement, including citalopram produced with potentially non-infringing processes, is clear from the contemporaneous facts: On 19 February 2002, the [employee function]* of Alpharma ApS considered the option of switching to Matrix, which he considered to be non-infringing, as an alternative to a deal with Lundbeck, not as an option that could still be pursued after an agreement with Lundbeck had been concluded.¹⁸⁴⁰ Secondly, on 20 February 2002, Alpharma considered about the draft agreement with Lundbeck: *"I miss something stating that Lundbeck don't carry on with the same old argument after June 2003. If we for instance change to Matrix API and we are free of the Lundbeck patent, then I don't want to be dragged round the circus once more"* (emphasis added).¹⁸⁴¹ This statement implies that Alpharma believed that it could sell Matrix citalopram, which Alpharma believed to be non-infringing, only after expiry of the agreement with Lundbeck. The words *"for instance"* imply that Alpharma considered that it could also not sell potentially non-infringing citalopram from other API suppliers than those used by Tiefenbacher. Thirdly, as mentioned in recital (543) above, an e-mail from Lundbeck to Alpharma of 7 November 2002 asked whether part of the tablets Alpharma had to deliver to Lundbeck under the agreement were *"Matrix new"*, thereby referring to the potentially non-infringing new Matrix process.
- (1052) Alpharma also argued, in this respect, that *"The fact that 'Citalopram' is capitalized [in the agreement] strongly suggests that it is intended to have a specific meaning because other capitalized terms in the Agreement are defined."*¹⁸⁴² This meaning would then be something narrower in scope than all citalopram. This argument disregards, however, that in the very first 'Whereas' of the agreement, it is stated that *"WHEREAS, Lundbeck owns intellectual property rights including, in particular patent rights relating to the manufacture and production of the active chemical substance Citalopram, including the patents set out in Appendix A hereto."* Clearly, Citalopram is not limited to the patents set out in Appendix A. It "includes" the

¹⁸⁴⁰ See recital (518) above.

¹⁸⁴¹ See recital (519) above.

¹⁸⁴² For Alpharma, see ID 6056, page 6. For Lundbeck, see ID 5394, page 228.

patents set out in Appendix A ("*including the patents set out in Appendix A*" and not "*consisting in...*"). Moreover, "Citalopram", with a capital "C", is meant to refer to 'all citalopram' in this first 'Whereas'. Lundbeck would never accept that its patent rights on the manufacture of citalopram would extend to anything less than the manufacture of all citalopram.¹⁸⁴³ Moreover, almost all of the agreements that are the subject of this Decision use the word "Citalopram" a) with a capital; b) without defining that word and c) using that word simply to mean citalopram.¹⁸⁴⁴ The GUK United Kingdom agreement contains an extensive list of definitions, but neither Cipramil nor citalopram figure in that list. One cannot therefore conclude from the fact that citalopram was written in the agreement with Alpharma with a capital C that parties intended to somehow narrowly define this term.

- (1053) Parties also invoked the consent order to argue for a narrow interpretation of the meaning of "*pharmaceutical products containing Citalopram*". Lundbeck argued, in its reply to the Statement of Objections, that "*The wording of the consent order actually confirms the true scope of the Agreement. As the consent order is tantamount to a voluntary injunction, its scope would naturally be the same as that of the settlement agreement in consideration of which it is entered into.*"¹⁸⁴⁵ This United Kingdom consent order of 2 May 2002 covered "*pharmaceutical products containing citalopram utilising any of the processes claimed under GB patents 2 357 762 B and GB 2 36 199 B or any equivalent patent granted or applied for in relation to any relevant territories...*" While being limited to processes claimed under the two patents Lundbeck had specifically invoked in the agreement against Alpharma, the United Kingdom consent order, which had been drafted by the parties, extended to claims of patent infringement outside of the United Kingdom, as well as to patents that had only been applied for abroad, but not yet granted.¹⁸⁴⁶ *In extremis*, this could mean that Alpharma could be held in contempt of the United Kingdom court for trying to sell in other Contracting Parties of the EEA Agreement citalopram products utilising a process for which Lundbeck had filed a patent application.
- (1054) Even though the United Kingdom product scope of this consent order was narrowly drafted, it does not follow that the agreement should be given the same narrow scope as the United Kingdom consent order. Firstly, the geographic scope of the agreement was the entire EEA, whereas the consent order concerned only United Kingdom legal proceedings (even if the behaviour concerned could pertain to other Contracting Parties of the EEA Agreement). Secondly, the agreement and the consent order were and remained two separate legal instruments. The agreement had a life of its own separately from the United Kingdom consent order, including the possibility for Lundbeck to sue Alpharma for breach of contract if Alpharma did not comply with any of the provisions of the agreement. While parties could possibly have tried to

¹⁸⁴³ Alpharma argued in its reply to the Statement of Objections that "*a reasonable interpretation is that the parties intended to define "Citalopram" as the active chemical substance manufactured or produced pursuant to the processes covered by Lundbeck's patent rights set out in Appendix A.*" See ID 6056, page 15. This interpretation turns the actual sentence in the first 'Whereas' on its head: The sentence states that Lundbeck has certain patent rights on the production of citalopram; it does not say that citalopram (or Citalopram) is only that material which is covered by Lundbeck's patent rights.

¹⁸⁴⁴ The only exception is the GUK United Kingdom agreement, which refers to Cipramil, thereby referring to Lundbeck citalopram, and citalopram (without a capital), referring to citalopram in general.

¹⁸⁴⁵ Alpharma made a similar argument in its reply to the Statement of Objections. See ID 6056, pages 6 and 14.

¹⁸⁴⁶ See recital (536) above.

give the United Kingdom consent order the same wide scope as their agreement¹⁸⁴⁷, there was no guarantee that a court would have accepted such broad language in a consent order. Thirdly, and perhaps most importantly, the consent order could be drafted narrowly because, as already mentioned in recital (1043) above, Article 1.2 of the agreement obliged Alpharma to "*voluntarily submit to an interim injunction by any competent court in any applicable country in the Territory*" and to "*sign any document necessary to obtain such injunctions.*" It would, therefore, not have been difficult for Lundbeck to present any intended sale by Alpharma of any citalopram whatsoever, including potentially non-infringing citalopram, in EEA markets to the competent courts, as an admitted infringement of its process patents, justifying an immediate interim injunction, unless of course Alpharma decided to breach the agreement by not agreeing to such a consent order, in which case Lundbeck could have immediately stopped the instalments of the payment and could have sued for damages.

- (1055) In its reply to the Statement of Objections, Lundbeck also referred to a Danish press release of Alpharma of 28 February 2002, which stated: "*Our analysis tells us that we have a problem in relation to Lundbeck's process patent when looking at the product we have in stock. As a result, we have decided to postpone the launch of Cipramil until at least after the summer holiday* (translated from Danish)."¹⁸⁴⁸ Lundbeck argued that this meant that Alpharma believed it was free under the agreement to sell non-infringing citalopram. Alpharma made a similar argument in its reply to the Statement of Objections.¹⁸⁴⁹ This argument overlooks the fact that the agreement was confidential (see Article 3.1) and that Alpharma did not inform the press that it had concluded an agreement with Lundbeck, let alone that Lundbeck had agreed to pay it USD 12 million. The press release therefore suggested that the decision not to launch generic citalopram was a unilateral decision of Alpharma, with no precise duration. The press release may also have served to provide an explanation (other than the agreement with Lundbeck) to Alpharma's customers of why Alpharma decided not to supply them with generic citalopram.
- (1056) Finally, Alpharma mentioned a Lundbeck internal e-mail of 12 March 2002 stating: "*...there are many unknowns but we do not believe that Alpharma will launch in the foreseeable future in the UK (ref. Alpharma's statements to Reuters 14 days ago and the patents situation).*"¹⁸⁵⁰ Alpharma considered that "*This statement would make no sense if the Settlement Agreement prevented Alpharma from selling non-infringing products.*"¹⁸⁵¹ This document does not discuss the scope of Alpharma's obligation in Article 1.1 of the agreement with Lundbeck. The Commission also does not consider that this e-mail necessarily implies a narrow interpretation by Lundbeck of the words "*pharmaceutical products containing Citalopram*" in Article 1.1 of the agreement. The e-mail makes it clear that Lundbeck did not believe that Alpharma would launch citalopram in the foreseeable future in the United Kingdom, which is precisely what Alpharma was committed to doing under Article 1.1 of the agreement with

¹⁸⁴⁷ In Arrow's case, the two consent order following the agreement between Arrow and Lundbeck were, in fact, considerably broader even than the agreement. See section 12.4 above.

¹⁸⁴⁸ ID 5394, page 230.

¹⁸⁴⁹ ID 6056, page 17.

¹⁸⁵⁰ ID 723, page 55.

¹⁸⁵¹ ID 7025, page 2.

Lundbeck. As mentioned in recital (1051) above, Alpharma considered itself that the agreement prevented it from selling non-infringing citalopram during its term.

- (1057) In conclusion, the Commission considers that the arguments of the parties, based on the agreement as a whole and on secondary documents, are incapable of providing a credible alternative interpretation of the words "*pharmaceutical products containing Citalopram*" in Article 1.1 of the agreement, which the Commission interprets in the basis of the plain wording to cover all pharmaceutical products containing citalopram, irrespective of the API supplier and irrespective of whether such products would or would not infringe Lundbeck's process patents. Infringement litigation could not have produced this result for Lundbeck.

The notion of "*infringing*" citalopram

- (1058) As mentioned in recital (1044) above, both Alpharma and Lundbeck argued that their agreement was limited to "*infringing*" citalopram only. In its reply to the Commission's request for information of 12 March 2010, Lundbeck stated: "*...the agreement applies only to infringing products. If another source of citalopram, from API suppliers other than Cipla and Matrix, were to infringe, that other source would be covered by the agreement. Non-infringing products would not be covered.*"¹⁸⁵² Regarding Cipla and Matrix, Lundbeck had written in the same reply: "*As Alpharma's product would be based on Tiefenbacher's registration, which was for product supplied by Cipla and Matrix, Lundbeck was confident that Alpharma's citalopram products were infringing.*"¹⁸⁵³
- (1059) Based on this statement, and taking into account that the agreement did not provide for any mechanism whatsoever to determine in an objective way whether a product was infringing or not, it is clear that even if the term "*pharmaceutical products containing Citalopram*" were limited to "*infringing*" citalopram, its scope went considerably beyond that of the Cipla citalopram Alpharma had in stock at the time of conclusion of the agreement and against which Lundbeck could have started infringement litigation. Based on this statement, the agreement covered in any case:
- the Cipla citalopram Alpharma had already in stock (produced with Cipla's original process)¹⁸⁵⁴;
 - the citalopram Alpharma had ordered from Tiefenbacher but not yet received (which might be produced by Matrix or with a new and allegedly non-infringing process of Cipla)¹⁸⁵⁵;

¹⁸⁵² ID 823, page 37.

¹⁸⁵³ ID 823, page 24. It should be noted that at the time it concluded the agreement with Alpharma Lundbeck had also tested citalopram products produced with the original Matrix process (which according to Matrix were not being sold in the EEA) and considered that these were also infringing its crystallisation patent (application). See ID 5394, pages 170 to 172. Lundbeck stated in its reply to the Statement of Objections that at the time when it concluded the agreement with Alpharma, "*Lundbeck could not be entirely certain that they did not also use Matrix's API.*" See ID 5394, page 170.

¹⁸⁵⁴ According to Article 2.2 of the agreement, Alpharma agreed to deliver 9 400 000 tablets "*presently in Alpharma's possession*" to Lundbeck.

¹⁸⁵⁵ According to Article 2.2 of the agreement, Alpharma agreed to deliver to Lundbeck an additional 16 000 000 tablets "*consisting of i) any additional tablets delivered to Alpharma by its contract manufacturer prior to 31 March 2002, and ii) all of Alpharma's right title and interest in and to the purchase orders listed in Appendix C placed with Alpharma's contract manufacturer for the remaining tablets.*" As mentioned in recital (543) above, an e-mail from Lundbeck to Alpharma of 7 November

- any citalopram which Cipla or Matrix produced during the term of Alpharma's agreement with Lundbeck, including with new and allegedly non-infringing processes which Cipla and Matrix developed in the course of 2002, at least if Lundbeck considered such citalopram to be infringing;
 - any citalopram from other API suppliers that Lundbeck considered infringing.
- (1060) The Commission notes that Alpharma had an obligation under its agreement with Tiefenbacher to buy the active ingredient citalopram exclusively from Tiefenbacher for a period of five years after Alpharma's launch of the product in the United Kingdom.¹⁸⁵⁶ This meant that for the period covered by the agreement with Lundbeck, Alpharma was in principle bound to order any citalopram products only from Tiefenbacher. Unless Alpharma had been able to get out of this contract with Tiefenbacher (for instance because of the alleged infringement of the initial Cipla product¹⁸⁵⁷), Alpharma would contractually not have been able to buy citalopram from other API suppliers than the ones used by Tiefenbacher, which were Cipla and Matrix. It is unclear whether Lundbeck knew this at the time it concluded the agreement with Alpharma.¹⁸⁵⁸ In any case, this does not detract from the scope of the obligations Alpharma accepted under the agreement with Lundbeck.

Conclusion

- (1061) In conclusion, the Commission considers that Alpharma's commitment in Article 1.1 of the agreement with Lundbeck not to sell "*pharmaceutical products containing Citalopram*" in the EEA for the term of the agreement meant that Alpharma was not allowed to sell any generic citalopram products, irrespective of the API supplier and irrespective of whether the manufacturing process used would be likely to infringe any Lundbeck patents or not. As mentioned in recital (1059) above, even if one were to follow the parties' interpretation that only "*infringing*" products were covered, which is not supported by the wording of Article 1.1 of the agreement, Alpharma's commitment not to sell "*pharmaceutical products containing Citalopram*" still went considerably beyond what Lundbeck could have achieved by continuing its infringement action against Alpharma.

12.6.5.2. Alpharma's commitment to voluntarily submit to interim injunctions

- (1062) Article 1.2 of the agreement ensured that Lundbeck had the possibility, which Alpharma could not prevent without violating the agreement, to obtain interim injunctions in any Contracting Party of the EEA Agreement if ever Alpharma had the intention of trying to import or sell products containing citalopram. This is clear from the wording of Article 1.2 which stated: "*In the event of any breach of the obligation set forth in Article 1.1 or at the request of Lundbeck, Alpharma and Alpharma's Affiliates will voluntarily submit to an interim injunction by any competent court in any applicable country in the Territory. Lundbeck shall be*

2002 asked whether part of the tablets Alpharma had to deliver to Lundbeck under the agreement were "*Matrix new*", thereby referring to the allegedly non-infringing new Matrix process.

¹⁸⁵⁶ Article 2.1 of the agreement with Tiefenbacher of 25 June 2001, see ID 746, page 212.

¹⁸⁵⁷ Xellia Pharmaceuticals ApS stated in its reply to the Commission's request for information of 14 March 2011: "*The contract [between Tiefenbacher and Alpharma of 31 July 2000] contains a right for the customer to terminate in the event AET [Tiefenbacher] is unable to supply the "products" for any reason including patent infringement.*" See ID 1220, page 12.

¹⁸⁵⁸ Arrow, which had different provisions in this respect in its contract with Tiefenbacher, believed itself free under its contract with Tiefenbacher to buy API from other suppliers than Cipla or Matrix.

entitled to obtain such injunction without providing any kind of security. Alpharma and Alpharma's Affiliates waives any confirmatory action pursuant to any law or regulation in any applicable country in the Territory relating to such injunction proceedings and shall upon request from Lundbeck sign any document necessary to obtain such injunctions."

- (1063) Article 1.2 of the agreement meant that even if, as in the case of the United Kingdom consent order, the commitment in the order was limited to processes "utilising" any of the processes patented by Lundbeck, Alpharma had to cooperate if Lundbeck wanted to obtain an interim injunction against any intended importation or sale by Alpharma of products containing citalopram. Alpharma could simply not argue before the courts in the EEA that the product it intended to sell did not utilise any of the processes patented by Lundbeck without violating this Article 1.2 of the agreement. If so, Lundbeck could under Article 4.2 of the agreement have forthwith terminated the agreement and stopped the instalments of the payments to Alpharma. Lundbeck could even have re-claimed the instalments already made for breach of contract. Article 1.2 provided in its last sentence: *"Furthermore, in the event of any wilful or negligent breach of the obligations set forth in Article 1.1, Alpharma shall pay to Lundbeck non-refundable liquidated damages ("konventionalbod") equal to the payments made by Lundbeck under this Agreement."* Lundbeck could also have started court action to claim damages from Alpharma for breach of contract.
- (1064) The words *"In the event of any breach of the obligation set forth in Article 1.1 or at the request of Lundbeck"* (emphasis added) in Article 1.2 show that even if one interpreted Article 1.1 as only covering 'infringing' citalopram, as claimed by the parties (whatever 'infringing' might mean in the absence of any mechanism to determine that), the fact of the matter was that as soon as Lundbeck simply requested it, Alpharma had to give its full cooperation to obtain an interim injunction for Lundbeck, sign any document Lundbeck asked Alpharma to sign, and waive any confirmatory action before the courts in the EEA. Therefore, however one interprets the words *"pharmaceutical products containing Citalopram"* in Article 1.1, Alpharma had no means, without violating the agreement, to prevent Lundbeck from obtaining an interim injunction against any intended importation or sale by Alpharma in the EEA of citalopram products during the term of the agreement, whether or not those products had been manufactured utilising a process patented by Lundbeck. Given that Alpharma's net present value business case for entering the market was no better than the 12 USD million that Lundbeck offered to pay in cash to Alpharma for staying out of the market, money which Lundbeck could have stopped paying or even reclaimed under Article 1.2 if Alpharma did not co-operate, Alpharma had no incentive to question Lundbeck's interpretation that any citalopram it could have imported during the term of the agreement must have been infringing. As Alpharma faithfully implemented the agreement and did not try to sell citalopram anywhere in the EEA during the term of the agreement, there was no need for Lundbeck to request any (voluntary) interim injunctions, as foreseen by Article 1.2, in any Contracting Party to the EEA Agreement against Alpharma. The proceedings in the United Kingdom were stayed on 2 May 2002 with a consent order. Alpharma's commitment to sell its citalopram products in stock and on order to Lundbeck
- (1065) In Article 2.2 of the agreement, Alpharma agreed to sell to Lundbeck Alpharma's entire stock of 9,400,000 Cipla citalopram tablets as well as 16,000,000 further

tablets that Alpharma had ordered from Tiefenbacher (which could be produced with API from either Cipla or Matrix). The sale of Alpharma's entire stock of citalopram tablets to Lundbeck, including all of the tablets on order, gave Lundbeck certainty that these tablets would not be sold in the EEA, whether by Alpharma or by another generic undertaking to which Alpharma could have sold the tablets and the corresponding marketing authorisations. Lundbeck itself could not sell these tablets as the agreement did not provide for Alpharma to transfer its marketing authorisations to Lundbeck. This indicates that Lundbeck had no intention to sell the tablets in question itself. Instead it destroyed them.¹⁸⁵⁹ Article 1.3 of the agreement merely foresaw that Alpharma had to give Lundbeck a copy of its United Kingdom marketing authorisation.¹⁸⁶⁰ This was meant to give Lundbeck certainty that Alpharma was really allowed to sell the tablets and that therefore the payments to prevent Alpharma from doing so were justified.

12.6.6. Lundbeck transferred considerable value to Alpharma in exchange for Alpharma's commitments under the agreement

- (1066) Article 1.3 of the agreement provided that "*As compensation for Alpharma's obligations set forth in this Agreement and in order for Lundbeck to avoid the cost and time of litigation, Lundbeck shall pay to Alpharma USD 12 million (USD 12,000,000.00), of which USD 11 million (USD 11,000,000.00) shall be for Alpharma's products containing Citalopram.*"¹⁸⁶¹
- (1067) The words "*As compensation for Alpharma's obligations set forth in this Agreement*" shows a clear link between Lundbeck's payment of USD 12 million and Alpharma's commitments not to sell for the term of the agreement generic citalopram in the EEA and to transfer all of its citalopram tablets in stock and on order to Lundbeck. In the absence of any other counter-performance by Alpharma, Lundbeck's payment of USD 12 million was a clear inducement to Alpharma to give up its independent efforts to enter EEA markets and to accept the commitments identified in section 12.6.5 above.
- (1068) The fact that Lundbeck might have saved time and litigation costs of USD 1 million by making the agreement with Alpharma does not change this. Time and cost savings by Lundbeck are not a counter-performance by Alpharma. The fact remains that Alpharma was rewarded with USD 12 million for accepting the commitments it made in the agreement. If savings made by Lundbeck could justify payments to competitors persuading them to stay out of the market, the costs in foregone profits such agreements avoided for Lundbeck (by preventing generic entry that would have likely led to significant decreases in Lundbeck profits) would justify these agreements as legal. It is not because Lundbeck avoided certain costs or saved time or profits by making an agreement in which a competitor is paid to stay out of the market that such an agreement becomes partly or entirely legal. Alpharma also saved time and litigation costs by entering into the agreement. Indeed, if anything, since Alpharma allegedly agreed to Lundbeck's findings that there were substantial reasons for infringement and agreed not to enter EEA markets, it would, under this alleged logic, have been more reasonable for Alpharma to pay saved litigation costs to

¹⁸⁵⁹ See recital (541) above.

¹⁸⁶⁰ See recital (525) above.

¹⁸⁶¹ See recital (525) above.

Lundbeck.¹⁸⁶² In the final analysis, Lundbeck's payment to Alpharma of USD 1 million for allegedly saved litigation costs was simply part of Lundbeck's overall payment package to Alpharma of USD 12 million, for which Alpharma had to do nothing else than stay out of the citalopram market in the EEA for the duration of the agreement and transfer its entire current stock of citalopram and all citalopram on order to Lundbeck.

- (1069) Article 1.3 of the agreement provided that Lundbeck would pay the amount of USD 12 million in three instalments of USD 4 million each, the last instalment being paid the last day of operation of the agreement. This shows that the payments were directly linked to Alpharma's continued compliance with its commitment to stay out of EEA markets. The fact that Article 1.3 also provided that Lundbeck could stop its payments if Lundbeck did not receive a copy of Alpharma's marketing authorisation in the United Kingdom confirms that Lundbeck's willingness to pay the USD 12 million depended not only on whether or not it received Alpharma's entire stock of products but also on whether Alpharma could prove that it was actually allowed to sell citalopram in the United Kingdom. This shows, in other words, that Lundbeck wanted to be certain that it paid not just to receive generic citalopram (which it destroyed), but that it received citalopram which could otherwise have been sold in the market in competition with Lundbeck's own citalopram. The real value to Lundbeck of the citalopram it bought from Alpharma was therefore the value in saved money for Lundbeck by keeping that citalopram out of the United Kingdom and other EEA markets.
- (1070) Article 1.2 of the agreement provided that if Alpharma wilfully or negligently breached its commitment in Article 1.1 not to import, make or sell citalopram in EEA markets, Lundbeck would be entitled to receive back from Alpharma the money it had already paid under the agreement. This included notably any payments Lundbeck had already made for Alpharma's stock. This shows that the payments Lundbeck made to Alpharma for its stock of citalopram tablets served also, and indeed primarily, as a reward for Alpharma's commitment in Article 1.1 to stay out of EEA citalopram markets.
- (1071) Lundbeck explained to the Commission that "*Under the agreement with Alpharma, and in lieu of any damages that might be available to Alpharma in the event that its citalopram products were not infringing, Lundbeck provided Alpharma with \$12 million - \$11 million of which was payment for Alpharma's stock of products containing citalopram.*"¹⁸⁶³ The reference to "in lieu of any damages" in this statement implies that Lundbeck's payment of USD 12 million, including USD 11 million for Alpharma's 25.4 million citalopram tablets, was meant to cover not only Alpharma's purchase cost of those tablets, but also Alpharma's profit if it had successfully sold those products in EEA markets. In other words, Lundbeck paid Alpharma the resale value of the tablets, not the purchase cost. The statement as a whole amounts to saying that Lundbeck was willing to reward Alpharma, in advance, as if Alpharma had already been proven to be non-infringing and had already successfully sold its products in the EEA, provided only that Alpharma refrained from actually continuing the litigation and refrained from actually selling the tablets in question, and any citalopram at all, in EEA markets. That Lundbeck's payment of

¹⁸⁶² See recital (640) above.

¹⁸⁶³ See recital (526) above.

USD 12 million, including USD 11 million for the tablets, roughly matched the resale value of those tablets in EEA markets, and therefore expected profits, is also clear from Appendix C to the agreement, which indicates that Alpharma paid EUR 3.7 million for the 25.4 million tablets which Lundbeck purchased, less than a third of the USD 12 million amount Lundbeck agreed to pay to Alpharma.¹⁸⁶⁴ Finally, as mentioned in recital (1027) above, Alpharma considered internally, three days before concluding the agreement with Lundbeck, that "*the business case...has an NPV of USD 10 million.*" The USD 12 million transfer of value Lundbeck agreed to pay to Alpharma therefore roughly matched the profit Alpharma could only have hoped for if it had actually entered EEA markets, plus the purchase cost of the tablets.¹⁸⁶⁵ In the end, Lundbeck did not pay the entire USD 11 million it had promised upon receipt of the tablets, but only USD 10.1 million, because Alpharma transferred only 23.3 million tablets instead of the promised 25.4 million.¹⁸⁶⁶ The total actual transfer of value from Lundbeck to Alpharma thereby became USD 11.1 million (EUR 11.7 million).¹⁸⁶⁷

- (1072) At the same time, as has been analysed in recitals (198) to (201) above, the avoidance of generic entry Lundbeck achieved through the agreement with Alpharma was worth a lot more to Lundbeck than the value Lundbeck transferred to Alpharma.
- (1073) The Commission notes that neither of the parties rebutted the Commission's conclusions on the value transfer by providing different, legitimate reasons.
- (1074) The Commission concludes from the facts described in this section 12.6.6 that Lundbeck transferred considerable value to Alpharma in exchange for Alpharma's commitments under the agreement, that is to say (i) not to sell pharmaceutical products containing Citalopram, (ii) submit to an injunction at the request of Lundbeck; and (iii) to sell its Citalopram product in stock and on order to Lundbeck.

12.6.7. Intentions of the parties

- (1075) This section deals with the intentions of the parties regarding the aim of the agreement. Alpharma's intentions relevant for the existence of potential competition have already been analysed in sections 12.6.3 and 12.6.4 above.
- (1076) Lundbeck's intentions to delay generic entry have already been described in detail in Chapter 6 and have been summarised, in particular for the United Kingdom, in recitals (803) to (808) above. Those recitals apply here as well. In Lundbeck's overall strategy, time in the form of delay in generic entry was needed to prolong profits on

¹⁸⁶⁴ See recital (528) above.

¹⁸⁶⁵ Expected profits according to Alpharma at the time of USD 10 million + purchase cost of the tablets of USD 3.9 million (EUR 3.7 million) = USD 13.9 million. Using an average annual exchange rate for 2002 of 1 EUR = 0.94557 USD, source European Central Bank. In its reply to the Statement of Objections, Alpharma claimed certain additional cost elements, which it alleged would have reduced its profit from entry. See ID 6056, page 62. The Commission points out, however, that the contemporaneous assessment by the [employee function]* of Alpharma ApS three days before concluding the agreement that "*the business case...has an NPV of USD 10 million*" already takes account of all estimated costs and is clearly the most reliable indication in this respect. Moreover, if Alpharma's expected profit had really been less than USD 10 million, this would have meant that Lundbeck's payment of USD 12 million provided Alpharma with an even greater inducement to stop its independent efforts to enter EEA markets.

¹⁸⁶⁶ See recital (545) above.

¹⁸⁶⁷ Using an average annual exchange rate for 2002 of 1 EUR = 0.94557 USD, source European Central Bank.

cialtopram in the EEA, including the United Kingdom, and obtain a window of opportunity for the launch of Lundbeck's successor product escitalopram.

- (1077) Alpharma's intentions in entering into the agreement with Lundbeck are apparent from contemporaneous documents. On 21 January 2002, an internal Alpharma e-mail from the [employee function]* of Alpharma ApS stated:

"Subject: Lundbeck

Have just had the US on the line...Apart from [initials], none of them is particularly keen on a deal – in any case, not unless there is significant advantage for us.

....

Flag up [with Lundbeck] what we see as two or three possibilities:

a) only dollars for example, as we said 18-20;

b) combination of dollars and rights to a licence in Europe;

c) combination of dollars, licence rights in Europe and early entry to [third country].
¹⁸⁶⁸

As mentioned in recital (1027) above, three days before concluding the agreement with Lundbeck, the [employee function]* of Alpharma considered three options:

- launching the Cipla citalopram Alpharma had purchased;
- switching to Matrix citalopram which Alpharma considered non-infringing; or
- making a deal with Lundbeck.

His conclusion was:

*"Our recommendation is to pursue a deal with Lundbeck if a reasonable settlement can be achieved serving our legal and commercial interests."*¹⁸⁶⁹

It is clear from these contemporaneous documents that Alpharma was willing to give up its independent efforts to enter EEA markets with generic citalopram - and therefore its potential competition with Lundbeck - if, and only if, Lundbeck made it a more lucrative financial offer.

- (1078) Both parties can have had no doubt that in signing the agreement Alpharma gave up, for the duration of the agreement, any possibility to enter EEA markets with generic citalopram, whether such products would actually infringe any Lundbeck patents or not. Alpharma itself was certainly best placed to appreciate that the payments Lundbeck committed to make in the agreement roughly matched the profit (plus purchase cost of the tablets) Alpharma could have made in EEA markets if it had successfully entered those markets.¹⁸⁷⁰ As for the link between Lundbeck's payments and Alpharma's commitment to stay out of EEA markets with generic citalopram, this link was, in the absence of any other counter-performance by Alpharma than the transfer of all of its citalopram to Lundbeck, obvious in the agreement and the two parties could not have been unaware of it.

¹⁸⁶⁸ See recital (495) above.

¹⁸⁶⁹ See also recital (518) above.

¹⁸⁷⁰ See section 12.6.6 above.

(1079) The Commission concludes from the facts described in this section 12.6.7 that both parties knew or should have known that their agreement was anti-competitive.

12.6.8. The agreement restricted competition to an appreciable degree in one or more of the markets covered by the agreement

(1080) The Commission refers to sections 6.6 and 11.9 for its considerations on the appreciable degree to which the agreements in question restricted competition and to section 13.4 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 States¹⁸⁷¹, the Commission does not have to prove an appreciable restriction of competition, but that in any case each (set of) agreement(s) did restrict competition to an appreciable degree.¹⁸⁷²

(1081) In the specific case of Alpharma, the Commission notes that the agreement with Lundbeck covered the entire EEA. In most national markets within the EEA Lundbeck held at the time when it concluded the agreement with Alpharma market shares considerably exceeding 10%.¹⁸⁷³

12.6.9. Conclusion on restriction by object

(1082) The facts described and assessed in legal terms in sections 12.6.1 to 12.6.4 above show that at the time the undertakings Alpharma and Lundbeck concluded their agreement of 22 February 2002, they were potential competitors in markets for citalopram in Contracting Parties of the EEA Agreement. As analysed in section 12.6.5 above, under the agreement, Alpharma accepted several commitments which ensured that Alpharma would not compete with Lundbeck in citalopram markets in Contracting Parties of the EEA Agreement for the term of the agreement. Alpharma's obligation not to sell covered "*any*" "*pharmaceutical products containing Citalopram*." This covered any citalopram products whatsoever, irrespective of the API supplier and irrespective of whether the manufacturing process used would be likely to infringe any Lundbeck patents or not. Even if the parties' argument were accepted that only "*infringing*" products were meant, the agreement in any case covered:

- the Cipla citalopram Alpharma had already in stock (produced with Cipla's original process);
- the citalopram Alpharma had ordered from Tiefenbacher but not yet received (which might be produced by Matrix or with a new and allegedly non-infringing process of Cipla);
- any citalopram which Cipla or Matrix produced during the term of Alpharma's agreement with Lundbeck, including with new and allegedly non-infringing processes which Cipla and Matrix developed in the course of 2002, at least if Lundbeck considered such citalopram to be infringing;

¹⁸⁷¹ See recital (724) above. For the effect on trade between Member States of each (set of) agreement(s), see chapter 13 below.

¹⁸⁷² See in particular section 6.6 above. The Commission notes, in this respect, that since each (set of) agreement(s) covered the United Kingdom, where Lundbeck succeeded through the agreements in preventing widespread generic competition from January 2002 to October 2002, each (set of) agreement(s) restricted competition to an appreciable degree in at least one of the markets covered by the agreement.

¹⁸⁷³ See recital (215) above.

- any citalopram from other API suppliers that Lundbeck considered infringing.

As analysed in section 12.6.6 above, Lundbeck transferred considerable value to Alpharma in exchange for Alpharma's acceptance of these commitments. Section 12.6.7 has shown that this agreement formed part of Lundbeck's strategy to delay generic entry for citalopram and that Alpharma knew or should have known that Lundbeck's transfer of value to it served to persuade Alpharma to accept the commitments in question and thereby to eliminate the incentive for Alpharma to continue its independent efforts to enter citalopram markets in Contracting Parties of the EEA Agreement for the term of the agreement.

- (1083) Given that Alpharma's acceptance of these limitations on its commercial autonomy was achieved not by the strength of Lundbeck's patents, but by the transfer of value from Lundbeck to Alpharma, the Commission considers that these limitations constitute restrictions of competition within the meaning of Article 101(1) of the Treaty.
- (1084) Moreover, since these limitations on Alpharma's commercial autonomy, obtained by Lundbeck through the transfer of considerable value to Alpharma, were by their very nature injurious to the proper functioning of normal competition and followed directly and necessarily from the clauses of the agreement itself, the Commission considers that they are restrictions of competition by object. Indeed, the provisions of the agreement considered together and in their context make it clear that it was an objective aim, a necessary consequence of the agreement to make it impossible, for the term of the agreement, for Alpharma to sell any citalopram in the EEA, in exchange for the considerable transfer of value from Lundbeck.
- (1085) Alpharma's commitment not to sell products containing citalopram existed irrespective of whether or not such citalopram would infringe Lundbeck's process patents. Lundbeck could not have obtained this complete exclusion of Alpharma from citalopram markets in the EEA through court enforcement of its process patents against the process used to produce the tablets Alpharma had purchased, even if Lundbeck had been successful in these efforts, which was far from evident when the agreement was concluded.¹⁸⁷⁴
- (1086) Finally, it should be noted that the agreement was not aimed at solving the underlying issue of alleged patent infringement. Also, there was no commitment from Lundbeck in the agreement that Lundbeck would refrain from infringement proceedings if Alpharma entered the market with generic citalopram after expiry of the agreement.¹⁸⁷⁵ The agreement therefore essentially ensured that Alpharma could not sell generic citalopram during the term of the agreement, without any guarantee of market access thereafter.
- (1087) In conclusion, the Commission finds that the agreement between Lundbeck and Alpharma, as examined in this section 12.6, including in particular the facts that:

¹⁸⁷⁴ The commitment therefore fell both within the scope of Lundbeck's patents and outside. As explained in recitals (659) and (660) above, the Commission also considers such commitments within the scope of the patent illegal if they are induced by a transfer of value from the originator undertaking.

¹⁸⁷⁵ See recital (519) above. In its reply to the Commission's Letter of Facts of 12 April 2013, Lundbeck stated: *"...this simply reflects the fact that Lundbeck did not want to commit to restrictions that would prevent it from challenging any patent infringement in the future."* See ID 6814, page 114.

- Lundbeck and Alparma were at the moment when they concluded their agreement at least potential competitors in a number of Contracting Parties of the EEA Agreement;
- Lundbeck transferred significant value to Alparma in the agreement;
- this transfer of value was linked to the acceptance by Alparma of the limitations on entry in the agreement, notably Alparma's commitment not to sell any generic citalopram in the EEA between 22 February 2002 and 30 June 2003;
- the transferred value roughly matched the profit Alparma expected if it had successfully entered EEA markets;
- Lundbeck could not have obtained those limitations on entry through enforcement of its process patents, the obligations on Alparma in the agreement going beyond the rights granted to holders of process patents; and
- the agreement contained no commitment from Lundbeck to refrain from infringement proceedings if Alparma entered the market with generic citalopram after expiry of the agreement;

constitutes a restriction of competition by object.

12.7. The agreement between Lundbeck and Ranbaxy regarding the EEA restricted competition by object under Article 101(1) of the Treaty

12.7.1. Introduction

(1088) The general factual context for the legal assessment of the agreements dealt with in this Decision has been set out in chapters 4 to 6 above. The specific factual context for the legal assessment of the Ranbaxy agreement has been set out in sections 3.2, 3.6 and 7.7 above. The general legal context for the assessment of the agreements dealt with in this Decision has been set out in chapters 8 to 11 above. The current section will make a specific legal assessment of the Ranbaxy agreement, examining its compliance with Article 101(1) of the Treaty, based in particular on the criteria identified in recital (661) and the other factors mentioned in recital (662) above. This assessment will be made in the manner indicated in recital (735) above, taking into account the actual content and objectives of the agreement, the legal and economic context of the agreement, the implementation of the agreement and the intentions of the parties.

12.7.2. The agreement between Lundbeck and Ranbaxy was an agreement between undertakings within the meaning of Article 101(1) of the Treaty

(1089) Article 101(1) of the Treaty prohibits "*agreements between undertakings*" that restrict competition. For the general legal assessment of these quoted terms, the Commission refers to section 9.3 above. An agreement within the meaning of Article 101(1) of the Treaty can be said to exist when there is a concurrence of wills between two parties regarding the future behaviour of one or both of them. An undertaking is any entity engaged in an economic activity, such as offering goods or services on a given market, regardless of its legal status and the way in which it is financed. In the present case, Lundbeck and Ranbaxy were at the time of events economic entities that offered goods on given markets. They were therefore undertakings. As for the "*Settlement Agreement*" these two undertakings concluded on 16 June 2002, this document, as signed by H. Lundbeck A/S and Ranbaxy Laboratories Limited, reflected a concurrence of wills between these two undertakings with respect to the

commitments embodied in the document. It therefore qualifies as an agreement between undertakings within the meaning of Article 101(1) of the Treaty.

12.7.3. Lundbeck and Ranbaxy were at least potential competitors at the time they concluded the agreement

- (1090) For its general legal assessment of potential generic competition for citalopram in the relevant period, the Commission refers to section 9.4 above. By the time Ranbaxy and Lundbeck entered into a *"Settlement Agreement"* on 16 June 2002 covering the EEA (as well as certain third countries) for a year, later extended with another half year until 31 December 2003, Lundbeck's basic patent on the citalopram compound (which included the two original processes to produce the compound) had lapsed by January 2002 in most Contracting Parties of the EEA Agreement. This meant that citalopram markets in those Contracting Parties of the EEA Agreement were open to generic competition, as generic citalopram medicine could henceforth be freely sold provided it met regulatory requirements as to quality, safety and efficacy, as confirmed by a marketing authorisation. Generic undertakings with a business plan to sell generic citalopram in markets in the EEA and a realistic prospect to obtain supplies of generic citalopram medicines and an accompanying marketing authorisation in the near future were potential competitors to Lundbeck and to each other.¹⁸⁷⁶
- (1091) Ranbaxy, a producer/supplier of API as well as a producer/supplier of generic medicines, had started developing its own process to manufacture citalopram as early as January 2001.¹⁸⁷⁷ In the period leading up to the conclusion of the agreement, Ranbaxy had explored cooperation with Lundbeck in order to become a contract supplier of citalopram API to Lundbeck. Ranbaxy explained to Lundbeck that it had *"consciously not pursued other opportunities coming our way as we opted to work with M/s Lundbeck."* Lundbeck nevertheless cancelled the co-operation, considering internally: *"That was exactly what we were playing for when we started the dialogue"*.¹⁸⁷⁸
- (1092) After Lundbeck had informed Ranbaxy in July 2001 that it was no longer interested in using Ranbaxy as a contract supplier for citalopram, Ranbaxy began to explore concrete possibilities of selling its citalopram API to the EEA. In December 2001, Ranbaxy sent a potential customer in Italy a technical data package on its citalopram API, followed in 2002 (before concluding the agreement with Lundbeck) by 16 kgs of citalopram API.¹⁸⁷⁹ The French company GNR Pharma received a technical data package from Ranbaxy in January 2002.¹⁸⁸⁰ In 2002, before concluding the agreement with Lundbeck, Ranbaxy also sent a small quantity of its citalopram API to a potential customer in Sweden.¹⁸⁸¹
- (1093) A first contact between an American wholesaler representing Ranbaxy and Arrow in the United Kingdom took place on 11 January 2002.¹⁸⁸² After a further contact with

¹⁸⁷⁶ See section 9.4 above.

¹⁸⁷⁷ See recital (549) above.

¹⁸⁷⁸ See recital (552) above.

¹⁸⁷⁹ See recital (566) above. See also ID 597, page 1 and ID 5176, page 36.

¹⁸⁸⁰ See recital (566) above.

¹⁸⁸¹ See recital (566) above. See also ID 597, page 1 and ID 5176, page 36.

¹⁸⁸² See recital (554) above.

Arrow in April 2002¹⁸⁸³, Ranbaxy (through its American wholesaler) made Arrow on 14 May 2002 a concrete price offer for the sale of 500 to 1,000 kgs of citalopram API.¹⁸⁸⁴ It should be noted that under its contract with Tiefenbacher, Arrow had the possibility of purchasing already existing marketing authorisations from Tiefenbacher. Through a type II variation¹⁸⁸⁵, these marketing authorisations could after three to four months have been used for the supply of Ranbaxy citalopram API. Arrow interpreted its contract with Tiefenbacher as allowing it to purchase citalopram API from other suppliers than Tiefenbacher.¹⁸⁸⁶

- (1094) On 14 June 2002, two days before concluding the agreement with Lundbeck, Ranbaxy filed a Drug Master File for its citalopram API with the United Kingdom authorities, thereby allowing suppliers of generic medicines in the EEA to apply for a marketing authorisation or a type II variation of an existing marketing authorisation to sell generic citalopram medicines manufactured with citalopram API from Ranbaxy. At the same time, the dossier necessary for Ranbaxy's application for a marketing authorisation to sell citalopram medicines itself was sent from India to Ranbaxy's United Kingdom office, even if the actual application only took place in early August 2002.¹⁸⁸⁷

¹⁸⁸³ See recital (557) above.

¹⁸⁸⁴ See recital (559) above.

¹⁸⁸⁵ As Ranbaxy itself stated to Lundbeck (see recital (558) above), it was deemed possible to obtain a type II variation to an existing marketing authorisation within three to four months if the information submitted was correct and complete. According to a March/April 2002 publication of the United Kingdom Medicines Control Agency in the United Kingdom, for instance, the Agency processed all type II variations within 90 days from the acknowledgement letter (and 85% within 60 days), resulting either in an approval or a request for supplementary information. For type I variations, the corresponding figures were 100% in 30 days and 84% in 20 days. Whether an applicant actually obtains approval within these time periods depends on the completeness and accuracy of the information it supplies to the agency. See ID 1910, page 16. See also ID 848, page 36, a Lundbeck document of 28 June 2002 which estimates the time needed to obtain a type II approval at 3-4 months. In its reply to the Statement of Objections, Ranbaxy stated that a generic supplier with a marketing authorisation who was interested in buying Ranbaxy API "would have to wait for at least three, and more likely four to five, months before obtaining such a variation." See ID 5176, page 36. In its reply to the Statement of Objections, Lundbeck claimed that a type II variation would require more time, that is to say "...at least nine to 12 months...". See ID 5394, page 246.

¹⁸⁸⁶ In this respect, Arrow stated to the Commission: "*The contract did not contain an exclusive purchasing obligation (and indeed no obligation to purchase, only an option to do so)...Arrow Group did discuss a possible supply agreement with Tiefenbacher, but as far as it can ascertain this was never concluded. Under the terms of the contract, Arrow Group was expressly permitted to supply products sourced from third parties, subject to payment of a royalty to Tiefenbacher if it did so [x]% of gross sales if Arrow Group manufactured its own tablets with Tiefenbacher's API (which would have been sourced from either Cipla or Matrix...), or [y]% of gross sales if it manufactured its own tablets with API from a third party...*". See recital (375) above. It is also recalled that in Denmark and Sweden, Arrow intended to buy a marketing authorisation that had already been granted based on Tiefenbacher's dossier. See recital (454) above. For Denmark, on 3 June 2002 Arrow concluded an agreement with Lundbeck preventing it from selling "products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights in the Territory" for the term of the agreement. See section 7.5 above. Lundbeck reported to the Commission that "Arrow did sell citalopram in Sweden (through another company acting as Arrow's distributor)." See ID 5394, page 199.

¹⁸⁸⁷ In its reply to the Statement of Objections, Ranbaxy argued that "It would not have been possible for Ranbaxy to file the dossier earlier than August 2002 since it had to await the results of bioequivalence studies which it had initiated in May 2002 and which constitute the basis upon which a generic marketing authorization is granted" (see ID 5176, page 28). However, in the time line which Ranbaxy annexed (see ID 5182), Ranbaxy stated for the month of May 2002: "Stability studies on exhibit batches

(1095) With respect to Ranbaxy's intentions to compete with Lundbeck, on 17 April 2002, according to a Lundbeck report, Ranbaxy told Lundbeck at a meeting in London:

- *"We have a non-infringing process*
- *Not crystallising the free base*
- *[Lundbeck] knows our process*
- *We will file now for UK & Germany, where we have our own subs – expect registration in 8 months*
- *We are discussing with a partner for Northern Europe, who will be able to bring our product to the market in 3-4 months – signature is close*
- *Q: Is that Tiefenbacher? A: No, we are also talking to Tiefenbacher, but it is not them [Most likely it is Tiefenbacher/Delta – however it could also [be] Merck Generics if Natco really is infringing]*
- *Annual capacity for [third countries] & EU – 4.5 ton*
- *Do you want a deal? Please let us know before end of April!"*

Below this, the Lundbeck representative wrote in the report:

*"Do we want a deal? I guess a deal will be \$10M-\$20M or even more. My opinion is that it will be difficult – antitrust wise, costs and value for money..."*¹⁸⁸⁸

(1096) Ranbaxy therefore announced to Lundbeck in this meeting that it would, in the absence of a deal, start selling generic citalopram medicine in the EEA through its own subsidiaries as soon as those subsidiaries would have received a marketing authorisation (which Ranbaxy estimated would take 8 months).¹⁸⁸⁹ Ranbaxy also told Lundbeck that it was close to signing an agreement for the supply of Ranbaxy

as well as bioequivalence studies both completed in May 2002." For the month of June 2002, the time line stated: *"Stability data finished on 14 June and Dossier sent from India to UK office."* Ranbaxy stated for the months July and August 2002: *"Dossiers and MA app. filed with UK reg. authority."* It is difficult to see why if the dossier was ready and sent to the United Kingdom on 14 June 2002, it took Ranbaxy until early August 2002 to actually make the application to the United Kingdom authorities.

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See recital (558) above.

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Ranbaxy's estimate that it could obtain its own marketing authorisation within eight months was in line with the provisions of the then applicable Directive 2001/83, which stated that a Member State in principle had to complete the procedure for granting a marketing authorisation within seven months of the submission of a valid application. See recital (85) above. In fact, however, and in retrospect, having come to an agreement with Lundbeck, Ranbaxy submitted its first request for a marketing authorisation in the United Kingdom in August 2002 and obtained a marketing authorisation there only in January 2004, immediately after the expiry of the agreement with Lundbeck. See recitals (575) and (589) above. In its reply to the Statement of Objections, Ranbaxy claimed that *"If one examines all approvals filed in the UK by Ranbaxy between 2002 and 2004, the citalopram procedure (which took 512 days from end to end) was one of the fastest procedures (well below the average figure of 727 days)"* and *"the truth of matter is that Ranbaxy did not have any short term prospect of entering the EEA with citalopram API or medicines when it negotiated this deal with Lundbeck between February and June 2002."* See ID 5176, pages 29 and 53. However, what matters for the assessment of whether potential competition existed is how quickly Ranbaxy could have obtained a marketing authorisation, as assessed at the point in time when the agreement was concluded, not how long it actually took Ranbaxy to obtain one. As mentioned in recital (85) above, if the application was correct from the beginning, generic companies could obtain a marketing authorisation within 7 months. How much longer the procedure would actually take would depend on the number of deficiencies in the application and the speed with which the applicant acted to correct those.

citalopram API to an unidentified partner¹⁸⁹⁰ who already had marketing authorisations and who would take care of the distribution of medicines made with Ranbaxy's API in Northern Europe. With respect to this second option, it would, according to Ranbaxy, take approximately three to four months for the marketing authorisation agencies to recognise Ranbaxy as a new authorised API supplier for existing marketing authorisations (through the so-called type II variation of the marketing authorisation). Ranbaxy claimed that it had the capacity to produce 4.5 tonnes of citalopram API per year worldwide (which would correspond to 225 million tablets of 20 mg).¹⁸⁹¹

- (1097) It is clear from Lundbeck's reaction to Ranbaxy's presentation in the meeting of 17 April 2002 that Lundbeck took Ranbaxy's threat of prospective market entry in the EEA seriously. This applied in particular to the possibility for Ranbaxy to be added within a couple of months as a recognised API supplier to existing marketing authorisations. Lundbeck knew that Ranbaxy had at least 400 kg of citalopram ready for sale.¹⁸⁹² Lundbeck suspected that Ranbaxy was considering becoming an API supplier to either Tiefenbacher or Merck Generics, both of which had already approved marketing authorisations in the EEA.¹⁸⁹³ On 21 May 2002 Lundbeck wrote internally that the alternative to an agreement with Ranbaxy was:

*"Alternative: Piggy-bag Tifi [Tiefenbacher] and hit the market in August 2002."*¹⁸⁹⁴

- (1098) If Ranbaxy had succeeded in becoming API supplier to Tiefenbacher, Merck, Arrow or any other generic undertaking that held valid marketing authorisations in the EEA, Ranbaxy could through a type II variation of the marketing authorisation of its generic partner (what Lundbeck called "piggy-backing") have started selling its citalopram API to the EEA within a matter of months. In this manner, in Lundbeck's estimate, Ranbaxy could *"hit the market in August 2002"*.¹⁸⁹⁵ Alternatively or in addition, Ranbaxy estimated that it could obtain its own marketing authorisations in the United Kingdom and Germany, where Ranbaxy had subsidiaries, *"in 8 months"*.¹⁸⁹⁶ In either or both of these concrete realistic possibilities, Ranbaxy would have been able to sell its citalopram in the EEA, whether as API to generic suppliers of citalopram medicines or as medicines through its own subsidiaries in the EEA,

¹⁸⁹⁰ Based on the contacts Ranbaxy had already had with Arrow and the concrete price offer it made to Arrow on 14 May 2002, this unidentified partner might have been Arrow. It should be recalled that before 3 June 2002, Arrow had only agreed with Lundbeck not to sell in the United Kingdom. As of 3 June 2002, Arrow also agreed with Lundbeck not to sell in Denmark. Arrow remained in principle free to sell in other EEA Contracting Parties.

¹⁸⁹¹ By comparison, in 2002 Lundbeck produced [...] tonnes of citalopram (ID 387 page 3).

¹⁸⁹² See recital (552) above.

¹⁸⁹³ See recital (558) above. Tiefenbacher's marketing authorisation for citalopram, using Cipla and Matrix as authorised suppliers of API, had been approved in the Netherlands in September 2001 and was being extended to other EEA Contracting Parties through the mutual recognition process. The United Kingdom marketing authorisation was approved in July 2002. See recital (168). Merck (GUK) had obtained a marketing authorisation in Sweden on 3 May 2002 and had applied for marketing authorisations in a number of other EEA Contracting Parties. See recital (347) above.

¹⁸⁹⁴ See recital (561) above.

¹⁸⁹⁵ See recital (561) above. It is true that under its agreement with Lundbeck, Arrow would not have been able to sell Ranbaxy citalopram in the United Kingdom until the agreement's expiry on 31 December 2002. If, however, Arrow had not concluded the agreement with Lundbeck regarding Denmark on 3 June 2002, Arrow would have been able to sell in Denmark and in any case in other EEA countries, including Sweden, as soon as Arrow had obtained a type II variation.

¹⁸⁹⁶ See recital (1095) above.

well before June 2003, the initial term of the agreement with Lundbeck. When it concluded the agreement with Lundbeck, Ranbaxy had made a concrete price offer for its citalopram API to Arrow, had just submitted a Drug Master File and had its dossier for a marketing authorisation application ready. It had also made initial sales of citalopram API to Italy and Sweden.

- (1099) The preamble of the agreement concluded between the two parties recognised that Ranbaxy had *"manufactured pharmaceutical products containing Citalopram with the intention of marketing such products in the Territory through affiliates, licensees or customers of Ranbaxy"*.¹⁸⁹⁷
- (1100) Ranbaxy stated in its reply to the Statement of Objections: *"In fact, it is unrealistic to believe that Ranbaxy had plans to invest in additional production methods. It had struggled for several years to find a production process that would be **commercially viable**. Ranbaxy had eventually managed to find a process for which it had filed patent applications -- first in India (March - July 2001) and now on a global scale (March - July 2002) – and it was ready to file its DMF for citalopram in the UK (14 June 2002). It was now time for Ranbaxy to move from the R&D phase to the phase of seeking regulatory approvals with a view to selling citalopram medicine in Europe (emphasis added)."*¹⁸⁹⁸
- (1101) The Commission concludes from these concrete realistic possibilities Ranbaxy had of entering one or more Contracting Parties of the EEA Agreement with own-manufactured citalopram (whether API or medicines) in the near future that Ranbaxy and Lundbeck were at least potential competitors at the time they concluded their agreement. Indeed, the very fact that Lundbeck agreed to transfer considerable value to Ranbaxy if it accepted not to enter EEA markets for the term of the agreement shows that Lundbeck considered that Ranbaxy's market entry in one or more EEA markets was plausible and that Lundbeck perceived Ranbaxy as a competitive threat to its position in those markets.
- (1102) The Commission concludes from these concrete realistic possibilities Ranbaxy had of entering one or more Contracting Parties of the EEA Agreement with generic citalopram in the near future that Ranbaxy and Lundbeck were at least potential competitors at the time they concluded their agreement. Indeed, the very fact that Lundbeck agreed to transfer considerable value to Ranbaxy if it accepted not to enter EEA markets for the term of the agreement shows that Lundbeck considered that Ranbaxy's market entry in one or more EEA markets was plausible and that Lundbeck perceived Ranbaxy as a competitive threat to its position in those markets.

12.7.4. The possibility of infringement of Lundbeck's process patents did not prevent Ranbaxy from being at least a potential competitor to Lundbeck

- (1103) This section responds to arguments raised by Ranbaxy and Lundbeck claiming that there could be no potential competition between Lundbeck and Ranbaxy when they concluded their agreement because Ranbaxy's manufacturing process risked infringing Lundbeck's process patents. This section will show that despite any concerns Ranbaxy may have had over Lundbeck's process patents, Ranbaxy had real concrete possibilities of entering one or more EEA markets in the near future. If

¹⁸⁹⁷ See recital (567) above.

¹⁸⁹⁸ ID 5176, page 44.

Lundbeck had challenged such market entry with patent infringement litigation, evidence shows that even Lundbeck was uncertain of the outcome. Moreover, evidence shows that the parties thought that a court might not have found Lundbeck's patents valid and infringed.

- (1104) With respect to the patent situation in the EEA for generic citalopram, the Commission refers to its general considerations in recitals (745) and (746) above. These general considerations, notably those regarding the fact that Lundbeck's process patents did not cover all possible processes to manufacture citalopram that met regulatory requirements in the EEA, the inherent difficulty of enforcing process patents and the distinct possibility that a court might hold the crystallisation patent invalid, also apply to other Contracting Parties of the EEA Agreement than the United Kingdom.
- (1105) With respect to Ranbaxy specifically, according to contemporaneous documents dating from before and during the period of operation of the agreement with Lundbeck, Ranbaxy consistently stated to third parties that it believed it had a non-infringing process. In May 2001, Ranbaxy asked Lundbeck: "*On Citalopram, can we agree that the contract would be signed subject to Ranbaxy demonstrating non-infringing technology. Can we fix timelines for this?*"¹⁸⁹⁹ In December 2001, Alpharma stated: "*Ranbaxy claim to have developed non-infringing API with full supporting documentation.*"¹⁹⁰⁰ In the meeting of 14 April 2002 cited in recital (1095) above, Ranbaxy told Lundbeck:

- "*We have a non-infringing process*
- "*Not crystallising the free base*
- "[Lundbeck] *knows our process*"¹⁹⁰¹

Ranbaxy noted in the preamble of the agreement with Lundbeck that it "*disputed the claim of Lundbeck that the Patent filed by Ranbaxy and the production method used by Ranbaxy infringe Lundbeck's intellectual property rights.*"¹⁹⁰² In May 2003, Ranbaxy Laboratories Limited wrote to Arrow: "*You had expressed interest during the meeting, as you believe your current source is infringing. We believe, our product is clear of all such issues.*"¹⁹⁰³

- (1106) At the time Ranbaxy and Lundbeck concluded their agreement, Lundbeck's crystallisation patent was still under examination at the EPO, with no guarantee that it would be granted at all or in its entirety. As mentioned in recital (555) above, a contemporaneous Ranbaxy document of 21 March 2002 shows that Ranbaxy had certain concerns over Lundbeck's crystallisation patent application at the EPO, in particular claim 11 thereof. Ranbaxy was at that time apparently not aware that this claim had already been withdrawn by Lundbeck in its application to the EPO.¹⁹⁰⁴

¹⁸⁹⁹ See recital (551) above.

¹⁹⁰⁰ See recital (553) above.

¹⁹⁰¹ See recital (558) above.

¹⁹⁰² See recital (567) above.

¹⁹⁰³ See recital (580) above.

¹⁹⁰⁴ Nevertheless, after having split off the product claims in a divisional, Lundbeck did obtain a patent on the crystalline form itself (EP 1 227 088). This patent was opposed before the EPO and subsequently revoked by the EPO (see recital (151) above), whereas Lundbeck's patent on the crystallisation process (EP 1169314) was significantly amended and the scope of its claims limited before the EPO. See recital

Although this product claim apparently remained present in the United Kingdom patent for the crystallisation patent (patent GB 2357762) as granted in the United Kingdom on 30 January 2002, it would, given that Ranbaxy analysed it as "*part of prior art*" and that it was ultimately revoked by the EPO, have been vulnerable to a claim of invalidity. In the document of 21 March 2002 (before the agreement with Lundbeck), Ranbaxy intended to oppose the United Kingdom patent. In supplementary comments to its reply to the Statement of Objections, Ranbaxy stated that it "*believed it had at least a reasonable defence of non-infringement and invalidity that it could raise against the Crystallisation patent but that its process was not free of patent risk.*"¹⁹⁰⁵

- (1107) As mentioned in recital (556) above, the same document of 21 March 2002 shows that Ranbaxy had no concerns over another process patent application for citalopram of Lundbeck's, WO 01/68631. This PCT application was later withdrawn by Lundbeck.
- (1108) In reply to the Commission's Letter of Facts of 12 April 2013; Lundbeck stated: "*Ranbaxy's statements concerning the Crystallization Patent and patent application WO 01/68631 are irrelevant for the assessment of the legality of the agreement with Ranbaxy. Indeed, neither of these intellectual property rights were mentioned in the Agreement, because Lundbeck could not reasonably establish that Ranbaxy infringed them...*"¹⁹⁰⁶
- (1109) As mentioned in recital (564) above, in May 2002 Lundbeck analysed reaction schemes allegedly representing Ranbaxy's actual production process and concluded that an argument could be made that this production process infringed Lundbeck's patent application EP 1159274: Method for the preparation of citalopram (the iodo process patent)¹⁹⁰⁷ and Lundbeck's patent EP 1015416: Method for the preparation of citalopram (the amide process patent).¹⁹⁰⁸ Regarding the former, Lundbeck's [employee function]* considered in this document: "*EP 1159274 has a claim 11 covering the intermediate 5-iodo-citalopram per se. Since such a claim may be considered analogous with a process claim, importation of a product which is a direct result of conversion of 5-iodo-citalopram to citalopram may be considered infringement of EP 1159274.*"¹⁹⁰⁹ Regarding the latter, he took the view that "*...it is possible that the conversion of 5-carboxamido-citalopram to citalopram in step two of the Ranbaxy process will be regarded as an infringement of EP 1015416.*" In its reply to the Statement of Objections, Lundbeck went a step further and claimed that it had analysed Ranbaxy's process a number of times since 4 December 2000 and "*... had established that Ranbaxy's process infringed its patents.*"¹⁹¹⁰

(166) above. As for the British patent GB 2357762, this patent appears to have been granted with the product and pharmaceutical composition claims included. There is no indication in the case file that Ranbaxy opposed this patent, as it intended to do before it concluded the agreement with Lundbeck. See recital (151) above.

¹⁹⁰⁵ ID 6539, page 5.

¹⁹⁰⁶ ID 6814, page 119.

¹⁹⁰⁷ This patent was granted by the EPO on 26 March 2003, see Espacenet and ID 5176, page 15.

¹⁹⁰⁸ See recital (564) above.

¹⁹⁰⁹ ID 8, pages 336-337.

¹⁹¹⁰ ID 5394, pages 240-242. At the same time, Lundbeck admitted in its reply to the Statement of Objections that Ranbaxy "*nevertheless denied that it was infringing Lundbeck's patents.*" See ID 5394, page 234.

- (1110) The Commission notes that the contemporaneous document quoted in recital (1108) above does not show any firm belief on the part of Lundbeck that Ranbaxy infringed its patents. The wording used ("*may be considered*" and "*it is possible that*") are cautious and leave room for considerable doubt. Moreover, even if Lundbeck had been fully convinced that Ranbaxy's process infringed, Lundbeck's opinion would remain a subjective view, which does not demonstrate that Ranbaxy was actually infringing or that a court would have found its patent valid and infringed.¹⁹¹¹ As Ranbaxy stated in supplementary comments to the replies of other parties to the Statement of Objections: "[Lundbeck employee] *does not appear to take into account the possibility that Ranbaxy might have claimed that the relevant patents were invalid if it had been forced to defend itself in an infringement proceeding. Ranbaxy therefore submits that Lundbeck overstates the point when stating that at the end of May 2002, it became "certain that Ranbaxy was infringing"...*".¹⁹¹²
- (1111) The two process patents which Lundbeck believed might be infringed by Ranbaxy (the iodo process patent application and the amide process patent) were also mentioned in the preamble of the agreement, together with Ranbaxy's claim that its process did not infringe any Lundbeck patents.
- (1112) In its reply to the Statement of Objections, Ranbaxy claimed, albeit not on the basis of contemporaneous documents¹⁹¹³ that at the time it had "*concerns*" about the amide process patent (patent EP 1015416). According to Ranbaxy, these concerns were related to the third step of Ranbaxy's process (as opposed to the second step in Lundbeck's analysis¹⁹¹⁴). Ranbaxy noted, in its reply to the Statement of Objections, that the third step of its process was different from that described in Lundbeck's patent, but nevertheless argued that it believed that Lundbeck could have considered that claim 20 of its patent covered Ranbaxy's amide CON-H. Also, according to Ranbaxy, spontaneous alkylation could occur, which would create "*...the exact intermediate protected by Lundbeck's patent...*"¹⁹¹⁵
- (1113) In its reply to the Statement of Objections, Ranbaxy also claimed, albeit again not on the basis of contemporaneous documents¹⁹¹⁶, that it had "*apprehensions*" and faced "*uncertainty*" at the time about whether its process as described in its own Indian patent application 246/DEL/2001 might conflict with Lundbeck's prior iodo process patent application (EP 1159274).¹⁹¹⁷ This was, according to Ranbaxy, the more so because Lundbeck's application had not yet been granted at the time of events. According to Ranbaxy: "*There was an ever present risk that the scope of Lundbeck's claims could be widened (so as to catch Ranbaxy product or processes which might be considered just outside the scope of the existing claims) or narrowed (thus making it more difficult to attack the patent as not new or obvious in the light of prior published material.*"¹⁹¹⁸ Moreover, Ranbaxy pointed to the "*... principle of*

¹⁹¹¹ See Case 193/83 *Windsurfing International v Commission*, [1986] ECR 611, paragraph 52. The patent holder cannot substitute "*...its discretion for the decisions of national courts, which were the proper forum for actions...*"

¹⁹¹² ID 6539, page 4

¹⁹¹³ ID 5176, page 16.

¹⁹¹⁴ See recital (1108) above.

¹⁹¹⁵ ID 5176, page 22.

¹⁹¹⁶ ID 5176, page 16.

¹⁹¹⁷ ID 5176, pages 13 and 19 to 21.

¹⁹¹⁸ ID 5176, page 19.

'purposive construction'..." which may broaden the scope of patent claims through interpretation.¹⁹¹⁹

(1114) Documentary evidence shows that Lundbeck believed:

- that it "*may be considered*" that Ranbaxy's alleged production process infringed Lundbeck's iodo process patent application (if the patent were granted and valid);
- and that "*it is possible*" that its amide process patent (if valid) was infringed.

Ranbaxy's *ex post facto* claimed:

- that "*its process was not free of patent risk*" with respect to the crystallisation patent;
- that it had "*concerns*" over possible infringement of Lundbeck's amide process patent; and
- that it had "*apprehensions*" and faced "*uncertainty*" over the iodo process patent application.

None of these pieces of evidence or of these claims show that Ranbaxy had given up its plan of entering EEA markets.

(1115) In its reply to the Statement of Objections Lundbeck argued that the fact that on 9 January 2004 Ranbaxy wrote to Lundbeck asking about the possibility to obtain a licence for Lundbeck's United Kingdom iodo process patent "... *unambiguously shows that Ranbaxy was indeed using the Iodo Process to produce its API at the time of the Ranbaxy Agreement.*"¹⁹²⁰ It may, however, also simply have meant that in January 2004, when Lundbeck was giving up its efforts to combat sales of generic citalopram in many EEA markets, Ranbaxy thought Lundbeck might well be willing to sell it a license for a low price, thereby avoiding any risk of potential patent infringement at little cost.

(1116) In conclusion on this point, the mere fact that both before and during the period of operation of the agreement with Lundbeck, Ranbaxy consistently stated to third parties that its production process of citalopram did not infringe¹⁹²¹ clearly shows that Ranbaxy intended to enter the market even taking Lundbeck's patent into account. This contributes to showing the existence of potential competition.

(1117) Moreover, at the time when Ranbaxy and Lundbeck concluded their agreement, there was considerable uncertainty whether the crystallisation patent application at the EPO would be granted and, if so, in what form (in fact, claim 11 which Ranbaxy considered most worrisome had already been withdrawn by Lundbeck) and whether the iodo process patent would be granted and, if so, in what form. This uncertainty was inherent to the fact that the court had not ruled on these patents by a final decision. Nor was it at all certain that an inspection of Ranbaxy's production process would actually be able to show any infringement of any of Lundbeck's process patents. Even if any of Lundbeck's patents had been infringed, Ranbaxy could have challenged the validity of the patent concerned before the courts in the EEA.

¹⁹¹⁹ ID 5176, page 18.

¹⁹²⁰ ID 5394, page 242. See recital (588) above.

¹⁹²¹ See recital (1105) above.

Ranbaxy could also have opposed Lundbeck's patents before patent offices, as Ranbaxy's management intended to do in the United Kingdom for the crystallisation patent (but never did once the agreement with Lundbeck was concluded).¹⁹²² Ranbaxy, which had been investing in a citalopram manufacturing process since at least January 2001, which had already produced 500 kg of citalopram API (corresponding to 25 million tablets of 20 mg) and which had an alleged worldwide production capacity of 4.5 tonnes of citalopram API per year, could, if it had had any concern of infringing patents, also have modified its production process to further reduce or eliminate the risk of any patent infringement¹⁹²³, as Cipla and Matrix did in the course of 2002. That Ranbaxy would, in the absence of the agreement, have simply given up its independent efforts to enter the EEA with own-manufactured citalopram because of "concerns" over Lundbeck's process patents is not backed up by any contemporaneous document. On the contrary, the fact that Ranbaxy had submitted a Drug Master File for its citalopram API with the United Kingdom authorities on 14 June 2002, two days before signing the agreement with Lundbeck, and had at the same time transmitted its dossier to apply for a marketing authorisation to its United Kingdom subsidiary, shows that Ranbaxy was preparing to enter EEA markets with its own-manufactured citalopram, in full awareness of Lundbeck's process patents.

- (1118) In sum, the facts analysed in this section 12.7.4 show that, after Lundbeck's patent on the compound and the two original production processes had expired, Ranbaxy, despite concerns over Lundbeck's process patents, had real concrete possibilities of entering one or more EEA markets in the near future. If Lundbeck had challenged such market entry with patent infringement litigation, evidence shows that even Lundbeck was uncertain of the outcome. The Commission therefore concludes that Lundbeck's process patents did not prevent Ranbaxy from being a potential competitor to Lundbeck at the time they concluded their agreement.

12.7.5. Commitments accepted by Ranbaxy in the agreement with Lundbeck

- (1119) In the agreement with Lundbeck, Ranbaxy accepted several commitments that limited its freedom of action to enter citalopram markets in the EEA.

12.7.5.1. Ranbaxy's commitment to desist from any manufacture or sale of citalopram based on any production method used by Ranbaxy during the term of the agreement with Lundbeck

- (1120) Article 1.1 of the agreement stated:

"Subject to the terms and conditions of this Agreement and subject to payment of the Settlement Amount by Lundbeck, Ranbaxy shall not in the Territory claim any rights on the Patent Application or any production method used by Ranbaxy and shall cancel, cease and desist from any manufacture or sale of pharmaceutical products

¹⁹²² See recital (555) above. Ranbaxy did not oppose the crystallisation patent before the EPO either, see ID 2773, footnote 13.

¹⁹²³ As Lundbeck stated in its reply to the Statement of Objections: "...by fudging slightly with a given process, the generic can at least initially claim it now has a new, non-infringing process..." See footnote 138 above. Lundbeck also mentions in its reply to the Statement of Objections that Ranbaxy allegedly modified its manufacturing process in 2001 to avoid infringement of Lundbeck's 2005 process patent, see ID 5394, page 240.

based hereon, in the Territory through itself, its Affiliates and/or any third party during the term of the Agreement."¹⁹²⁴

- (1121) In this provision, Ranbaxy accepted for the term of the agreement not to make or sell "*pharmaceutical products*" based on the production method for citalopram covered by Ranbaxy's patent applications in India or on "*any production method used by Ranbaxy*".¹⁹²⁵ In the view of the Commission, Ranbaxy accepted in this provision not to make or sell own-manufactured citalopram, whether in the form of API or medicines, in the EEA for the term of the agreement, irrespective of the production method Ranbaxy used to produce such citalopram. The Territory, as defined in Appendix A, covered the then EEA and several surrounding third countries.
- (1122) Article 1.2 of the agreement provided Lundbeck with the means to enforce this obligation on Ranbaxy. As will be further analysed in section 12.7.5.2 below, this provision obliged Ranbaxy "*at the request of Lundbeck*" to "*voluntarily submit to an interim injunction by any competent court in the Territory*" and to "*sign any document necessary to obtain such injunctions.*" It would, therefore, not have been difficult for Lundbeck to present any intended sale by Ranbaxy of any own-manufactured citalopram, whether API or medicines, and irrespective of the production process used by Ranbaxy, to the competent courts in EEA markets as an admitted infringement of Lundbeck's process patents. This could have justified an immediate interim injunction, unless of course Ranbaxy decided to breach the agreement by not agreeing to such a consent order and defending itself in court against Lundbeck's infringement allegations. In this case Lundbeck could, under Article 3.2 of the agreement, have stopped the instalments of the transfer of value, terminated the agreement and sued Ranbaxy for damages for breach of contract.¹⁹²⁶
- (1123) Ranbaxy complied with its obligation in Article 1.1 by not selling any citalopram, whether API or medicines, in EEA markets during the term of the agreement.¹⁹²⁷ On 25 October 2002, Ranbaxy Laboratories Limited in India wrote to Lundbeck: "*This is to confirm that we have not sold any citalopram, not only in Europe but in the entire world after June 02*".¹⁹²⁸ On 5 November 2003, Ranbaxy wrote to Lundbeck informing it, as a matter of courtesy, "*that Ranbaxy will be launching its Citalopram*

¹⁹²⁴ See recital (568) above.

¹⁹²⁵ The words "*based hereon*" logically refer back to "*the Patent Application or any production method used by Ranbaxy*". The words "*the Patent Application*" refer to the production process Ranbaxy was using in June 2002 when the agreement was concluded, which Ranbaxy considered to be non-infringing, and for which Ranbaxy had already filed two patent applications in India. The words "*Patent Application*" are not defined in the agreement. Although the preamble of the agreement also mentions a patent application by Lundbeck, it obviously would make no sense for Ranbaxy to claim any rights on patent applications of Lundbeck.

¹⁹²⁶ See recital (548) above.

¹⁹²⁷ The only exception was 2.5 kg of citalopram API which Ranbaxy sold to the company Pharmacare in Italy in July 2002, one month after the agreement with Lundbeck had been concluded. See ID 597, page 1. Presumably this was a small violation of the agreement, although the citalopram in question was in fact never re-sold in the EEA. Ranbaxy stated in its reply to the Statement of Objections "*that this company acted as a broker in the past and may well have been doing so in this instance in which case the API would have been destined for a market outside the EEA.*" See ID 5176, page 37. It appears that Ranbaxy later issued credit notes to the Italian company against the invoices concerned. According to Ranbaxy, this meant that the product never found an ultimate buyer. See ID 5176, page 37.

¹⁹²⁸ See recital (577) above.

product in the United Kingdom and elsewhere in Europe, as soon as practicable after 31 December 2003."¹⁹²⁹

- (1124) While according to the terms of the agreement Ranbaxy was in principle free to distribute in the EEA citalopram medicines produced by another API supplier, and while Ranbaxy did in-license in May 2003, during the operation of the agreement with Lundbeck, a (future) marketing authorisation in France together with citalopram from another API producer, no actual sales by Ranbaxy under this agreement took place during the period of operation of the agreement with Lundbeck.¹⁹³⁰

The meaning of "pharmaceutical products"

- (1125) In its reply to the Statement of Objections, Ranbaxy (but not Lundbeck!) argued that the words "*pharmaceutical products*" in Article 1.1 should be understood to refer only to medicines and not to API.¹⁹³¹ The Commission does not share this restrictive interpretation. Article 1.1 does not refer to 'pharmaceutical finished products', which could be interpreted to refer to medicines only, but to 'pharmaceutical products'. API is, clearly, a 'pharmaceutical product'. API can be and was manufactured using Ranbaxy's production process which Lundbeck claimed was infringing. Changing that API into tablets or other finished forms uses an entirely different, downstream production process, for which there was no risk of infringing any Lundbeck patents. The production of citalopram API was therefore the crucial production stage for which Lundbeck claimed patent infringement and which it wanted Ranbaxy to stop, thereby preventing both the production and possible sale of API and of finished form medicines, both of these constituting "*pharmaceutical products*".
- (1126) It is also clear from the negotiations leading up to the agreement that when Ranbaxy mentioned to Lundbeck in the meeting of 17 April 2002 that "*We are discussing with a partner for Northern Europe, who will be able to bring our product to the market in 3-4 months – signature is close*", this was at least as likely to refer to sales of citalopram API to a partner who would produce the final tablets as to sales of medicines.¹⁹³² On 14 May 2002, before Ranbaxy concluded the agreement with Lundbeck, the American wholesaler acting for Ranbaxy confirmed to Arrow that his company was "*doing follow up work on API's for the market in Europe with the authorisation of Ranbaxy's API export department.*"¹⁹³³ In another e-mail to Arrow of the same day, the American wholesaler acting for Ranbaxy stated: "*...we hereby transmit our offer: 500 to 1,000kg of Citalopram @ \$3,500/kg CIF Dublin.*"¹⁹³⁴ This was a clear reference to citalopram API and not to tablets.¹⁹³⁵ Tablets exist in different strengths (10 mg, 20 mg and 40 mg) and any price offer for tablets would

¹⁹²⁹ See recital (583) above.

¹⁹³⁰ See recital (580) above.

¹⁹³¹ ID 5176, page 38.

¹⁹³² See recital (558) above.

¹⁹³³ ID 1354, page 11.

¹⁹³⁴ See recital (419) above.

¹⁹³⁵ Arrow stated in reply to the Commission request for information of 9 March 2011: "*When it first entered the market, Arrow Group purchased tablets from Tiefenbacher...Arrow Group's ultimate goal was always, however, to bring manufacture of the tablets in-house if it could...In October 2003, Arrow Pharm (Malta), Arrow Group's Malta subsidiary, began to produce validation stock, to support an application for a variation of Arrow Group's product licences...Commercial manufacture began once approval had been received in Sweden in February 2004. Arrow Group's in-house tablets were produced using an API produced by [different API supplier].*" See ID 1297, page 29.

have indicated the number of tablets of each strength and their price. Indeed, given that it was only a small manufacturing step to turn citalopram API into citalopram tablets, it is unlikely that Lundbeck would have paid Ranbaxy a considerable sum of money not to sell citalopram medicines in the EEA, while leaving it free to sell citalopram API which could be easily transformed into citalopram medicines, the API having been produced with the same allegedly infringing manufacturing process.¹⁹³⁶

- (1127) It was undoubtedly to eliminate even the slightest doubt in this regard that two days before the conclusion of the agreement Lundbeck sent Ranbaxy a side letter to the agreement which it asked Ranbaxy to sign. The side letter stated:

*"The Agreement is signed by Lundbeck and returned to Ranbaxy subject to the explicit proviso that the term "pharmaceutical products" also covers bulk and any other form containing the active ingredient..."*¹⁹³⁷

Ranbaxy signed this side letter one day after the agreement had been concluded.

- (1128) In its reply to the Statement of Objections, Ranbaxy argued that the word *"bulk"* in this side letter should be interpreted to mean *"bulk blisters or bulk tablets"* and not API.¹⁹³⁸ This is incorrect. The term 'bulk', especially when used as a noun (as opposed to an adjective, as for instance, in 'bulk product' or 'bulk medicine') is frequently used in the industry to refer to API. That this was also the meaning Lundbeck attached to it must have been clear to Ranbaxy from Lundbeck's formulation *'bulk and any other form containing the active ingredient'* in the side letter, which clearly aimed at being all-encompassing and at covering anything containing the active ingredient. Moreover, Ranbaxy was no doubt aware that on 11 January 2001, Lundbeck had sent it a warning letter entitled *"Citalopram – Bulk"*. This letter started out by saying: *"We are aware that you are involved in the development of a process for the manufacture of our compound having the INN-name citalopram, which is the active ingredient in our anti-depressant drug CIPRAMIL/CIPRAM/SEROPRAM/CELEXA."* The word *"bulk"* in this letter clearly meant API, as it did in the side letter which Ranbaxy signed.¹⁹³⁹

- (1129) As already mentioned, on 25 October 2002, Ranbaxy Laboratories Limited in India wrote to Lundbeck: *"This is to confirm that we have not sold any citalopram, not only in Europe but in the entire world after June 02"*.¹⁹⁴⁰ This also confirms that Ranbaxy knew that its agreement with Lundbeck covered not only citalopram medicine but also citalopram API.

- (1130) The Commission notes that after Ranbaxy and Lundbeck had agreed on 19 February 2003 to extend their agreement until 31 December 2003, Ranbaxy proposed to Arrow on 27 March 2013 to send Arrow a sample of its citalopram (in all likelihood API).¹⁹⁴¹ The Commission does not interpret this as meaning that Ranbaxy must have

¹⁹³⁶ See footnote 1939 below.

¹⁹³⁷ See recital (568) above.

¹⁹³⁸ ID 5176, page 38.

¹⁹³⁹ ID 850, pages 144 to 147. In reply to the Commission's Letter of Facts of 12 April 2013, Lundbeck stated: *"Lundbeck has no comment concerning this point, other than that the warning letter makes it absolutely clear that Lundbeck was concerned with Ranbaxy's development of one, and only one, infringing process."* See ID 6814, page 117.

¹⁹⁴⁰ See recital (577) above.

¹⁹⁴¹ See recitals (579) and (580) above.

considered itself free to sell API to the EEA during the term of the agreement with Lundbeck. Offering a sample for testing is not the same as making an actual price offer for supplies of API, as Ranbaxy had made to Arrow on 14 May 2002, before concluding the agreement with Lundbeck.¹⁹⁴² The sampling in March 2003 could, if these contacts between Arrow and Ranbaxy had been pursued further, have led to a supply contract entering into force after 31 December 2003, when Ranbaxy's agreement with Lundbeck terminated. Offering a sample for testing does not prove that Ranbaxy considered that it was free to sell citalopram API to the EEA during the term of the agreement with Lundbeck.

The meaning of "or any production method used by Ranbaxy"

- (1131) By its reference to "*the Patent Application*"¹⁹⁴³, Article 1.1 of the agreement clearly covered the production process Ranbaxy was actually using at the time it concluded the agreement with Lundbeck and for which it had submitted two patent applications in India. The importance of this fact is underlined by the following statement of Ranbaxy in its reply to the Statement of Objections: *"In fact, it is unrealistic to believe that Ranbaxy had plans to invest in additional production methods. It had struggled for several years to find a production process that would be commercially viable. Ranbaxy had eventually managed to find a process for which it had filed patent applications -- first in India (March - July 2001) and now on a global scale (March - July 2002) -- and it was ready to file its DMF for citalopram in the UK (14 June 2002). It was now time for Ranbaxy to move from the R&D phase to the phase of seeking regulatory approvals with a view to selling citalopram medicine in Europe."*¹⁹⁴⁴ Ranbaxy's commitment in Article 1.1 of the agreement made citalopram sales based on Ranbaxy's actually used manufacturing process impossible for the term of the agreement.
- (1132) Article 1.1 also obliged Ranbaxy during the term of the agreement not to sell in the EEA citalopram manufactured with "*any production method used by Ranbaxy*". Ranbaxy claimed that these words only covered any other production process (than the one for which Ranbaxy had submitted patent applications in India) that was "*currently used*" by Ranbaxy at the moment of conclusion of the agreement (as opposed to any future production processes that Ranbaxy might come to use during the term of the agreement.).¹⁹⁴⁵ Lundbeck made a similar claim in its reply to the Statement of Objections, arguing that the "*narrow reference to only EP patent No 1015416 and EP Patent Application No 1159274*"¹⁹⁴⁶ in the preamble indicated that the agreement exclusively targeted the processes that Ranbaxy was developing "*in the relevant period and that Lundbeck already knew were infringing its patents, and did not encompass any other possible production methods.*"¹⁹⁴⁷
- (1133) The Commission observes that the word "*used*" in Article 1.1 is in the passive tense and can in principle mean "currently used", "used in the past" or "used in the future".

¹⁹⁴² See recital (559) above.

¹⁹⁴³ See footnote 1925 above.

¹⁹⁴⁴ ID 5176, page 44.

¹⁹⁴⁵ For Ranbaxy, see ID 5176, page 43. For Lundbeck, see ID 5394, pages 247 to 249.

¹⁹⁴⁶ The Commission observes that the preamble actually claimed that Ranbaxy infringed "*Lundbeck's intellectual property rights, in particular EP patent No 1015416 and EP Patent Application No 1159274*" (emphasis added). In principle, therefore, Lundbeck invoked all of its process patents.

¹⁹⁴⁷ ID 5394, page 249.

Decisive is that Article 1.1 operated "*during the term of the Agreement*" and covered "*any production method used by Ranbaxy.*" In this context, the word "*used*" necessarily refers to any production method used "*during the term of the Agreement*", that is to say including any future production methods that Ranbaxy might come to develop in the course of the operation of the agreement.

- (1134) If Lundbeck and Ranbaxy had really wanted to limit the obligation of Article 1.1 to specific production processes actually used at that particular time by Ranbaxy, to the exclusion of any future production methods Ranbaxy might come to develop during the term of the agreement, they would surely have identified the precise production methods to be covered by the agreement. In the absence of such specification, it would always have been possible for Ranbaxy to claim that a particular process which Ranbaxy wanted to use during the term of the agreement (other than the one for which it had applied for patent protection in India) had not yet been used at the time of conclusion of the agreement. In that case, therefore, the words "*or any production method used by Ranbaxy*" in Article 1.1 would have been meaningless.
- (1135) In support of a narrow interpretation of the words "*or any production method used by Ranbaxy*", Ranbaxy argued in its reply to the Statement of Objections that "*Art. 1-1 must be read in light of the introductory recitals which unambiguously confirm that the purpose of the Agreement was confined to entering into a cease fire arrangement in order to avoid claims of one party against the other based on its patents or pending patent applications during the term of the Agreement.*" Lundbeck also mentioned that the preamble to the agreement only mentioned the iodo patent application and the amide patent.¹⁹⁴⁸
- (1136) In the view of the Commission, one cannot conclude from the preamble to this agreement, which focuses on the patent dispute caused by the intended sale by Ranbaxy of a particular product produced with a particular process, that the operational obligations which the generic undertaking accepted in the agreement in exchange for a significant transfer of value are also necessarily limited to that particular product produced with that particular production process.
- (1137) The Commission concludes that the commitment Ranbaxy accepted under Article 1.1 of the agreement covered the production method Ranbaxy actually used at the time of conclusion of the agreement, as well as any other production methods Ranbaxy might come to use during the term of the agreement. Lundbeck could not have obtained this result by patent infringement action against the production process Ranbaxy actually used at the time of conclusion of the agreement.

12.7.5.2. Ranbaxy's commitment to voluntarily submit to interim injunctions

- (1138) Article 1.2 of the agreement ensured that Lundbeck always had the possibility, which Ranbaxy could not prevent without violating the agreement, to obtain interim injunctions in any Contracting Party of the EEA Agreement if ever Ranbaxy had the intention of trying to sell in the EEA products containing citalopram, whether medicines or API. This is clear from the wording of Article 1.2 which stated that "*In the event of any breach of the obligation set forth in Article 1.1 or at the request of Lundbeck, Ranbaxy Laboratories Limited, Ranbaxy (UK) Limited and Ranbaxy's Affiliates will voluntarily submit to an interim injunction by any competent court in*

¹⁹⁴⁸

ID 5394, page 248.

*the Territory." Ranbaxy agreed to "waive any confirmatory action pursuant to any law or regulation in the Territory relating to such injunction and shall upon request from Lundbeck sign any document necessary to obtain such injunctions."*¹⁹⁴⁹

- (1139) Article 1.2 of the agreement meant that if ever Ranbaxy tried to sell citalopram API or medicines in the EEA, based on whatever production process of Ranbaxy, Ranbaxy had to cooperate with Lundbeck to ensure that Lundbeck would obtain an interim injunction against such sales. Ranbaxy could simply not argue before the courts in the EEA that the API or medicines it intended to sell did not infringe any Lundbeck patents without violating this Article 1.2 of the agreement. If so, Lundbeck could under Article 3.2 of the agreement have forthwith terminated the agreement and stopped the instalments of the payments to Ranbaxy. Lundbeck could also have started court action to claim damages from Ranbaxy for breach of contract.
- (1140) The words *"In the event of any breach of the obligation set forth in Article 1.1 or at the request of Lundbeck"* (emphasis added) in Article 1.2 show that even if one interpreted Article 1.1 as only covering medicines produced with Ranbaxy's production process as it existed at the time of the conclusion of the agreement, the fact of the matter was that as soon as Lundbeck simply requested it, Ranbaxy had to give its full cooperation to obtain an interim injunction for Lundbeck, sign any document Lundbeck asked Ranbaxy to sign, and waive any confirmatory action before the courts in the EEA. Therefore, however one interprets the words *"pharmaceutical products based hereon"* in Article 1.1, Ranbaxy had no means, without violating the agreement, to prevent Lundbeck from obtaining an interim injunction against any intended importation or sale by Ranbaxy in the EEA of citalopram API or medicines during the term of the agreement, produced with whatever production method Ranbaxy came to use. As Ranbaxy faithfully implemented the agreement and did not try to sell any citalopram, whether API or medicines, anywhere in the EEA during the term of the agreement¹⁹⁵⁰, there was no need for Lundbeck to request any (voluntary) interim injunctions, as foreseen by Article 1.2, in any Contracting Party to the EEA Agreement against Ranbaxy. Ranbaxy's commitment not to initiate legal proceedings against Lundbeck
- (1141) Article 1.4 of the agreement provided: *"During the term of this Agreement, Lundbeck and Ranbaxy undertake not to initiate legal proceedings against each other based on any of the patents set out above."*
- (1142) This provision ensured that Ranbaxy would not during the term of the agreement challenge Lundbeck's market position in the EEA by trying to clear the way for (future) Ranbaxy sales in the EEA, whether through an application for a finding of non-infringement or through efforts to invalidate one or more of Lundbeck's process patents. Whether this provision also extended to opposition procedures before patent offices is unclear. However, after having concluded the agreement with Lundbeck,

¹⁹⁴⁹ See recital (569) above.

¹⁹⁵⁰ The only exception being a minor quantity of 2.5 kgs, which Ranbaxy sold in July 2002 to the company Pharmacare in Italy. See ID 597, page 1. Ranbaxy stated in its reply to the Statement of Objections *"that this company acted as a broker in the past and may well have been doing so in this instance in which case the API would have been destined for a market outside the EEA."* See ID 5176, page 37. It appears that Ranbaxy later issued credit notes to the Italian company against the invoices concerned. According to Ranbaxy, this meant that the product never found an ultimate buyer. See ID 5176, page 37.

Ranbaxy in fact did not pursue its intention to oppose Lundbeck's United Kingdom crystallisation patent. Ranbaxy did not oppose the crystallisation patent at the EPO either.

- (1143) The Commission does not agree with Lundbeck's explanation in reply to the Commission's Letter of Facts of 12 April 2013 that *"Ranbaxy's commitment under Article 1.4 was limited to an obligation to refrain from initiating legal proceedings against Lundbeck based on its Indian patent applications."*¹⁹⁵¹ The text of this provision clearly refers to *"any of the patents set out above."* The preamble to the agreement mentioned not only Ranbaxy's Indian patent applications 264/DEL/201 and 779/DEL/2001 but also Lundbeck's EP patent 1015416 (the amide process patent) and patent application 1159274 (the iodo process patent). Ranbaxy was therefore prohibited from initiating legal proceedings against Lundbeck based on (alleged non-infringement or invalidity of) these two patents of Lundbeck.
- (1144) The Commission observes that point 209 of the Technology Transfer Guidelines¹⁹⁵² only applies to licensing agreements covered by the Technology Transfer Block Exemption. Ranbaxy's agreement with Lundbeck was not such an agreement. When, as in this case, a non-challenge clause between potential or actual competitors is directly linked to a transfer of considerable value, such a commitment may be incompatible with Article 101(1) of the Treaty.

12.7.6. Lundbeck transferred considerable value to Ranbaxy in exchange for Ranbaxy's commitments under the agreement

- (1145) Article 1.3 of the agreement provided that *"in consideration of the Settlement arrived at"* Lundbeck agreed to pay Ranbaxy an amount of USD 5 million, *"being the Settlement Amount"*, payable in five instalments spread over the duration of the term of the agreement, the last instalment being due on the last day of operation of the agreement.¹⁹⁵³
- (1146) Article 1.3 shows a clear link between on the one hand Lundbeck's payment of USD 5 million for the initial term of the agreement and on the other hand Ranbaxy's acceptance of the agreement, which obliged Ranbaxy not to manufacture or sell its citalopram in the EEA.
- (1147) The fact that the instalments foreseen in the agreement were spread out over the entire duration of the agreement indicates that the instalments were directly linked to the desired result that Ranbaxy refrained from selling its citalopram in the EEA.
- (1148) In the addendum extending the agreement to 31 December 2003, Lundbeck agreed to pay another USD 4.5 million, in two instalments, the second one being payable not later than 31 December 2003. Lundbeck agreed to make this payment *"In consideration of the prolongation of the term of the Agreement"* and *"in addition to the Settlement Amount"* in Article 1.3 of the original agreement.
- (1149) In Article 1.1 of the agreement Ranbaxy accepted its commitment not to manufacture or sell its citalopram in the EEA *"[s]ubject to the terms and conditions of this Agreement and subject to payment of the Settlement Amount..."*

¹⁹⁵¹ ID 6814, page 120.

¹⁹⁵² Point 209 of the Technology Transfer Guidelines states that *"In the context of a settlement and non-assertion agreement, non-challenge clauses are generally considered to fall outside Article 81(1)"*,

¹⁹⁵³ See recital (570) above.

- (1150) The words "*subject to payment of the Settlement Amount*" show, just as in Article 1.3, a clear link between on the one hand Lundbeck's payment of the Settlement Amount of USD 5 million and on the other hand Ranbaxy's acceptance of the obligations in Article 1.1 not to manufacture or sell its citalopram in the EEA.
- (1151) Moreover, the words "*Subject to the terms and conditions of this Agreement*" indicate that Ranbaxy accepted the obligation of Article 1.1 not only in exchange for Lundbeck's payment of the Settlement Amount, but also subject to the other terms of the agreement. In particular, Article 1.3 of the agreement (which started with the words "*In consideration of the Settlement arrived at*") provided that Ranbaxy would be given the right to sell Lundbeck citalopram tablets (10, 20 and 40 mg packs) in limited quantities in the United Kingdom at a purchase price from Lundbeck of 40% below Lundbeck's current ex-factory price. This offered Ranbaxy an attractive profit margin.¹⁹⁵⁴ For the initial year of operation of the agreement, Lundbeck estimated the cost to Lundbeck of this arrangement in the form of lost profit on these sales at GBP 1.5 million.¹⁹⁵⁵ Together with the outright payment to Ranbaxy of USD 5 million, Lundbeck listed the GBP 1.5 million transfer of lost profit to Ranbaxy in an internal Business Development document of 4 September 2002 as a "*Cost*" for which it gained "*Time*".¹⁹⁵⁶
- (1152) That the distribution agreement with Ranbaxy served to reward Ranbaxy for not selling its own citalopram in the EEA for the period of the agreement is also apparent from the following wording in the same document:
- "Ranbaxy*
- *Greater Europe*
 - *12 month deal*
 - *Until 10 June 2003*
 - *Distribution of 10% Cipramil volume in the UK plus cash settlement.*"¹⁹⁵⁷
- It is clear from this wording that the "*Distribution of 10% Cipramil volume in the UK plus cash settlement*" was part of the transfer of value Lundbeck made to Ranbaxy to obtain a "*12 month deal*" covering "*Greater Europe*".
- (1153) For the entire one and a half year period of operation of the agreement, the estimated cost of the distribution arrangement to Lundbeck in lost profit was around GBP 3 million.¹⁹⁵⁸
- (1154) In its reply to the Statement of Objections, Lundbeck admitted that "*The supply and distribution agreement was part of the value transfer under the settlement agreement...*"¹⁹⁵⁹
- (1155) In its reply to the Statement of Objections, Ranbaxy claimed, but without submitting evidence, that its distribution costs in the United Kingdom amounted to between 15% and 25% of sales value, not only because of transport and other logistic costs, but

¹⁹⁵⁴ See recital (571) above. See also recital (1155) below.

¹⁹⁵⁵ See recitals (561), (571) and (574) above.

¹⁹⁵⁶ See recital (574) above.

¹⁹⁵⁷ See recital (574) above.

¹⁹⁵⁸ See recital (585) above.

¹⁹⁵⁹ ID 5394, page 250.

also because of salary costs of its sales force, which according to Article 1.3 of the agreement had to promote the product. According to Ranbaxy, its estimated net profit from the distribution agreement with Lundbeck for the entire duration of the agreement was anywhere between GBP 1 million and GBP 1.8 million.¹⁹⁶⁰ The Commission observes that the value transferred by Lundbeck in terms of lost profits for Lundbeck does not necessarily correspond to the net profit Ranbaxy was able to make on these sales.

- (1156) In total, over the entire period of the extended agreement, Lundbeck transferred a value to Ranbaxy of USD 9.5 million as Settlement Amount plus GBP 3 million in lost profits for the distribution agreement (together corresponding to approximately EUR 12.7 million) as an inducement for Ranbaxy to give up its independent efforts to enter EEA markets and accept the commitments Ranbaxy undertook in the Settlement Agreement, including notably the commitment not to manufacture or sell its citalopram in the EEA.¹⁹⁶¹
- (1157) There are no contemporaneous documents indicating on what basis the parties calculated and negotiated the value transfers of Lundbeck to Ranbaxy. Evidence indicates that by June 2002 Ranbaxy had produced around 500 kg of citalopram API.¹⁹⁶² Assuming that the market value in the EEA of this 500 kg of citalopram would have been at most USD 2 million if sold as API¹⁹⁶³, and at most USD 6 million in the less immediate scenario that they would have been sold as medicines by Ranbaxy subsidiaries in the EEA¹⁹⁶⁴, Lundbeck's transfer to Ranbaxy of the equivalent of EUR 12.7 million in exchange for Ranbaxy not selling its citalopram to the EEA market considerably exceeded the profit Ranbaxy could have expected from selling the citalopram it had manufactured at the time of conclusion of the agreement.
- (1158) However, the amount Lundbeck was willing to transfer to Ranbaxy is likely to have been influenced by the fact that Ranbaxy was already then a large producer of generic APIs, as reflected in Ranbaxy's claim to Lundbeck that it had a worldwide production capacity of citalopram of 4.5 tonnes per year, and by Ranbaxy's claim that it was discussing early sales of API to a partner with marketing authorisations in Northern Europe. Ranbaxy's claim that its production process was non-infringing may also have played a role in this respect. In the end, as Lundbeck told the Commission, the agreed value transfers were a result of negotiation between the parties.¹⁹⁶⁵ It may be noted in this respect that following the meeting with Ranbaxy of 17 April 2002, in which Ranbaxy had made these claims, a Lundbeck representative considered: *"I guess a deal will be \$10-\$20M or even more."*¹⁹⁶⁶ At the same time, as has been analysed in recitals (198) to (201) above, the avoidance of

¹⁹⁶⁰ ID 5176, page 57. See also recital (585) above.

¹⁹⁶¹ See recital (587) above.

¹⁹⁶² Compare recitals (552) and (566).

¹⁹⁶³ In 2001, Ranbaxy had offered 400 kg of citalopram to Lundbeck for USD 1 million to USD 1.5 million. See recital (552) above. Natco sold its API to Merck (GUK) at a price of USD 3 900 per kg. If Ranbaxy had sold to European generic suppliers for the same price, the 500 kg it had already produced would have been worth almost USD 2 million.

¹⁹⁶⁴ In the early phase of generic entry, the resale price of citalopram medicine in the market was around three times the purchase cost. Compare footnotes 564 and recital (528).

¹⁹⁶⁵ ID 823, page 64.

¹⁹⁶⁶ See recital (1095) above.

generic entry Lundbeck achieved through the agreement with Ranbaxy was worth a lot more to Lundbeck than the value Lundbeck transferred to Ranbaxy.

- (1159) The Commission notes that neither of the parties rebutted the Commission's conclusions on the value transfer by providing different, legitimate reasons.
- (1160) The Commission concludes from the facts described in this section 12.7.6 that Lundbeck transferred considerable value to Ranbaxy in exchange for Ranbaxy's commitments under the agreement.

12.7.7. Intentions of the parties

- (1161) This section deals with the intentions of the parties regarding the aim of the agreement. Ranbaxy's intentions relevant for the existence of potential competition have already been analysed in sections 12.7.3 and 12.7.4 above.
- (1162) Lundbeck's intentions to delay generic entry have already been described in detail in Chapter 6 and have been summarised, in particular for the United Kingdom, in recitals (803) to (808) above. Those recitals apply here as well. In Lundbeck's overall strategy, time in the form of delay in generic entry was needed to prolong profits on citalopram in the EEA, including the United Kingdom, and obtain a window of opportunity for the launch of Lundbeck's successor product escitalopram.
- (1163) The specific intentions of the two parties regarding the nature of the agreement they concluded are evident from the contemporaneous documents concerning the negotiation of the agreement. After Lundbeck had in July 2001 rejected Ranbaxy's proposal to become a contract supplier of citalopram API to Lundbeck and had terminated the co-operation with Ranbaxy in this respect¹⁹⁶⁷, Ranbaxy started as of January 2002 exploring possibilities of selling its citalopram on EEA markets in competition with Lundbeck. Ranbaxy remained, however, keen to strike a co-operative deal with Lundbeck if possible. Lundbeck's report of the meeting with Ranbaxy in the latter's offices in London on 17 April 2002 shows that Ranbaxy painted a picture to Lundbeck that if Lundbeck did nothing, it would be faced within a couple of months with Ranbaxy citalopram being sold in Northern Europe. The citalopram would be sold by an alleged partner of Ranbaxy that already had marketing authorisations, followed a couple of months later by Ranbaxy sales through its own subsidiaries in the United Kingdom and Germany. In making this presentation, Ranbaxy claimed that its manufacturing process was non-infringing and emphasised that Lundbeck knew that Ranbaxy's manufacturing process did not crystallise the free base. Ranbaxy also claimed that it had an annual worldwide production capacity of 4.5 tonnes of citalopram per year. Having presented this scenario of intense competition with Lundbeck, Ranbaxy asked Lundbeck: "*Do you want a deal?*"¹⁹⁶⁸

¹⁹⁶⁷ See recitals (550) to (552) above.

¹⁹⁶⁸ See recital (558) above. In its reply to the Statement of Objections, Ranbaxy claimed that these statements may have been "*bluff*". See ID 5176, page 53. The Commission observes, firstly, that even if Ranbaxy's statements had been bluff, this would not change Lundbeck's perception of Ranbaxy as a potential competitor. Secondly, even if the intent of Ranbaxy was only to extract the maximum amount of money from Lundbeck, such an intention does not change the object of the agreement: sharing of the monopoly rent of Lundbeck and blocking market entry. What matters for a restriction by object is whether the agreements in question objectively aimed at restricting competition. See section 10.2 above.

- (1164) Both Lundbeck and Ranbaxy had no doubt what the deal would be about: money in exchange for Ranbaxy not competing with Lundbeck. The Lundbeck representative to the meeting considered: *"Do we want a deal? I guess a deal will be \$10M-\$20M or even more. My opinion is that it will be difficult – antitrust wise, costs and value for money..."*¹⁹⁶⁹ The words *"value for money"* show that Lundbeck weighed up the benefit to Lundbeck of preventing Ranbaxy citalopram from entering the EEA against the cost to Lundbeck of the monetary value it would have to transfer to Ranbaxy. Lundbeck apparently had doubts whether the benefits of a deal would really outweigh the cost in money. Lundbeck also thought that such a deal would be *"difficult – antitrust wise."* Nevertheless, Lundbeck proceeded.¹⁹⁷⁰
- (1165) Both parties therefore knew exactly what they were negotiating: How much was keeping Ranbaxy's citalopram out of the EEA for a certain period worth to Lundbeck? As Lundbeck summarised the situation following a meeting with Ranbaxy on 8 May 2002 in Paris:
- *"12 months ceasefire – possible patent infringement against*
 - *UK distribution: 10% volume at a 40% margin - £1-2M*
 - *Cash sum \$5.3M*
 - *Total cost – appr. \$7-8M*
 - *Alternative: Piggy-bag Tifi [Tiefenbacher] and hit the market in August 2002."*¹⁹⁷¹
- (1166) The Commission concludes from the facts described in this section 12.7.7 that both parties knew or should have known that their agreement was anti-competitive.
- 12.7.8. The agreement restricted competition to an appreciable degree in one or more of the markets covered by the agreement*
- (1167) The Commission refers to sections 6.6 and 11.9 for its considerations on the appreciable degree to which the agreements in question restricted competition and to section 13.5 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 States¹⁹⁷², the Commission does not have to prove an appreciable restriction of competition, but that in any case each (set of) agreement(s) did restrict competition to an appreciable degree.¹⁹⁷³

¹⁹⁶⁹ See recital (558) above.

¹⁹⁷⁰ In its reply to the Statement of Objections Lundbeck argued that *"...had Ranbaxy entered the market with infringing generic citalopram before the Lagap dispute was resolved, any potential finding of infringement in that litigation would have been seriously undermined"* and *"The launch of Ranbaxy's infringing products in the EEA would also have jeopardized the Agreements between Lundbeck and other generic companies."* See ID 5394, page 245.

¹⁹⁷¹ See recital (561) above.

¹⁹⁷² See recital (724) above. For the effect on trade between Member States of each (set of) agreement(s), see chapter 13 below.

¹⁹⁷³ See in particular section 6.6 above. The Commission notes, in this respect, that since each (set of) agreement(s) covered the United Kingdom, where Lundbeck succeeded through the agreements in preventing widespread generic competition from January 2002 to October 2002, each (set of) agreement(s) restricted competition to an appreciable degree in at least one of the markets covered by the agreement.

- (1168) In the specific case of Ranbaxy, this appreciable effect on competition was even greater because Ranbaxy was itself an API producer. Lundbeck's agreement with Ranbaxy therefore eliminated for the term of the agreement not only a potential generic supplier of citalopram medicine but also an actual producer of citalopram API with an allegedly non-infringing production process. Moreover, the agreement covered the entire EEA. In most national markets within the EEA Lundbeck held at the time when it concluded the agreement with Ranbaxy market shares considerably exceeding 10%.¹⁹⁷⁴

12.7.9. Conclusion on restriction by object

- (1169) The facts described and assessed in legal terms in sections 12.7.1 to 12.7.4 above show that at the time the undertakings Ranbaxy and Lundbeck concluded their agreement of 16 June 2002, they were potential competitors in markets for citalopram in EEA Contracting Parties. As analysed in section 12.7.5 above, under the agreement, Ranbaxy accepted several commitments which ensured that Ranbaxy would not compete with own-manufactured citalopram, whether in the form of medicines or API, with Lundbeck in markets in Contracting Parties of the EEA Agreement for the term of the agreement. As analysed in section 12.7.6 above, Lundbeck transferred considerable value to Ranbaxy in exchange for Ranbaxy's acceptance of these commitments. Section 12.7.7 has shown that this agreement formed part of Lundbeck's strategy to delay generic entry for citalopram and that Ranbaxy knew or should have known that Lundbeck's transfer of value to it served to persuade Ranbaxy to accept the commitments in question and thereby to eliminate the incentive for Ranbaxy to continue its independent efforts to enter citalopram markets in Contracting Parties of the EEA Agreement for the term of the agreement.
- (1170) Given that Ranbaxy's acceptance of these limitations on its commercial autonomy was achieved not by the strength of Lundbeck's patents, but by the transfer of value from Lundbeck to Ranbaxy, the Commission considers that these limitations constitute restrictions of competition within the meaning of Article 101(1) of the Treaty.
- (1171) Moreover, since these limitations on Ranbaxy's commercial autonomy and Ranbaxy's exclusion from the market, obtained by Lundbeck through the transfer of considerable value to Ranbaxy, were by their very nature injurious to the proper functioning of normal competition and followed directly and necessarily from the clauses of the agreement itself, the Commission considers that they are restrictions of competition by object. Indeed, the provisions of the agreement considered together and in their context make it clear that it was an objective aim, a necessary consequence of the agreement to make it impossible, for the term of the agreement, for Ranbaxy to sell its citalopram in the EEA, in exchange for the considerable transfer of value from Lundbeck.
- (1172) Ranbaxy's commitment not to sell own-manufactured citalopram existed irrespective of whether or not such citalopram would infringe Lundbeck's process patents. Lundbeck could not have obtained this complete exclusion of Ranbaxy's citalopram from markets in the EEA through court enforcement of its process patents against the process actually used by Ranbaxy at the time of conclusion of the agreement, even if Lundbeck had been successful in these efforts. The agreement, in preventing

¹⁹⁷⁴

See recital (215) above.

Ranbaxy from using any process to manufacture and sell citalopram in the EEA, went beyond any rights patent law could offer to holders of process patents.¹⁹⁷⁵

- (1173) Finally, it should be noted that the agreement was not aimed at solving the underlying issue of alleged patent infringement. Also, there was no commitment from Lundbeck in the agreement that Lundbeck would refrain from infringement proceedings if Ranbaxy entered the market with generic citalopram after expiry of the agreement. The agreement therefore essentially ensured that Ranbaxy could not manufacture and sell own-manufactured citalopram during the term of the agreement, without any guarantee of market access thereafter.
- (1174) In conclusion, the Commission finds that the agreement between Lundbeck and Ranbaxy, as examined in this section 12.7, including in particular the facts that:
- Lundbeck and Ranbaxy were at the moment when they concluded their agreement at least potential competitors in the EEA;
 - Lundbeck transferred significant value to Ranbaxy in the agreement;
 - this transfer of value was linked to the acceptance by Ranbaxy of the limitations on entry in the agreement, notably Ranbaxy's commitment not to manufacture or sell, whether through its own subsidiaries or third parties, its citalopram in the EEA between 16 June 2002 and 31 December 2003;
 - the transferred value considerably exceeded the sales value of the citalopram Ranbaxy had manufactured until then;
 - Lundbeck could not have obtained those limitations on entry through enforcement of its process patents, the obligations on Ranbaxy in the agreement going beyond the rights granted to holders of process patents; and
 - the agreement contained no commitment from Lundbeck to refrain from infringement proceedings if Ranbaxy entered the market with generic citalopram after expiry of the agreement,

constitutes a restriction of competition by object.

12.8. Single and continuous infringements

- (1175) The European Court of Justice stated in *Aalborg Portland* that "*An infringement of Article 85(1) of the Treaty may result not only from an isolated act but also from a series of acts or from continuous conduct. That interpretation cannot be challenged on the ground that one or several elements of that series of acts or continuous conduct could also constitute in themselves and taken in isolation an infringement of that provision...When the different actions form part of an 'overall plan', because their identical object distorts competition within the common market, the Commission is entitled to impute responsibility for those actions on the basis of participation in the infringement considered as a whole.*"¹⁹⁷⁶
- (1176) The General Court stated in *Cement*, that "...the concept of 'single agreement' or 'single infringement' presupposes a complex of practices adopted by various parties

¹⁹⁷⁵ The commitment therefore fell both within the scope of Lundbeck's patents and outside. As explained in recitals (659) and (660) above, the Commission also considers such commitments within the scope of the patent illegal if they are induced by a transfer of value from the originator undertaking.

¹⁹⁷⁶ Joined Cases C-204/00 etc. *Aalborg Portland et al.*, [2004] ECR I-123, paragraph 258.

in pursuit of a single anti-competitive economic aim."¹⁹⁷⁷ This conclusion is not at odds with the principle that responsibility for such infringements is individual in nature. Nor does it neglect an individual analysis of the evidence adduced or infringe the rights of defence of the undertakings involved.¹⁹⁷⁸

- (1177) While each of the six agreements covered by this Decision and each extension of them forms an "agreement" within the meaning of Article 101 of the Treaty in its own right, the Commission considers it appropriate, in this case, to consider each set of agreements between a particular generic undertaking and Lundbeck a single and continuous infringement.
- (1178) The Commission considers that the notion of single and continuous infringement applies to the two agreements Merck (GUK) concluded with Lundbeck. In reply to the Statement of Objections, Merck KGaA argued that the four agreements, that is to say the United Kingdom agreement, the first extension of the United Kingdom agreement, the second extension of the United Kingdom agreement and the EEA agreement, did not follow any "overall plan". According to Merck KGaA, the agreements were not interlinked.¹⁹⁷⁹ However, the Commission considers that the evidence does not support Merck KGaA's claim that the "*four Agreements were autonomous*".¹⁹⁸⁰ That the agreements were interlinked is obvious for the United Kingdom agreement and the two extensions thereof. Each extension specifically referred to the previous agreement(s) and stated that "*Capitalised expressions in this letter shall have the same meaning as set out in the Agreement*" and that "*The purpose of this letter is to vary the Agreement in the manner set out below*".¹⁹⁸¹
- (1179) But the United Kingdom agreement as a whole was also closely inter-linked with the agreement covering other Contracting Parties of the EEA Agreement than the United Kingdom. These two agreements concerned the same product, citalopram. Both agreements were concluded between the same undertakings, Merck and Lundbeck.¹⁹⁸² Both agreements pursued the same economic aim of stopping or preventing Merck (GUK) – and through Merck (GUK) Natco - from entering markets in the EEA with generic citalopram in exchange for a transfer of value from Lundbeck to Merck (GUK). In fact, the overall plan consisted on the one hand of Lundbeck "*not want[ing] a generic on the market*" and on the other hand of Merck (GUK)'s request that "*they could compensate us for the profit we would have made*".¹⁹⁸³ This plan first covered only the United Kingdom, and was later extended

¹⁹⁷⁷ Joined Cases T-25/95 and others, *Cement*, ECR [2000] II-491, paragraph 3699.

¹⁹⁷⁸ Case C-49/92P, *Commission v Anic Partecipazioni*, [1999] ECR I-4125, paragraphs 78 to 81, 83 to 85 and 203.

¹⁹⁷⁹ ID 5960, pages 332-351.

¹⁹⁸⁰ ID 5960, page 338.

¹⁹⁸¹ ID 8, pages 223 to 226.

¹⁹⁸² The agreement between the undertakings Lundbeck and Merck concerning the United Kingdom was signed by the legal entities Lundbeck Ltd and Generics (UK) Ltd. The agreement between the undertakings Lundbeck and Merck concerning the other Contracting Parties of the EEA Agreement than the United Kingdom was signed by the legal entities H. Lundbeck A/S and Generics (UK) Ltd. Lundbeck Ltd was at the time of signing a 100%-owned subsidiary of H. Lundbeck A/S. For the reasons explained in section 15.2, H. Lundbeck A/S and Lundbeck Ltd were at the time of signing part of the same undertaking. Generics (UK) Ltd was at the time of signing an indirect 100%-owned subsidiary of Merck KGaA. For the reasons explained in section 15.3, Generics (UK) Ltd and Merck KGaA were at the time of signing part of the same undertaking.

¹⁹⁸³ See recital (255) above.

also to the rest of the EEA with some delay in view of the marketing authorisations. The same individuals were involved in the negotiation of both agreements and there was therefore awareness by these individuals, which were leading representatives of Merck (GUK) and Lundbeck respectively¹⁹⁸⁴, of this identical economic aim that the two agreements (including the two United Kingdom extensions) pursued. Concluding and implementing the two agreements constituted continuous conduct by the two undertakings, even if the parties decided to extend Merck (GUK)'s market exclusion to the rest of the EEA only after they concluded the United Kingdom agreement, because in this way they continued and expanded in essence their anti-competitive conduct and strategy to the rest of the EEA, albeit with a couple of months delay. With respect to the duration of the two agreements, the second agreement (regarding other Contracting Parties of the EEA Agreement than the United Kingdom) fell entirely within the period of operation of the first agreement (regarding the United Kingdom). The two agreements were also terminated almost simultaneously. For these reasons, Merck's argument has to be rejected that the difference in timing would show that the agreements were autonomous.¹⁹⁸⁵

(1180) Lundbeck's two agreements with Merck were both referred to by the parties as a "*settlement agreement*"¹⁹⁸⁶ and were complementary in the sense that together they covered the entire EEA (even if the agreement regarding the United Kingdom was at the same time also referred to by the parties as a supply agreement). Indeed, the second agreement in its preamble refers back to the first agreement regarding the United Kingdom and goes on to cover the EEA Contracting Parties excluding the United Kingdom, precisely because the United Kingdom was already covered in the first agreement.¹⁹⁸⁷ Moreover, the first extension of the agreement regarding the United Kingdom was negotiated together with the agreement regarding the EEA: Around 28 May 2002, Lundbeck asked Merck for a "*valuation of a deal*" for:

- "*Sweden 12 months*
- "*UK 6 months extension*
- "*Remaining EU 12 months.*"

(1181) The difference in time of conclusion and geographic scope of the two agreements between Merck (GUK) and Lundbeck was dictated merely by Merck (GUK)'s closeness to market entry, an agreement being struck each time Lundbeck perceived the generic undertaking to be either on the verge of market entry or as having actually entered the market. As Lundbeck explained to the Commission, "*Lundbeck*

¹⁹⁸⁴ On the part of Lundbeck, the same key individuals at H. Lundbeck A/S were involved in all agreements, including those with Merck (GUK). As mentioned in recital (21), the same [position in Lundbeck]* signed all but one of the six agreements. This person also signed the United Kingdom agreement with Merck (GUK) (on behalf of Lundbeck Ltd). The only agreement he did not sign was the agreement with Merck (GUK) regarding other EEA countries than the United Kingdom (this agreement was signed by another person, a [position in Lundbeck]*), but he was directly involved in its negotiation (see for instance ID 682, page 181, ID 723, page 24, ID 903, page 129). As mentioned in recital (22), Merck (GUK)'s [employee function]* and its [employee function]* were involved in both agreements with Lundbeck.

¹⁹⁸⁵ ID 5960, pages 338-341.

¹⁹⁸⁶ See recitals (267) and (348).

¹⁹⁸⁷ The coverage of the entire EEA in the two agreements with Merck (GUK) is in line with the fact that Merck (GUK)'s Development and Supply Agreement regarding citalopram with Schweizerhall also covered the entire EEA. See recital (234).

*initially concluded an agreement with Generics UK covering only the UK because Generics UK initially had marketing authorization only in the UK.*¹⁹⁸⁸ This difference in timing and geographic scope was driven purely by the fact that Merck first obtained a marketing authorisation for citalopram in the United Kingdom and then used the mutual recognition procedure to subsequently obtain marketing authorisations in other EEA Contracting Parties.¹⁹⁸⁹ The two agreements were therefore closely inter-related and complementary to each other. Together, they covered the entire EEA, the second agreement covering all EEA markets the first agreement had not yet covered.

- (1182) Finally, the Commission observes that if the United Kingdom agreement and the agreement regarding other EEA Contracting Parties than the United Kingdom constituted separate infringements on the part of the undertaking Merck, as Merck KGaA claimed, the Commission would, given that it has found in this Decision that each of these two agreement constituted in itself a restriction of competition by object, have to impose two fines on the undertaking Merck rather than one.
- (1183) In the view of the Commission, the notion of single and continuous infringement also applies to the two agreements Arrow concluded with Lundbeck. These two agreements concerned the same product, citalopram. Both agreements were concluded between the same undertakings, Arrow and Lundbeck.¹⁹⁹⁰ Both agreements pursued the same economic aim of preventing Arrow from entering markets in the EEA with generic citalopram in exchange for a transfer of value from Lundbeck to Arrow. The same individuals were involved in the negotiation of both agreements and there was therefore awareness by these individuals, which were leading representatives of Arrow and Lundbeck respectively¹⁹⁹¹, of the identical economic aim the two agreements pursued. Concluding and implementing the two agreements constituted continuous conduct by the two undertakings. The duration of the two agreements fell within the same period of time, the second agreement (regarding Denmark) falling entirely within the period of operation of the first agreement (regarding the United Kingdom).
- (1184) The agreement regarding Denmark was very similar in nature and directly linked to the agreement regarding the United Kingdom by referring to the United Kingdom voluntary injunction against Arrow and making the duration of the agreement regarding Denmark dependent on the outcome of the litigation between Lundbeck and Arrow in the United Kingdom. As Lundbeck stated to the Commission: "*...the recitals in the agreement [regarding Denmark] refer to the court-ordered, voluntary*

¹⁹⁸⁸ See recital (310) above.

¹⁹⁸⁹ See recitals (311) to (314), (326), (328), (336), (342) and (347).

¹⁹⁹⁰ The agreement concerning the United Kingdom between the undertakings Lundbeck and Arrow was signed by the legal entities H. Lundbeck A/S and Arrow Generics Limited. The agreement between the undertakings Lundbeck and Arrow regarding Denmark was signed by the legal entities H. Lundbeck A/S and Arrow Group A/S. Arrow Generics Limited. was at the time of signing a 100%-owned subsidiary of Arrow Group A/S. For the reasons explained in section 15.3, Arrow Generics Limited. and Arrow Group A/S were at the time of signing part of the same undertaking.

¹⁹⁹¹ On the part of Lundbeck, the same key individuals at H. Lundbeck A/S were involved in all agreements, including those with Arrow. As mentioned in recital (21), the same [position in Lundbeck]* signed all but one of the six agreements. This person also signed both agreements with Arrow. As mentioned in recitals (22) above and (1257) below, for Arrow, [employee name]* signed the United Kingdom agreement with Lundbeck and was involved in the negotiation of the agreement with Lundbeck regarding Denmark.

injunction that had been issued against Arrow in the UK. The agreement with Arrow in effect extended the court-ordered injunction that had been issued in the UK, protecting Lundbeck's IP rights from infringement by Arrow in Denmark in addition to the UK."¹⁹⁹²

- (1185) The difference in time of conclusion and geographic scope of the two agreements between Arrow and Lundbeck was dictated merely by Arrow's closeness to market entry, an agreement being struck each time Lundbeck perceived the generic undertaking to be either on the verge of market entry. As Lundbeck declared to the Commission: *"The agreements with Arrow only covered the UK and Denmark because these were the only Member States where Arrow, to Lundbeck's knowledge, intended to market citalopram."*¹⁹⁹³ The two agreements were therefore closely inter-related and complementary to each other. That the agreement regarding Denmark ended several months earlier than the agreement regarding the United Kingdom is explained by the fact that, in Lundbeck's words: *"In April 2003 there were several generic companies selling citalopram in Denmark. Lundbeck considered it was too costly to defend its citalopram intellectual property rights via further litigation or settlement agreements in Denmark."*¹⁹⁹⁴ Likewise, Lundbeck terminated its United Kingdom agreement with Arrow after it had settled its litigation with Lagap, which basically ended Lundbeck's efforts to stop generic entry of citalopram into the United Kingdom.
- (1186) These reasons justify considering Merck's and Arrow's two agreements with Lundbeck each a continuous course of conduct constituting a single and continuous infringement. It would be artificial to split up such continuous conduct, characterised by a single over-arching purpose, by treating it as consisting of several separate infringements, when what was involved in each case was a single infringement which progressively manifested itself in the two complementary agreements Merck and Arrow each concluded with Lundbeck.¹⁹⁹⁵
- (1187) It would not, however, be appropriate to consider all of the agreements covered by this Decision a single and continuous infringement. To the extent that Lundbeck had any overall plan covering all the agreements covered by this Decision, the evidence in the file does not corroborate that Lundbeck shared such a plan with any of the four generic undertakings in question or that any of them was aware of such an overall plan of Lundbeck. Nor did the generic undertakings between themselves share any overall plan.
- (1188) Each generic undertaking made its own agreement(s) with Lundbeck, unaware, as far as the available facts indicate, of Lundbeck's on-going efforts to conclude similar agreements with other generic undertakings. The only common plans that the available facts of the case indicate were therefore between Lundbeck and each generic undertaking separately.
- (1189) The Commission therefore considers that in this case four separate infringements took place, consisting of:

¹⁹⁹² ID 823, pages 21-22.

¹⁹⁹³ See recital (474) above.

¹⁹⁹⁴ ID 823, page 47.

¹⁹⁹⁵ This also means that effects on trade and the application of Article 101(3) of the Treaty have to be assessed for the single infringement as a whole. See sections 13.1 and 14.1 below.

- Merck's agreements with Lundbeck regarding the United Kingdom and the EEA excluding the United Kingdom;
 - Arrow's agreements with Lundbeck regarding the United Kingdom and Denmark;
 - Alapharma's agreement with Lundbeck regarding the EEA; and
 - Ranbaxy's agreement with Lundbeck regarding the EEA.
- (1190) Finally, it should be noted that those infringements which contain only a single agreement are still, in themselves, continuous infringements, as they operated from the moment of their conclusion until the moment of their termination. During this entire period of operation, they were fully implemented by both parties. The infringement therefore continued at least during this period of operation of the agreement.

13. EFFECT ON TRADE BETWEEN UNION MEMBER STATES AND BETWEEN CONTRACTING PARTIES TO THE EEA AGREEMENT

13.1. Introduction

- (1191) Article 101(1) of the Treaty is applicable only in so far as agreements "*may affect trade between Member States*". Article 53(1) of the EEA Agreement imposes the same requirement for trade "*between EEA Contracting Parties*", meaning trade between EFTA countries or trade between Union Member States and EFTA countries. It is therefore necessary to assess whether this requirement is met for each of the infringements identified in this Decision.¹⁹⁹⁶
- (1192) According to well-established jurisprudence of the European Court of Justice, an agreement "*may affect trade*" when it is "*possible to foresee with a sufficient degree of probability on the basis of a set of objective factors of law or of fact that the agreement...may have an influence, direct or indirect, actual or potential, on the pattern of trade between Member States.*"¹⁹⁹⁷ Therefore, whilst Article 101 of the Treaty "*does not require that agreements referred to in that provision have actually affected trade between Member States, it does require that it be established that the agreements are capable of having that effect*"¹⁹⁹⁸. The concept of "*trade*" covers all cross-border economic activity including establishment.¹⁹⁹⁹ "*Trade*" can take place between different undertakings or between different parts of the same undertaking.²⁰⁰⁰ The concept of "*trade*" also encompasses cases where agreements affect the competitive structure of the Internal Market, for instance by eliminating a

¹⁹⁹⁶ See case 56/65 *Société technique minière* [1966] ECR 282, paragraph 7; Case 42/84 *Remia e. o.* [1985] ECR 2545, paragraph 22 and joined cases T-25/95 *Cimenteries CBR* [2002] ECR II—491. Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 12.

¹⁹⁹⁷ Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 23, referring to jurisprudence of the Court.

¹⁹⁹⁸ Case C-306/96 *Javico*, [1998] ECR I-1983, paragraphs 16 and 17; see also Case T-374/94, *European Night Services*, [1998] ECR II-3141, paragraph 136.

¹⁹⁹⁹ Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 19.

²⁰⁰⁰ Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 30.

potential or actual competitor within the Community.²⁰⁰¹ Trade "*between Member States*" refers to trade between at least two Member States. It is not required that trade between all or most Member States is (potentially) affected.²⁰⁰² Trade between Member States may also be (potentially) affected where the relevant geographic market is national in scope.²⁰⁰³ Nor is it necessary to establish a link between the alleged restriction of competition and the capacity of the agreement as a whole to affect trade between Member States.²⁰⁰⁴ With respect to agreements that limit imports, there is an inherent link between the alleged restriction of competition and the effects on trade, since the very purpose of the restriction is to prevent flows of goods between Member States, which would otherwise be possible.²⁰⁰⁵

- (1193) Finally, it is the continuous course of conduct as a whole that must be capable of affecting trade between Member States. It is not required that each individual practice, each provision of an agreement or each agreement that forms part of a single and continuous infringement is capable of doing so.²⁰⁰⁶ In the case at hand, therefore, the effect on trade has to be analysed for the set of agreements between Lundbeck and Merck, the set of agreements between Lundbeck and Arrow, the agreement between Lundbeck and Alpharma and the agreement between Lundbeck and Ranbaxy.²⁰⁰⁷

13.2. Effect on trade of the set of agreements between Lundbeck and Merck

- (1194) As mentioned in section 12.8 above, the single and continuous infringement committed by Lundbeck and Merck covered the entire EEA by means of a set of two agreements, one covering the United Kingdom and the other covering other EEA Contracting Parties than the United Kingdom. As has been analysed in sections 12.2 and 12.3 above, these agreements prevented during their operation Merck (GUK) from selling generic citalopram in each of the national markets covered by the agreements, whether directly or via other Merck Generics subsidiaries in those countries. The agreements therefore eliminated, for the duration of their operation, a potential competitor from national markets in the EEA. As such the infringement was by its very nature capable of affecting trade between Union Member States and between Contracting Parties to the EEA Agreement.
- (1195) The set of agreements was, moreover, capable of affecting specific cross-border economic activity which in its absence could have come about between EU Member States and between EEA Contracting Parties. In the period of operation of the set of agreements with Lundbeck, Merck (GUK) was located in the United Kingdom, but

²⁰⁰¹ Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 20.

²⁰⁰² Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 21.

²⁰⁰³ Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 22.

²⁰⁰⁴ Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 16.

²⁰⁰⁵ Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 63.

²⁰⁰⁶ Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, points 12 and 14.

²⁰⁰⁷ See section 12.8 above.

stored its Natco product in Ireland.²⁰⁰⁸ Merck (GUK) acted within the Merck Generics group as raw material support group. In this capacity it bought raw materials not just for itself, but also for other Merck Generics subsidiaries in the EEA. Had it not been for the set of agreements with Lundbeck, Merck (GUK) could have sold Natco citalopram not only on the United Kingdom market, where it already had a marketing authorisation, but also on several other EEA markets, either directly or via other Merck subsidiaries. In Sweden, in fact, Merck (GUK) had already been selling to the Swedish company NM Pharma at the time the agreement with Lundbeck was concluded.²⁰⁰⁹ These sales to Sweden were stopped because of Merck (GUK)'s agreement with Lundbeck. In the course of the operation of the agreement with Lundbeck regarding other EEA Contracting Parties than the United Kingdom, the Merck Generics group obtained marketing authorisations in ten additional EEA markets (Austria, Belgium, Norway, Denmark, Luxembourg, Germany, Finland, Portugal, Ireland and France).²⁰¹⁰ The agreement with Lundbeck regarding other EEA Contracting Parties than the United Kingdom prevented potential sales by Merck (GUK) to those countries. This agreement with Lundbeck therefore prevented cross-border economic activity which could have come about between Ireland, the United Kingdom and the countries concerned and possibly also between the countries concerned.

- (1196) Together these actual and potential effects on EEA markets were appreciable, as Lundbeck's citalopram sales in the EEA in 2002 amounted to EUR [400-600]* million²⁰¹¹, and as generic competition tends to quickly replace originator sales.
- (1197) The Commission concludes that the set of agreements between Lundbeck and Merck regarding the United Kingdom and the EEA excluding the United Kingdom was capable of affecting trade between Member States within the meaning of Article 101(1) of the Treaty and between Contracting Parties within the meaning of Article 53(1) of the EEA Agreement.

13.3. Effect on trade of the set of agreements between Lundbeck and Arrow

- (1198) As mentioned in section 12.8 above, the single and continuous infringement committed by Lundbeck and Arrow covered the United Kingdom and Denmark by means of a set of two agreements, one covering the United Kingdom and the other covering Denmark. As has been analysed in sections 12.4 and 12.5 above, these agreements prevented during their operation Arrow from selling generic citalopram in the United Kingdom or Denmark. The agreements therefore eliminated, for the duration of their operation, a potential competitor from the United Kingdom and Danish national markets. As such the infringement was by its very nature capable of affecting trade between Union Member States.
- (1199) The set of agreements was, moreover, capable of affecting specific cross-border economic activity that in its absence could have come about between different Union Member States. When Arrow signed the two agreements with Lundbeck, Arrow was perceived to be on the verge of obtaining marketing authorisations in both the United

²⁰⁰⁸ See recital (319) above.

²⁰⁰⁹ See recital (346) above.

²⁰¹⁰ See recital (347) above.

²⁰¹¹ See recital (26) above.

Kingdom and Denmark.²⁰¹² The set of agreements with Lundbeck prevented Arrow's potential market entry into the United Kingdom and Denmark. The set of agreements with Lundbeck therefore prevented cross-border economic activity which could have come about between the United Kingdom, where Arrow Generics Limited was located, and Denmark, where the parent company Arrow Group A/S was located.

- (1200) Moreover, as Arrow had a supply contract with the German company Tiefenbacher for its citalopram, cross-border economic activity between Tiefenbacher in Germany and Arrow in the United Kingdom and Denmark was also potentially affected by the infringement. Trade between Germany, the United Kingdom and Denmark was also potentially affected by Arrow's set of agreements with Lundbeck because Arrow's citalopram was packaged and labelled by the company Dragenopharm in Germany.
- (1201) Together, the potential effects on trade between Union Member States of the set of agreements between Lundbeck and Arrow were appreciable, as Lundbeck's sales of citalopram in 2002 amounted to EUR [40-150]* million in the United Kingdom²⁰¹³ and to EUR [0-30]* million in Denmark.²⁰¹⁴
- (1202) The Commission concludes that the set of agreements between Lundbeck and Arrow regarding the United Kingdom and Denmark was capable of affecting trade between Union Member States within the meaning of Article 101(1) of the Treaty.

13.4. Effect on trade of the agreement between Lundbeck and Alpharma

- (1203) As mentioned in section 12.8 above, the infringement committed by Lundbeck and Alpharma covered the entire EEA by means of a single agreement. As has been analysed in section 12.6 above, this agreement prevented during its operation Alpharma from selling generic citalopram anywhere in the EEA. The agreement therefore eliminated, for the duration of its operation, a potential competitor from national markets in the EEA. As such the infringement was by its very nature capable of affecting trade between Union Member States and between Contracting Parties to the EEA Agreements.
- (1204) The agreement was, moreover, capable of affecting specific cross-border economic activity that in its absence could have come about between Union Member States and between EEA Contracting Parties. In the period of operation of the agreement with Lundbeck, Alpharma had an intermediate parent company, Alpharma ApS, in Denmark with sales subsidiaries in France, Germany, the United Kingdom, the Netherlands, Sweden, Finland, Norway and (as of 3 June 2003) Belgium.²⁰¹⁵ When Alpharma ApS concluded the agreement with Lundbeck, Alpharma already had four marketing authorisations, for the Netherlands, Finland, Denmark and Sweden. Alpharma obtained four more during the operation of the agreement, in Norway, Germany, Austria and the United Kingdom.²⁰¹⁶ The agreement with Lundbeck prevented Alpharma from potentially entering a number of EEA markets and thus prevented cross-border economic activity which could have come about between Denmark, where Alpharma ApS was located, and the countries concerned and possibly also between the countries concerned.

²⁰¹² See recitals (390) and (454) above.

²⁰¹³ ID 983, page 18.

²⁰¹⁴ ID 970, page 20.

²⁰¹⁵ See recital (41) above.

²⁰¹⁶ See recital (516) above.

- (1205) Moreover, as Alpharma had a supply contract with the German company Tiefenbacher for its citalopram, the agreement with Lundbeck prevented cross-border economic activity which could have come about between Tiefenbacher in Germany and Alpharma in Denmark (or other EEA markets where Alpharma would have sold). Also, as Alpharma's citalopram tablets were manufactured by Omega Farma in Iceland, the agreement with Lundbeck prevented trade which could have come about between Iceland and Denmark (or other EEA markets where Alpharma would have sold). Finally, as Alpharma's citalopram was packaged and labelled by the German company Dragenopharm, the agreement with Lundbeck prevented trade which could have come about between Iceland, Germany and Denmark (or other EEA markets where Alpharma would have sold).
- (1206) Together these potential effects on EEA markets were appreciable, as Lundbeck's citalopram sales in the EEA in 2002 amounted to EUR [400-600]* million²⁰¹⁷ and as generic competition tends to quickly replace originator sales.
- (1207) The Commission concludes that the agreement between Lundbeck and Alpharma regarding the EEA was capable of affecting trade between Member States within the meaning of Article 101(1) of the Treaty and between Contracting Parties within the meaning of Article 53(1) of the EEA Agreement.

13.5. Effect on trade of the agreement between Lundbeck and Ranbaxy

- (1208) As mentioned in section 12.8 above, the infringement committed by Lundbeck and Ranbaxy covered the entire EEA by means of a single agreement. As has been analysed in section 12.7 above, this agreement prevented during its operation Ranbaxy from selling generic citalopram anywhere in the EEA. The agreement therefore eliminated, for the duration of its operation, a potential competitor from national markets in the EEA. As such the infringement was by its very nature capable of affecting trade between Union Member States and between Contracting Parties to the EEA Agreement.
- (1209) The agreement was, moreover, capable of affecting specific cross-border economic activity that in its absence could have come about between different Union Member States and between EEA Contracting Parties. When the agreement with Lundbeck was concluded, Ranbaxy had a European headquarters in the United Kingdom and sales subsidiaries in the United Kingdom, Germany, France, Ireland and the Netherlands.²⁰¹⁸ Ranbaxy indicated to Lundbeck at the time that it intended to obtain marketing authorisations in the United Kingdom and Germany within eight months and intended to partner up with a supplier in northern Europe, who would bring Ranbaxy's citalopram to market within three to four months²⁰¹⁹ The agreement with Lundbeck thus prevented Ranbaxy from potentially entering several EEA markets within a number of months. It therefore prevented cross-border economic activity which could have come about between Ranbaxy's headquarters in the United Kingdom and those other EEA markets and possibly also between those other EEA markets.

²⁰¹⁷ See recital (26) above.

²⁰¹⁸ See recital (53) above.

²⁰¹⁹ See recital (558) above.

- (1210) Together these potential effects on EEA markets were appreciable, as Lundbeck's citalopram sales in the EEA in 2002 amounted to EUR [400-600]* million ²⁰²⁰, and as generic competition tends to quickly replace originator sales.
- (1211) The Commission concludes that the agreement between Lundbeck and Ranbaxy regarding the EEA was capable of affecting trade between Member States within the meaning of Article 101(1) of the Treaty and between Contracting Parties within the meaning of Article 53(1) of the EEA Agreement.

14. APPLICATION OF ARTICLE 101(3) OF THE TREATY AND ARTICLE 53(3) OF THE EEA AGREEMENT

14.1. Introduction

- (1212) Article 101(3) of the Treaty "*provides a defence to undertakings against a finding of an infringement of Article [101(1) of the Treaty]...*".²⁰²¹ 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. For the exemption of Article 101(3) of the Treaty to apply, four cumulative conditions must be met. The agreement must:
- (a) contribute to improving the production or distribution of goods or contribute to promoting technical or economic progress (hereafter also referred to as the requirement of 'efficiency gains');
 - (b) not impose on the undertakings concerned restrictions which are not indispensable to the attainment of these efficiency gains;
 - (c) allow consumers a fair share of the resulting benefits; and
 - (d) not afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.²⁰²²
- (1213) According to Article 2 of Regulation 1/2003, parties claiming the benefit of Article 101(3) of the Treaty for an infringement shall bear the burden of proving that each of the four conditions of that paragraph is met for the infringement concerned.²⁰²³
- (1214) The possibility that an agreement restricting competition may be exempted under Article 101(3) of the Treaty applies also to agreements restricting competition by object. However, severe restrictions of competition such as price fixing or limiting, controlling and sharing markets often do not to meet the conditions for an exemption under 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*

²⁰²⁰ See recital (26) above.

²⁰²¹ 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.

²⁰²² 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).

²⁰²³ 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.

benefit the consumer".²⁰²⁴ Instead, they may lead to "*transfers [of] value from consumers to producers [...] without producing any countervailing value to consumers....*"²⁰²⁵ 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.

(1215) With respect to the first condition, the existence of an efficiency gain, a party invoking Article 101(3) of the Treaty must substantiate each efficiency claim so that the following can be verified:

- the nature of the claimed efficiency;
- the link between the agreement and the claimed efficiency;
- the likelihood and magnitude of the claimed efficiency; and
- how and when the claimed efficiency would be achieved.²⁰²⁶

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.²⁰²⁷

(1216) 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.²⁰²⁸

(1217) From the different submissions of parties in the course of the proceedings, the Commission was able to identify three efficiency claims:

- an alleged efficiency gain resulting from avoided litigation costs;²⁰²⁹
- an alleged efficiency gain resulting from improved distribution of Lundbeck citalopram in the United Kingdom;²⁰³⁰
- an alleged efficiency gain consisting in GUK's claim that "*The Settlement Agreements allowed GUK to launch generic citalopram earlier than it would have been able to, had it not entered into the Settlement Agreements.*"²⁰³¹

²⁰²⁴ 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.

²⁰²⁵ 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.

²⁰²⁶ 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.

²⁰²⁷ 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.

²⁰²⁸ 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.

²⁰²⁹ For Lundbeck's claim, which concerned all four infringements, see ID 823, page 2. Of the generic undertakings, GUK, for example, also claimed efficiencies from avoided litigation, see ID 1978, page 13 and ID 6026, pages 99 to 104.

²⁰³⁰ For Lundbeck's claim, see ID 823, pages 23 and 50. For GUK's claim, see ID 6026, pages 99 to 104.

²⁰³¹ ID 6026, page 100.

- (1218) 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 any the alleged efficiencies with respect to any infringement. Indeed, no party even substantiated in the required detail the claimed efficiency gains within the meaning of recital (1215) 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 cannot apply.
- (1219) The Commission considers, in any case, that the restrictions by object identified in this Decision were not necessary to achieve any claimed efficiencies. 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 Lundbeck's patents in relation to the generic product concerned (and only that product). Moreover, none of the parties has submitted sufficient evidence that consumers would have received a fair share of any claimed efficiency.
- (1220) For the sake of completeness, with respect to each of the three alleged efficiencies the Commission makes the following additional observations:

14.2. Claimed efficiency gain from avoided litigation costs

- (1221) Lundbeck claimed that the (sets of) agreements covered by this Decision "*avoided costly, duplicative litigation in multiple jurisdictions*".²⁰³² GUK also claimed that its set of agreements with Lundbeck "*allowed GUK to avoid significant costs on litigation*".²⁰³³
- (1222) The Commission notes that Lundbeck informed the Commission that its agreements with Merck, Arrow, Alpharma and Ranbaxy "*did not remove any uncertainty over whether a generic's challenge would eventually succeed, because they did not finally resolve the dispute*" and "*did not...ultimately decide when any generic company could enter the market*".²⁰³⁴ Given that the four generic undertakings concerned were given no certainty whatsoever in the agreements that after expiry of these agreements they could enter the market unopposed by Lundbeck, there is no clear link between the agreements and the avoidance of any litigation costs. While the generic undertakings in question were, after the expiry of their agreements, in practice usually able to enter markets in the EEA without further litigation with Lundbeck, this was due not to the agreements but to the fact that in the United Kingdom and in several other EEA Contracting Parties other generic undertakings had competed with Lundbeck (including through litigation) and had managed to successfully entered the market, so that Lundbeck no longer bothered to litigate to defend its market position.
- (1223) Secondly, the Commission observes that no party has substantiated within the meaning of recital (1215) above what precise efficiency gain allegedly resulted from any avoided litigation costs.²⁰³⁵ In this respect, if the argument of parties is that mere cost savings for the parties concerned from avoided litigation constitute an efficiency gain within the meaning of Article 101(3) of the Treaty, then the Commission

²⁰³² ID 823, page 2, 11-14.

²⁰³³ ID 1978, page 13. See also ID 6026, page 101: "*...while avoiding costly and lengthy litigation in multiple jurisdictions*."

²⁰³⁴ ID 1683, pages 3 and 2.

²⁰³⁵ See recital (1215) above.

observes that a party has to show that the agreement contributed to improving the production or distribution of goods or to promoting technical or economic progress. In accordance with well-established jurisprudence of the Courts of the European Union, only objective benefits can be taken into account in this respect.²⁰³⁶ Efficiencies are not assessed from the subjective point of view of the parties. Cost savings which result from reduced competition between the parties, which merely allow the undertakings concerned to increase their profits and which do not produce any pro-competitive effects on the market are irrelevant from the point of view of Article 101(3) of the Treaty.²⁰³⁷ In the case at hand, no evidence has been submitted that any cost savings resulting from the agreements in question produced any pro-competitive effects on the market.

14.3. Claimed efficiency gain from improved distribution of Lundbeck citalopram in the United Kingdom

- (1224) Lundbeck claimed that its agreement with Merck for the United Kingdom, in which the parties agreed that Merck (GUK) would distribute Lundbeck citalopram in the United Kingdom, *"created efficiencies as Lundbeck gained access to Generics UK's successful UK distribution network."*²⁰³⁸ *"Given Generics UK's extensive distribution network in the UK, Lundbeck considered the supply arrangement would serve the ... purpose of ... improving Lundbeck's overall presence in the UK market."*²⁰³⁹ With respect to Ranbaxy, which also distributed Lundbeck citalopram in the United Kingdom, Lundbeck claimed: *"The arrangement was also beneficial to Lundbeck because it gave it access to Ranbaxy's distribution network and allowed it to benefit from Ranbaxy's promotional efforts."*²⁰⁴⁰
- (1225) The Commission notes, firstly, that claimed efficiencies should be considered for the continuous course of conduct between the parties as a whole. Any claimed efficiencies should thus be considered for Lundbeck's set of agreements with Merck covering the United Kingdom and other EEA Contracting Parties than the United Kingdom, instead of just for the United Kingdom.²⁰⁴¹ Similarly, claimed efficiencies from the agreement with Ranbaxy should be considered for the EEA as a whole, not just for the United Kingdom. It would be inappropriate to consider claimed efficiencies for an agreement in isolation where that agreement constitutes only part of a continuous course of conduct between two parties which together constitutes a single and continuous infringement. This means that even if the parties were able to prove that the distribution agreements in the United Kingdom created certain efficiencies in the United Kingdom, those efficiencies are unlikely to be able to outweigh restrictions of competition covering the entire EEA.
- (1226) Secondly, as already mentioned, Lundbeck did not substantiate its claim within the meaning of recital (1215) above. In particular, Lundbeck has not provided any evidence demonstrating that *"Lundbeck's overall presence in the UK market"* was actually improved due to the distribution agreement with Merck (GUK) or Ranbaxy,

²⁰³⁶ See for instance Joined Cases 56/64 and 58/66, *Consten and Grundig*, [1966] ECR 429.

²⁰³⁷ 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.

²⁰³⁸ ID 823, page 50.

²⁰³⁹ ID 823, pages 23 and 50.

²⁰⁴⁰ ID 5394, page 250.

²⁰⁴¹ See section 12.8 above.

whether in a quantitative or a qualitative sense, compared to the situation where Lundbeck would have continued to distribute its citalopram in the United Kingdom alone.

- (1227) Thirdly, the Commission does not see any reason why Lundbeck could not have concluded agreements with Merck (GUK) and Ranbaxy that allowed for the distribution of Lundbeck citalopram by these two undertakings without preventing sales by Merck (GUK) of generic citalopram products from Natco or any other API supplier or sales by Ranbaxy of own-manufactured citalopram. Lundbeck has not submitted any evidence that those restrictions on generic sales would be necessary to achieve the allegedly improved distribution of Lundbeck's citalopram in the United Kingdom.

14.4. Claimed efficiency gain from earlier launch of generic citalopram

- (1228) GUK claimed that its agreements with Lundbeck *"ensured the near-term launch of generic citalopram"* and that *"The Settlement Agreements enabled GUK to... launch its products earlier than it would have been possible had it sought to litigate..."*.²⁰⁴² Given that Lundbeck's agreements with Merck (GUK) actually prevented potential generic competition, including potentially an immediate launch of Natco product in the United Kingdom and other EEA markets, and contained no commitment from Lundbeck whatsoever to allow generic competition from Merck (GUK) once the agreements had expired, GUK's claim is not corroborated by the facts.
- (1229) Ranbaxy also claimed that *"... the Agreement provided Ranbaxy with an opportunity to enter the EEA market well before it had anticipated [...] and ultimately improved Ranbaxy's competition position..."*.²⁰⁴³ Given that Ranbaxy in the agreement agreed not to pursue for the term of the agreement its efforts to enter EEA markets with its own-manufactured product and instead merely entered the United Kingdom market as a distributor of Lundbeck's products, thereby preserving Lundbeck's market position in the United Kingdom and avoiding the fierce price competition generic entry would have brought, Ranbaxy's claim is not corroborated by the facts.²⁰⁴⁴
- (1230) Moreover, neither Merck (GUK) nor Ranbaxy has substantiated its claim within the meaning of recital (1215) above or explained why the restrictions on their own commercial freedom were necessary to achieve any such efficiency.

14.5. Conclusion on the applicability of Article 101(3) of the Treaty and Article 53(3) of the EEA Agreement

- (1231) The Commission concludes that no party has submitted the evidence required to demonstrate that one or more of the restrictions of competition found in this Decision would be exempted under Article 101(3) of the Treaty or Article 53(3) of the EEA Agreement because of one or more claimed efficiency gains.

²⁰⁴² ID 6026, page 101.

²⁰⁴³ ID 5176, page 30.

²⁰⁴⁴ In its Reply to the Statement of Objections Ranbaxy explained that *"it saw the distribution agreement with Lundbeck as a stepping stone that should facilitate its market entry into the UK with its own product, if and when it would obtain the required market authorizations"*. See ID 5176, page 49. If this were the actual and sole purpose of the agreement, Ranbaxy falls short of explanations why (i) it accepted the undertakings not to enter the market with its own-manufactured citalopram and agreed not to challenge Lundbeck's patent rights and why (ii) Lundbeck accepted a loss on the sales (see recital (565) above).

15. ADDRESSEES OF THIS DECISION

15.1. Introduction

- (1232) As mentioned in section 9.3, Article 101 of the Treaty addresses undertakings. The concept of 'undertaking' has an economic scope and encompasses any entity engaged in an economic activity. The 'undertaking' that committed the infringement can therefore be larger than the legal entity whose representatives actually took part in the infringing activities. As the European Court of Justice ruled in *Akzo Nobel* "*When such an economic entity infringes the competition rules, it falls, according to the principle of personal responsibility, to that entity [that is to say the undertaking] to answer for that infringement.*"²⁰⁴⁵
- (1233) 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.²⁰⁴⁶ It is accordingly necessary for the Commission to identify, for each undertaking that is to be held accountable for its infringement of Article 101 of the Treaty in this case, one or more legal entities that represent the undertaking concerned.
- (1234) It is well-established jurisprudence that the conduct of a subsidiary may be imputed to the parent company in particular where, although 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.²⁰⁴⁷
- (1235) The Court of Justice has ruled that the Commission cannot merely find that an undertaking is able to exert decisive influence over another undertaking. 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 undertakings may have over the other.²⁰⁴⁸ 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.²⁰⁴⁹
- (1236) However, for the specific case where a parent company has a 100% shareholding in a subsidiary which has infringed the Union competition rules, the Court of Justice has clarified that first, the parent company can exercise a decisive influence over the conduct of the subsidiary and, second, there is a rebuttable presumption that the parent company does in fact exercise a decisive influence over the conduct of its subsidiary.²⁰⁵⁰ In those circumstances, it is sufficient for the Commission to prove that the subsidiary is wholly owned by the parent company in order to presume that the parent exercises a decisive influence over the commercial policy of the

²⁰⁴⁵ Case C-79/08, *Akzo Nobel v Commission*, not yet reported, judgment of 10 September 2009, paragraph 56.

²⁰⁴⁶ Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraph 57.

²⁰⁴⁷ Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraphs 58-59 and the jurisprudence cited there.

²⁰⁴⁸ See for instance, Case T-587/08 *Fresh Del Monte Produce, Inc. v Commission*, judgment of 14 March 2013, paragraph 56 and the jurisprudence cited there.

²⁰⁴⁹ Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraph 74.

²⁰⁵⁰ Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraph 60; see also paragraph 74 of that judgment.

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, which has the burden of rebutting that presumption, adduces cogent evidence to show that its subsidiary acts independently on the market.²⁰⁵¹ This also applies to situations where the parent company indirectly holds a 100% ownership in a subsidiary, that is to say via one or more intermediary companies.²⁰⁵²

- (1237) In this case the Commission considers that parent companies which at the time of events exerted decisive influence over subsidiaries that signed any of the agreements covered by this Decision should be held responsible for the infringement committed by the undertaking, together with the subsidiary that actually signed the agreement. If the agreement was signed by a parent company located outside of the EEA, as was the case for Ranbaxy, the Commission may also hold a subsidiary located within the EEA jointly and severally liable with the parent company.

15.2. Lundbeck

- (1238) As described in section 3.2, the company H. Lundbeck A/S was at the time of events the parent company of the undertaking Lundbeck. As the facts in chapter 7 indicate, this company concluded itself all of the agreements that are the object of this Decision, with the exception of the United Kingdom agreement with Merck (GUK), which was concluded by its 100%-owned United Kingdom subsidiary Lundbeck Limited.²⁰⁵³ In light of the 100% ownership by H. Lundbeck A/S of Lundbeck Limited, the Commission presumes that H. Lundbeck A/S exercised a decisive influence over the commercial policy of Lundbeck Limited.
- (1239) It may, moreover, be noted that the negotiation of the United Kingdom agreement with Merck (GUK) was conducted by staff of H. Lundbeck A/S²⁰⁵⁴ and that the agreement was signed by two Lundbeck representatives who at that time held important functions not only in Lundbeck Limited but also in H. Lundbeck S.A.²⁰⁵⁵
- (1240) As the company H. Lundbeck A/S still exists, the Commission considers it appropriate to hold H. Lundbeck A/S responsible for the infringements which the undertaking Lundbeck committed in this case.
- (1241) In addition, since Lundbeck Limited signed the agreement with Merck (GUK) regarding the United Kingdom, the Commission considers it appropriate to hold Lundbeck Limited jointly and severally liable with H. Lundbeck A/S for the United Kingdom part of Lundbeck's infringement with Merck (GUK).
- (1242) For the infringements committed by the undertaking Lundbeck, this Decision is therefore addressed both to H. Lundbeck A/S and Lundbeck Limited, the former for

²⁰⁵¹ Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraphs 60-61 and 65 and the jurisprudence cited there.

²⁰⁵² See for instance Case T-190/06, *Total SA and Elf Aquitaine SA v Commission*, judgment of 14 July 2011, paragraph 42.

²⁰⁵³ The second extension of the Merck (GUK) agreement was signed "*for and on behalf of Lundbeck*", rather than Lundbeck Ltd. The person who signed for Lundbeck was the same person who had signed the original agreement for Lundbeck Ltd. See ID 8, page 226.

²⁰⁵⁴ See the documents referred to in recitals (241) to (266). These documents show that H. Lundbeck A/S was directly involved in, indeed directed, the negotiation of the United Kingdom agreement with Merck (GUK).

²⁰⁵⁵ ID 1634.

the infringement as a whole and the latter for the United Kingdom agreement with Merck (GUK) only, for which it is held jointly and severally liable.

15.3. Merck

- (1243) As described in section 3.3, the company Generics [UK] Limited, which entered into the agreements with Lundbeck regarding the United Kingdom and the EEA excluding the United Kingdom, was in the period of the operation of these agreements an indirect 100% subsidiary of the company Merck KGaA.²⁰⁵⁶ In light of the 100% ownership by Merck KGaA of Generics [UK] Limited, the Commission relies in this Decision on the presumption that Merck KGaA exercised a decisive influence over the commercial policy of Generics [UK] Limited.²⁰⁵⁷
- (1244) In its reply to the Statement of Objections, Merck KGaA argued that it did not actually exert decisive influence over Generics [UK] Limited's business and did not form a single economic unit with the latter.²⁰⁵⁸ In order to rebut the presumption that was applied in view of Merck KGaA's 100% ownership of Generics [UK] Limited, Merck KGaA submitted a number of arguments, which are discussed below in this section. In assessing these arguments, it has to be borne in mind that Merck KGaA had the burden of adducing sufficient evidence to show that its subsidiary acted independently on the market, a burden which in the Commission's view it has not met.
- (1245) First, Merck KGaA argued that Generics [UK] Limited's business activities were very distinct from Merck KGaA's. While Merck KGaA was an originator with a research business that was based on long-term strategy and relied on innovation, Generics [UK] Limited was a generic company that copied existing products, where speed was of essence.²⁰⁵⁹ Merck KGaA further submitted that Generics [UK] Limited, and the Merck Generics Group of companies, had their own departments, were structurally different and were autonomous in the development of their business strategy.²⁰⁶⁰ In fact, Merck KGaA contended that it was a mere financial investor, acted like one, and did not exert decisive influence over Generics [UK] Limited's business.²⁰⁶¹
- (1246) The Commission observes that according to Section 1, Article 2 of Merck KGaA's Articles of Association, Merck KGaA's business object is "*the manufacture and distribution of chemical [...] products, particularly pharmaceuticals, basic substances for medicinal products*".²⁰⁶² Also Generics [UK] Limited produced and distributed pharmaceuticals, the difference only being that its business focused on generic pharmaceuticals. In fact, synergies with Generics [UK] Limited's production and distribution of pharmaceuticals were the very reason, why Merck KGaA made the strategic business decision to acquire that company. The memorandum "Strategy Amerpharm" of "08-04-1994" set out Merck's strategy for acquiring the Amerpharm generics group to which Generics [UK] Limited belonged at the time.²⁰⁶³ It derives

²⁰⁵⁶ See recital (29) above.

²⁰⁵⁷ See recital (1235) above.

²⁰⁵⁸ ID 5960, pages 370-393.

²⁰⁵⁹ ID 5960, pages 375-377. ID 6633, page 54.

²⁰⁶⁰ ID 5960, pages 377-380.

²⁰⁶¹ ID 5960, pages 386-388.

²⁰⁶² ID 518, page 4.

²⁰⁶³ See ID 6040.

from this memorandum that Merck KGaA had identified a strategic business opportunity to expand from its pharmaceutical originator business into the pharmaceutical generics segment.²⁰⁶⁴ In particular, based on synergies in the areas of "management skills", "product range", "marketing skills", "chemical production", "filling and finishing", Merck KGaA had the "project goal" "to reach 500 million in generic sales and be present in all major markets". It concluded: "The fit looks pretty good."²⁰⁶⁵ In its Annual Report of 2001, Merck KGaA reported: "Ethicals used in the treatment of metabolic and cardiovascular diseases [and ...] generics [...] are the core of our pharmaceuticals business." The report further talked about "our [that is to say Merck KGaA's(!)] strategic plans for long-term growth".²⁰⁶⁶

- (1247) Merck KGaA, however, argued that "...the acquisition of Amerpharm's generics business [that is to say Generics [UK] Limited] was planned to become a venture into a new industry at first and ended as a **mere financial investment**".²⁰⁶⁷ The Commission observes that this is inconsistent with the 2001 Annual Report mentioned in recital (1246) (generics were "the core" of Merck KGaA's pharmaceutical business). Merck KGaA's sale of its generics business to Mylan in 2007, which shows a change in business strategy, does not make Merck a mere financial investor in the period before.²⁰⁶⁸ Moreover, the General Court stated in this respect 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."²⁰⁶⁹ Merck KGaA clearly did get involved in managing Generics [UK] Limited: Around 2001 Merck KGaA identified within Generics [UK] Limited the problem of fragmented procurement; from April 2001 until 2007, therefore, Merck KGaA seconded one of its executives to Generics [UK] Limited to remedy this situation. His mission was to unify and render more effective Generics [UK] Limited's procurement, and to implement "strategic sourcing".²⁰⁷⁰ While his operational reporting was to Generics [UK] Limited, his personal business targets were set by Merck KGaA, and his performance was assessed by Merck KGaA's [employee function]*.²⁰⁷¹ It goes without saying that the identification of a business need presupposes and suggests that Merck KGaA was well informed about, and supervised, Generics [UK] Limited. In addition that executive was not the only employee seconded by Merck KGaA to Generics [UK] Limited.²⁰⁷² Merck KGaA argued that those secondments were not successful, because Generics [UK] Limited's management tried to resist interference by Merck KGaA, wanted to maintain independence and prevented the seconded employee's

²⁰⁶⁴ E.g., ID 6040, page 2.

²⁰⁶⁵ ID 6040, page 4.

²⁰⁶⁶ Merck KGaA Annual Report 2001, pages 2, 18 and 25, available at: <http://businessinformation.de/documents/Merck-ar2001en.pdf>

²⁰⁶⁷ ID 5960, pages 39 and 386-388. (Highlighting in Original)

²⁰⁶⁸ See ID 5960, page 377. In reply to the Statement of Objections, Merck KGaA pointed to a quote of its former CEO from 2007 in relation to the sale of Merck KGaA's generic division that "mass markets were never the objective of Merck" (stating that the disposition was the "right step into the future"). However, this quote does not demonstrate that Merck KGaA did not exercise active control over the Merck generics group during the time the latter belonged to the Merck KGaA group of undertakings.

²⁰⁶⁹ Case T-392/09 *I. garantovaná a.s. v Commission*, judgment of 12 December 2012, paragraph 52.

²⁰⁷⁰ See ID 5973. Recording of the Oral Hearing of 14 March 2013, ID 6775, at: 5:14-5:22.

²⁰⁷¹ See ID 5973, page 2.

²⁰⁷² See ID 5989, in particular page 2.

involvement in strategic business decisions.²⁰⁷³ However, the lack of success of Merck KGaA's [...] executive at Generics [UK] Limited is hardly credible considering that his secondment lasted for 6 years (until the sale of Merck's generic business to Mylan in 2007). Even if the secondment had not been successful and had been obstructed, as Merck KGaA argued,²⁰⁷⁴ this would not put in question the existence of an economic unit, because the imposition of secondments of executives on Generics [UK] Limited clearly shows that Merck KGaA actively managed its subsidiary.²⁰⁷⁵ Moreover, as 100% owner of Generics [UK] Limited, Merck KGaA had at any time the power to appoint, and remove, executives of Generics [UK] Limited and of the Merck Generics Group of companies.²⁰⁷⁶ Finally, Merck KGaA explained that "*GUK was [...] delivering solid financial results, which is why there was little reason for Merck KGaA to attempt to gain control or to otherwise exercise influence over GUK or its activities. It is such lack of interest and reason to interfere with the doings at GUK that left Merck KGaA the role of a financial investor.*"²⁰⁷⁷ However, a "lack of reason to interfere" might also suggest, if at all, that Merck KGaA supervised Generics [UK] Limited, but saw no reason at that time to intervene, because Generics [UK] Limited was doing well. Whereas this can also be seen as a form of actually exercising control,²⁰⁷⁸ it certainly does not demonstrate that Generics [UK] Limited acted independently on the market.

- (1248) Second, the fact that Generics [UK] Limited and the Merck Generics Group of companies may have been structurally different and may have been more or less autonomous in the development of their business strategy, as Merck KGaA submitted in reply to the Statement of Objections, is in light of the considerations in recital (1247) above insufficient to rebut the presumption of Merck KGaA's active control over Generics [UK] Limited.²⁰⁷⁹ In this respect, the General Court held that

²⁰⁷³ See ID 5960, pages 381-385 and ID 6991, page 8. Merck KGaA claimed that "[Seconded employee] was never involved in strategic decisions at GUK".

²⁰⁷⁴ For Merck KGaA's arguments in this respect see ID 5960, pages 381-383 (the seconded employee was asked by Generics [UK] Limited to work from Merck KGaA headquarters; Generics [UK] Limited's executives did not readily share information with him (he would have been regarded as "a spy"); the seconded employee got involved only in already negotiated and finalised contracts). However, all these elements merely show that Merck KGaA could have maybe better managed the secondment(s).

²⁰⁷⁵ Generics [UK] Limited can therefore not be considered to have acted independently from its parent Merck KGaA, as Merck KGaA argued. For Merck KGaA's arguments submitted in reply to the Statement of Objections see ID 5960, pages 374 and 379-380.

²⁰⁷⁶ In 2003, when Merck KGaA discovered certain [...], it removed Generics [UK] Limited's [employee function], also in his function as [employee function] of Merck Generics Holding GmbH. It further removed the [employee function]. See ID 5960, page 379. Merck KGaA argued that "*any parent would have taken [such measures] regardless of being a pure financial investor or one with strategic interest*". See ID 6991, page 9. However, those measures nevertheless show that Merck KGaA was supervising its subsidiary. Indeed, according to the Court of Justice in *Eni*, the appointment of members of the board is at the core of the prerogatives of a parent company which enables the parent company to exercise decisive influence (Case C-508/11P *Eni SpA v Commission*, paragraphs 65-67, not yet reported).

²⁰⁷⁷ ID 6991, page 7. Merck KGaA, however, considers that this would show that GUK acted independently.

²⁰⁷⁸ See in particular footnote 2076 above, which illustrates that Merck KGaA was ready to intervene when necessary.

²⁰⁷⁹ For Merck KGaA's arguments see ID 5960, pages 377-380, 384. Elements invoked by Merck KGaA included in particular: different "*operational structures*"; "*almost no commercial contact between Merck companies in the UK and the Generics companies in the UK*"; GUK's own decisions on remuneration and bonuses of executives; "*tax and transfer pricing issues*"; the use by GUK of external

"... it may be concluded from the case-law [...] that a – greater or lesser – degree of autonomy of a subsidiary in its own commercial management is not necessarily incompatible with the parent company's decisive influence, within the meaning of the case-law [...], over that subsidiary."²⁰⁸⁰ The Commission considers that the following fact rather suggests that Merck KGaA was directly coordinating its business activities with Generics [UK] Limited. In fact, Merck KGaA offered to Generics [UK] Limited that it could use Merck KGaA's Indian production facilities; however, Generics [UK] Limited rejected this offer and was allowed to build up a new production facility for its own purposes in India.²⁰⁸¹ Merck KGaA argued in this respect that Generics [UK] Limited was "not only in a position to reject [the] offer by its 100% parent but has the freedom to build its own [facility] without having to consider existing capacities within the conglomerate [... This] is clear evidence for GUK's autonomy".²⁰⁸² However, this could also show the opposite: Merck KGaA through internal coordination firstly made itself aware that GUK required capacity in India, secondly offered its capacity and thirdly accepted and therefore decided that GUK could build up its own production facility. In the Commission's view, while this rather suggests the actual exercise of control, it certainly cannot prove that Generics [UK] Limited acted independently on the market.

Finally, as confirmed by Merck KGaA, Generics [UK] Limited was integrated into the Merck Generics Group of companies forming together with the latter an integrated economic unit.²⁰⁸³ As explained in section 3.3, in the period concerned Generics [UK] Limited acted as the operative lead company and raw material support group for the entire Merck Generics Group in the EEA,²⁰⁸⁴ and "was delivering all the services to all its sister companies" of the Merck Generic Group.²⁰⁸⁵ However, regarding the Merck Generics Group, the Commission considers that Merck KGaA has not substantiated and proven, for instance by submitting cogent documentary evidence, that it acted independent from Merck KGaA on the market.²⁰⁸⁶

- (1249) Third, even though it is true that Generics [UK] Limited had a different logo from Merck KGaA (whereas the "Merck generics" used a Merck logo), the General Court has held that "... it cannot be inferred a contrario on the basis of that case-law that it is sufficient [...] that a company] has its own name and logo, distinct from those used by its parent company, for the conclusion to be drawn that the parent company does not exert decisive influence over the subsidiary".²⁰⁸⁷

lawyers instead of Merck KGaA's legal department. However, these elements are insufficient to show that Generics [UK] Limited acted independently on the market considering the evidence of Merck KGaA's actual exercise of control as analysed in recital (1247) above.

²⁰⁸⁰ Case T-392/09 *I. garantovaná a.s. v Commission*, judgment of 12 December 2012, paragraph 48.

²⁰⁸¹ See ID 5960, pages 377-378.

²⁰⁸² ID 6991, page 9.

²⁰⁸³ See ID 6991, pages 4-5.

²⁰⁸⁴ See recital (30) above.

²⁰⁸⁵ See recital (30) above.

²⁰⁸⁶ In particular, Merck KGaA failed to provide a comprehensive list of management minutes and reports of Merck KGaA and of the Merck Generics Group to prove that the parent Merck KGaA did not exercise actual control over the Merck Generics Group, and that the latter acted independently on the market.

²⁰⁸⁷ Case T-392/09 *I. garantovaná a.s. v Commission*, judgment of 12 December 2012, paragraph 56.

(1250) Fourth, Merck KGaA claimed to have obtained no or only little information on Generics [UK] Limited.²⁰⁸⁸ However, Merck KGaA was not only informed of Generics [UK] Limited's agreements with Lundbeck as demonstrated by the fact that the employee of Merck KGaA in charge of [function]* in the period concerned²⁰⁸⁹ was made aware of the United Kingdom agreement with Lundbeck within days after it had been concluded²⁰⁹⁰ and of the agreement with Lundbeck regarding the EEA excluding the United Kingdom even before that agreement was concluded.²⁰⁹¹ In addition, with respect to both agreements that employee, formally part of Merck KGaA, was personally managing Merck Generics' commercial relationship with Natco during the term of the agreements. In fact, as "Responsible" of "[...]"* of "Merck Generics" (using, however, an email address of Merck KGaA) he sent a letter to Natco explaining why Merck Generics had withdrawn Natco citalopram from the market throughout the EEA by concluding those agreements with Lundbeck. He also explained to Natco Merck Generics' future strategy with respect to Natco citalopram launch after expiry of the agreements.²⁰⁹² This person, as mentioned, reported with respect to his business targets to Merck KGaA's [...]*. This shows direct involvement of Merck KGaA in the illegal conduct. Also, one of the [...]* of Generics [UK] Limited at the time was simultaneously [...]* of Merck Generics Holding GmbH, one of the intermediate parent companies of Generics [UK] Limited below Merck KGaA. This same person was in charge of [...]*. The [employee function]* at Generics [UK] Limited who, as mentioned, was directly involved in both agreements with Lundbeck, reported to this person.²⁰⁹³ That [employee function]* developed and coordinated in this capacity the business of the Merck Generics Group [...]*.²⁰⁹⁴ In the words of Merck KGaA, "*we assume that he had full responsibility for MG's [...]* business.*"²⁰⁹⁵ Also, it was this person who signed Generics [UK] Limited's agreement for other EEA Contracting Parties than the United Kingdom.²⁰⁹⁶ As indicated in recital (1248), Merck KGaA failed to demonstrate independence of the Merck Generics Group from Merck KGaA. Finally, shortly after the conclusion of the agreement related to the United Kingdom in February 2002, Merck KGaA's press service inquired with Generics [UK] Limited, what this agreement was about.²⁰⁹⁷ This query, although not evidence of any business strategy instructions given by Merck KGaA to Generics [UK] Limited, nevertheless shows that Merck KGaA operated as a conglomerate regarding communication together with its subsidiary Generics [UK] Limited, which is consistent with the existence of an economic unit, even if Generics [UK] Limited had enjoyed considerable autonomy.

²⁰⁸⁸ See ID 5960, pages 381-385.

²⁰⁸⁹ ID 1707, page 1.

²⁰⁹⁰ ID 673, page 316. Furthermore, the majority of the Directors of Merck Generics Holding GmbH's Board of Directors were copied into that e-mail communication.

²⁰⁹¹ ID 673, pages 386-387. Again, the majority of Merck Generics Holding GmbH's Board of Directors was copied into that e-mail communication.

²⁰⁹² See recital (362) above.

²⁰⁹³ ID 1707, page 1.

²⁰⁹⁴ ID 1689, page 1.

²⁰⁹⁵ ID 1707, page 1.

²⁰⁹⁶ ID 1977, page 1.

²⁰⁹⁷ See ID 1024, page 72. See recital (279) above.

- (1251) Finally, Generics [UK] Limited's financial accounts were consolidated with Merck KGaA's accounts in the period concerned. Furthermore, in 2002, Merck KGaA concluded a domination and profit transfer agreement ("DPL-Agreement") with Merck Generics Holding GmbH, of which Generics [UK] Limited was an (indirect) subsidiary.²⁰⁹⁸ In reply to the Statement of Objections, Merck argued that the "*only reason for concluding the (boilerplate) DPL-Agreement was to establish fiscal unity with Merck KGaA and to facilitate the preparation of profit and loss accounts.*"²⁰⁹⁹ However, the General Court has ruled 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*".²¹⁰⁰ This must all the more apply to domination and profit transfer agreements.
- (1252) Considering all these elements, the Commission concludes that Merck KGaA did not adduce sufficient evidence to show that Generics [UK] Limited or Merck Generics Holding GmbH acted independently on the market.
- (1253) As mentioned in recital (33) above, in October 2007 Merck KGaA sold the Merck Generics business, including Generics [UK] Limited, to the United States undertaking Mylan. Generics [UK] Limited has continued to exist as a separate legal entity within the undertaking Mylan. Given that the company Generics [UK] Limited negotiated, concluded and implemented the two agreements with Lundbeck, as the facts in section 7.2 indicate, and is at present no longer part of the undertaking Merck, the Commission considers it appropriate to hold Generics [UK] Limited jointly and severally liable for the infringement committed by the undertaking Merck. This Decision is therefore addressed to Generics [UK] Limited.
- (1254) Moreover, as the company Merck KGaA still exists, the Commission considers it appropriate to hold Merck KGaA, as the parent company managing the undertaking Merck at the time of the infringement, responsible for the infringement which the undertaking Merck committed in this case.
- (1255) For the infringement committed by the undertaking Merck, this Decision is therefore addressed both to Generics [UK] Limited and Merck KGaA.

15.4. Arrow

- (1256) As the facts in section 7.4 indicate, Arrow's agreement with Lundbeck regarding the United Kingdom was entered into by the Arrow Group through the United Kingdom subsidiaries Arrow Generics Limited and Resolution Chemicals Limited. Together Arrow Generics Limited and Resolution Chemicals Limited were referred to as "*ARROW*" in the agreement. ARROW accepted the commitments in the agreement "*on its own behalf and on behalf of all associated and related entities*", meaning the entire Arrow Group. The agreement was signed for ARROW by [employee name]*²¹⁰¹, who also played a prominent role in the negotiation and implementation of the agreement. [...] was at that time [...] of Arrow Generics Limited and Resolution Chemicals Limited.²¹⁰² [...] was at the same time [...] of Arrow Group

²⁰⁹⁸ See ID 5982.

²⁰⁹⁹ See ID 5960, pages 385-386; see also ID 6991, pages 4-5.

²¹⁰⁰ Case T-392/09 *I. garantovaná a.s. v Commission*, judgment of 12 December 2012, paragraph 57.

²¹⁰¹ ID 1325, page 9.

²¹⁰² ID 610, page 16.

A/S, which at this time [...]*. ²¹⁰³ As Arrow informed the Commission, *"in practice [...] performed the role of [employee function]* at that time."* ²¹⁰⁴

- (1257) The agreement with Lundbeck regarding Denmark was entered into by two representatives of the parent company Arrow Group A/S. However, the facts in section 7.5 show that [employee name]*, who had signed the United Kingdom agreement, also played a role in the negotiation of the Danish agreement. ²¹⁰⁵ It is clear from these facts that the Arrow group of companies operated as a single economic actor in concluding the United Kingdom and Danish agreements, including through the actions of its [employee function]* in practice.
- (1258) As mentioned in section 3.4, at the time of signing of the United Kingdom agreement, Arrow Group A/S was the 100% parent company of Arrow Generics Limited and Resolution Chemicals Limited. In light of this 100% ownership, the Commission applied the presumption in the Statement of Objections that Arrow Groups A/S exercised a decisive influence at that time over the commercial policy of Arrow Generics Limited and Resolution Chemicals Limited. ²¹⁰⁶ Such presumption has not been rebutted. ²¹⁰⁷
- (1259) In August 2003, Arrow Group A/S was re-named Arrow Group ApS. Arrow has confirmed that Arrow Group ApS is the legal successor to Arrow Group A/S. ²¹⁰⁸
- (1260) Given that:

²¹⁰³ ID 1325, page 4.

²¹⁰⁴ ID 1991, page 1.

²¹⁰⁵ See for instance ID 1327, mentioned in recital (451), showing that a draft of the Danish agreement was sent by Lundbeck to [employee name]* in the United Kingdom on 11 March 2002. It should be noted that until 27 May 2002, a few days before the actual signing of the Danish agreement on 3 June 2002, draft texts of the Danish agreement mentioned Arrow Generics Limited and Resolution Chemicals Ltd as the legal entities signing for the Arrow Group. See recital (455). See also ID 610, page 16.

²¹⁰⁶ Arrow Group A/S owned throughout the period of the operation of the United Kingdom agreement (that is to say until 20 October 2003) 100% of Resolution Chemicals Ltd. After Arrow had entered the United Kingdom agreement with Lundbeck on 24 January 2002, Arrow Group A/S diluted its ownership of Arrow Generics Limited from 100% to 76%, 24% of the shares being distributed among individual key staff members of Arrow Generics Limited. This happened in February 2002 and lasted until 2009, Arrow has confirmed to the Commission that this share dilution *"did not lead to any change in the measure of actual control exerted by Arrow Group ApS [Arrow Group ApS is the legal successor to Arrow Group A/S, see recital (1259) below] over Arrow Generics Limited's commercial behaviour."* See ID 1591, page 1. As Arrow explained to the Commission: *"...Arrow Generics Limited is an English incorporated company and under English company law, key decisions (termed Special Resolutions) require the approval of 75% of shareholders. Given that Arrow Group ApS' shareholding in Arrow Generics Limited was diluted to 76%, Arrow Group ApS retained the ability to pass any Special Resolution and equally, the ability to block any Special Resolutions that other shareholders may propose. Further, the Articles of Association of Arrow Generics Limited have never conferred any special or veto rights on minority shareholders and no Shareholder Agreement has existed conferring such rights. Arrow Group ApS' 76% shareholding therefore continued to give Arrow Group ApS sole control over Arrow Generics Limited at all material times."* See ID 1591, page 1.

²¹⁰⁷ It follows from settled case-law that, in the particular case in which a parent company holds all or almost all of the capital in a subsidiary which has committed an infringement of the European Union competition rules, there is a rebuttable presumption that that parent company exercises an actual decisive influence over its subsidiary. In such a situation, it is sufficient for the Commission to prove that all or almost all of the capital in the subsidiary is held by the parent company in order to take the view that the presumption is fulfilled, see most recently, Judgment of the ECJ of 8 May 2013 in Case C-508/11P *Eni SpA v Commission*, not yet reported, paragraph 47.

²¹⁰⁸ ID 1325, page 4.

- Arrow Group A/S concluded the Danish agreement;
- Arrow Group A/S headed the Arrow group of companies at the time of the conclusion of the United Kingdom and Danish agreements;
- Arrow Group A/S owned at that time 100% of the shares of Arrow Generics Limited and Resolution Chemicals Limited, which signed the United Kingdom agreement; and
- the United Kingdom agreement was concluded on behalf of the Arrow group of companies,

the Commission considers it appropriate to hold Arrow Group ApS, the legal successor of Arrow Group A/S, responsible for the infringement which the undertaking Arrow committed in this case.

- (1261) The Commission also considers it appropriate to hold Arrow Generics Limited responsible for the United Kingdom agreement. As Arrow stated in reply to the Commission's request for information of 19 March 2010: *"Once the Arrow Group started trading, Arrow's project to develop and launch a finished citalopram product was led by Arrow Generics Limited."*²¹⁰⁹ This United Kingdom subsidiary of Arrow Group A/S co-signed the United Kingdom agreement on behalf of the Arrow Group of companies. It accepted the commitment under this agreement not to sell in the United Kingdom *"the said Citalopram"* or *"any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights..."* The Commission therefore holds Arrow Generics Limited jointly and severally liable for the United Kingdom part of the infringement committed by the undertaking Arrow.
- (1262) Finally, the Commission also holds Resolution Chemicals Limited jointly and severally liable for the United Kingdom part of the infringement committed by the undertaking Arrow. As the facts in section 12.4 indicate, Resolution Chemicals Limited signed the United Kingdom agreement on behalf of the Arrow Group of companies. In this agreement it accepted not to manufacture citalopram that Lundbeck alleged to be infringing.²¹¹⁰
- (1263) In its reply to the Statement of Objections, Resolution argued that it should not be held liable for the United Kingdom agreement, based on several arguments:
- (1264) Firstly, Resolution argued that while [employee name]* of Arrow had signed the original agreement and the first addendum twice, once for Arrow Generics Limited and once for Resolution Chemicals Limited, [...] had signed the second addendum

²¹⁰⁹ ID 610, page 5. See also recital (373).

²¹¹⁰ The fact that the United Kingdom agreement was signed for Arrow Generics Limited and Resolution Chemicals Limited by the same person [employee name]*, and at the same time [...] of Arrow Generic Limited and Resolution Chemicals Limited) contributes to show that the parent was involved in the day-to-day business of its subsidiary and exercised decisive influence. However, this does not exonerate the subsidiary. According to the Court of Justice (judgment of 17 May 2013 in Case T-146/09, *Parker ITR v Commission*, paragraph 151, not yet reported), "[i]t must be borne in mind that, according to settled case-law, for an infringement of Article 85 EC to be attributed to an undertaking it is not necessary for there to have been action by, or even knowledge on the part of, the partners or principal managers of the undertaking concerned by that infringement; action by a person who is authorised to act on behalf of the undertaking suffices (see, as regards the EC Treaty, Joined Cases 100/80 to 103/80 *Musique Diffusion française and Others v Commission* [1983] ECR 1825, paragraph 97, and Case T-15/99 *Brugg Rohrsysteme v Commission* [2002] ECR II-1613, paragraph 58)."

only once, at the place indicated for Arrow Generics Limited.²¹¹¹ This would mean that Resolution *"was not a party to the second addendum."*²¹¹² While it is true that there is no separate signature on the second addendum for Resolution, the Commission does not agree that it would follow from this that Resolution was not a party to this second addendum. The parties to the agreement knew very well that [employee name]* represented both Arrow Generics Limited and Resolution Chemicals Limited and that [...] signature, whether written once or twice, would cover both legal entities. The second addendum explicitly indicates as party to the agreement *"Resolution Chemicals Ltd, By [[employee name]* of Arrow Group], duly authorised to sign."* Also the cover page of the second addendum explicitly mentions *"Resolutions Chemicals Ltd"* [sic] as party to the agreement. There is no indication in the case file whatsoever, nor has any indication been brought to the attention of the Commission by Resolution, that parties would have intended not to make Resolution a party to the second addendum. In substance, there is no difference whatsoever in terms of the commitments accepted by Resolution and the other Arrow entities between the original agreement, the first addendum and the second addendum. The second addendum includes, for instance, the obligation on Resolution not to make any citalopram which Lundbeck alleged to infringe its patents.

- (1265) Secondly, Resolution argued that *"[t]he link to Resolution is based solely on the actions of a single non-executive director who was in reality acting as [employee function]* of Arrow [meant is [employee name]*]."*²¹¹³ The Commission observes, in this respect, that the liability of Resolution does not merely follow from the actions of [employee name]*. If this had been the case, the Commission could just as well have held all other Arrow subsidiaries liable. The liability of Resolution follows, firstly, from the fact that its name figures expressly as a party to the United Kingdom agreement and, secondly, from the fact that in this agreement Resolution, as producer of APIs within the Arrow Group, accepted the obligation for the term of the agreement not to make citalopram which Lundbeck alleged to infringe its patents. The fact that during the term of the agreement Resolution was not yet producing marketable citalopram is irrelevant, as this was not known with certainty when parties concluded the agreement in January 2002.
- (1266) It is also not possible to dissociate Resolution from the actions of the [employee name]* of Arrow, who was also [company function]* of Resolution. This person had the power to - and did - represent Resolution in the contacts and the United Kingdom agreement with Lundbeck. That the [employee function]* of Resolution allegedly knew nothing of the United Kingdom agreement is more a sign that key decisions of Resolution were taken by [employee name]* without any further consultation than of the claim that Resolution was not involved in the infringement. Also, the fact that Resolution was 100% owned by Arrow Group A/S is not a reason for not including Resolution as an addressee, given that Resolution was a party in its own right to the agreement and accepted obligations under the agreement which pertained only to itself.²¹¹⁴

²¹¹¹ ID 8, pages 240, 245, 251 and 252.

²¹¹² ID 4937, page 2.

²¹¹³ ID 4937, page 2.

²¹¹⁴ In its reply to the Statement of Objections of 15 October 2012, Resolution Chemicals put forward the additional argument that it should not be held liable because *"no payments [were] made from Lundbeck*

- (1267) The Commission does, on the other hand, accept Resolution's argument that Resolution should not be held liable for the Danish agreement. Having reviewed the evidence, the Commission accepts that there is too little factual evidence to hold Resolution liable for the Danish Agreement, which was concluded by Arrow Group ApS. The same applies for Arrow Generics Limited (which in any case still belongs to the same undertaking as Arrow Group ApS, which is held liable for the Danish agreement).
- (1268) For the infringement committed by the undertaking Arrow, this Decision is therefore addressed to Arrow Group ApS for the entire infringement, and to Arrow Generics Limited and Resolution Chemicals Limited for the United Kingdom agreement only, for which the three entities are held jointly and severally liable.

15.5. AlphaPharma

- (1269) As the facts described in section 7.6 indicate, AlphaPharma's agreement with Lundbeck regarding the EEA was signed by AlphaPharma ApS. The agreement contained obligations not only on AlphaPharma ApS but also on AlphaPharma's affiliates, meaning the entire group of AlphaPharma companies. As mentioned in section 3.5, AlphaPharma ApS at the time of the conclusion of this agreement and during its operation owned a number of subsidiaries of the AlphaPharma group of companies in EEA Contracting Parties.
- (1270) AlphaPharma ApS itself was at that time indirectly 100% owned by AlphaPharma Inc., a United States company. In light of the 100% ownership by AlphaPharma Inc. of AlphaPharma ApS, the Commission presumes that AlphaPharma Inc. exercised a decisive influence over the commercial policy of AlphaPharma ApS. The Commission notes, moreover, that [employee function]* of AlphaPharma ApS, who signed the agreement with Lundbeck, was at the same time [employee function]* and [employee function]* at AlphaPharma Inc. between 2000 and 2004.²¹¹⁵
- (1271) As mentioned in recital (52) above, AlphaPharma Inc. was acquired by another United States company, King Pharmaceuticals, Inc. in December 2008. King Pharmaceuticals in turn was acquired by the American company Pfizer Inc. in February 2011. As for AlphaPharma Inc., it was initially changed into a limited liability company, AlphaPharma, LLC, in April 2010. However, on 15 April 2013, AlphaPharma, LLC changed its name to Zoetis Products LLC as part of re-structuring that consolidated Pfizer's animal health businesses under a new publicly listed company Zoetis Inc.
- (1272) The Commission considers it appropriate in this case to hold Zoetis Products LLC, as legal successor to AlphaPharma Inc., the parent company of the undertaking AlphaPharma at the time of the infringement, responsible in this case for the infringement committed by the undertaking AlphaPharma.

With respect to AlphaPharma ApS, as indicated in recital (51) above, this company was sold by AlphaPharma Inc. in March 2008 to an international investment group after which the company was first renamed Axellia Pharmaceuticals ApS and then, as of 2010, Xellia Pharmaceuticals ApS. As the facts in section 7.6 indicate that AlphaPharma

²¹¹⁵ *to Resolution*". See ID 4937, page 6. This argument has no bearing since the payment was made to "ARROW". Under the agreement, ARROW refers to both Arrow Generics and Resolution Chemicals. ID 1005, page 17. See also ID 1599, page 7.

ApS not only signed the agreement with Lundbeck but also played a prominent role in the negotiation and implementation of the agreement and is moreover no longer part of the same undertaking as Alpharma Inc, the Commission considers it appropriate in this case to hold Xellia Pharmaceuticals ApS, as legal successor to Alpharma ApS, jointly and severally liable for the infringement committed by the undertaking Alpharma.

- (1273) In the period concerned, A.L. Industrier AS' overall shareholding in Alpharma, Inc. amounted to between around 23% and 26,8%. Meanwhile A.L. Industrier AS held and exercised special control rights of Alpharma, Inc. attached to its B-shares.

A.L. Industrier AS and Alpharma formed an economic unit

- (1274) 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 I-6375, 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".²¹¹⁶ In this respect, all the relevant economic, organisational and legal links which tie the subsidiary to the parent company have to be considered.²¹¹⁷ 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."²¹¹⁸ Nor is actual knowledge of the parent company necessary regarding the anticompetitive conduct.²¹¹⁹ "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".²¹²⁰ In particular, the economic unit may have an informal basis in form of personal links between the two companies.²¹²¹ Relevant is namely whether "two companies were controlled by the same persons, who held key functions within the companies' management boards".²¹²² What ultimately matters is economic reality.²¹²³ When the economic actors can take, in their internal

²¹¹⁶ See most recently, order of the Court of Justice of 15 June 2012 in Case C-494/11P *Otis Luxembourg Sàrl and others v Commission*, paragraph 43, and judgment of the General Court of 14 March 2013 in Case T-587/08 *Fresh del Monte Produce, Inc. v Commission*, paragraph 56.

²¹¹⁷ Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraph 74.

²¹¹⁸ AG Kokott's opinion in Case C-97/08, *Akzo Nobel v Commission* of 23 April 2009, paragraphs 89 and 91. See also Case C-97/08P, *Akzo Nobel NV and others (Choline Chloride) v Commission*, [2009] ECR, I-8237, paragraph 73.

²¹¹⁹ Case C-97/08P, *Akzo Nobel NV and others (Choline Chloride) v Commission*, [2009] ECR, I-8237, paragraph 59.

²¹²⁰ AG Kokott's opinion in Case C-97/08, *Akzo Nobel v Commission* of 23 April 2009, paragraph 93.

²¹²¹ AG Kokott's opinion in Case C-440/11 P *Commission v Stichting Administratiekantoort Portielje and Gosselin Group NV* of 29 November 2012, paragraph 74.

²¹²² Case T-392/09 *I. garantovaná a.s. v Commission européenne*, judgment of 12 December 2012, paragraph 29.

²¹²³ AG Kokott's opinion in Case C-440/11 P *Commission v Stichting Administratiekantoort Portielje and Gosselin Group NV* of 29 November 2012, paragraph 72.

relationship with one another, advantage of the 'group privilege', they form an economic unit.²¹²⁴

(1275) The Commission considers that the body of evidence contained in recitals (43) to (49) shows that at least since 1994 A.L. Industrier AS operated as a single economic undertaking together with its subsidiary Alpharma, Inc., in particular but not only because of the strong personal links between the two companies.

(1276) As concerns the strong personal links, [...] ²¹²⁵, [...] ²¹²⁶ [...] ²¹²⁷ [...] ^{*}

The Commission observes that Alpharma Inc.'s board was involved in day-to-day business of Alpharma, a point which is in principle confirmed by A.L. Industrier AS itself.²¹²⁸

The minutes of Alpharma Inc.'s board meetings of the years 2002 and 2003 that were submitted to the Commission show that the six directors acted jointly and decisions were taken unanimously, together also with the rest of the board.²¹²⁹ Moreover, Alpharma, Inc.'s Contract Policy provided that the Board of Directors of Alpharma Inc. approved key commercial decisions even below the commercial value of Alpharma's contract with Lundbeck. Even though the existence of that Contract Policy is not proven for the time before June 2002, the Contract Policy certainly existed as of that date and showed rules allowing for a tight grip and control of the board over the business operation of Alpharma, Inc. in the period concerned.²¹³⁰ In fact, also before the 2002 Contract Policy, the preparation of the launch of specific pharmaceutical products (namely the business strategy including general contracts to be concluded in this respect), such as for instance Gabapentin, were discussed and authorised by Alpharma Inc.'s board.²¹³¹ In addition, A.L. Industrier AS held the majority of votes in Alpharma, Inc.'s shareholder meetings. Alpharma confirmed this economic reality to the SEC in its Form 10K by stating during the period concerned:

"As a result, A.L. Industrier, and ultimately [...] ^{}, can control the Company [Alpharma, Inc.]."*²¹³²

(1277) A.L. Industrier AS intended to obtain and maintain control over Alpharma, Inc., because when it merged its pharmaceutical activities into Alpharma, Inc. in 1994, it negotiated the continued holding of Class B-shares with preferential voting rights in Alpharma, Inc. Not only did it exercise these control rights. But it also created an extraordinarily strong personal link between the two companies [...] ^{*}:

²¹²⁴ AG Kokott's opinion in Case C-440/11 P *Commission v Stichting Administratiekantoor Portielje and Gosselin Group NV* of 29 November 2012, paragraphs 31 and 32; see also paragraph 50.

²¹²⁵ Excluding the A.L. Industrier AS shareholder meeting of 30 June 2003.

²¹²⁶ Whether or not under Norwegian corporate law, [...] ^{*} is therefore irrelevant. See in this respect A.L. Industrier AS' arguments in ID 6788, pages 4-7 and 10; ID 4921, pages 5-10.

²¹²⁷ The board acted by simple majority, see ID 2562, pages 4-5 and 17-18.

²¹²⁸ See ID 6788, page 2

²¹²⁹ See ID 6559, pages 4-56.

²¹³⁰ See recital (48) above.

²¹³¹ See, for example, Alpharma, Inc.'s Minutes of The Regular Board Meeting of the Board of Directors of January 31, 2002 and February 1, 2002, ID 6559, pages 53-54. In reply to the Letter of Facts, A.L. Industrier AS pointed out that Alpharma, Inc.'s board only discussed the "strategy to prepare for commercial sale". However, it neither reviewed nor accepted any specific contract. See ID 6974, page 7.

²¹³² See recital (46).

"[...]*)"2133

- (1278) In particular, [...] the A.L. Industrier AS group of companies including Alpharma, Inc. which together therefore formed an economic unit.

A.L. Industrier AS was not a mere financial investor

- (1279) A.L. Industrier AS argued that in 1994, it became a mere financial investor. Firstly, paragraph two of A.L. Industrier AS' articles of association was amended and provided that "*the corporate purpose of the company is to conduct investment activities and other activities related thereto*".²¹³⁴ This amendment reflected A.L. Industrier AS' board decision at the time that Alpharma, Inc. should act as a group parent for the pharmaceutical business.²¹³⁵ Secondly, "[a]ll subsidiaries of A.L. Industrier AS were set up to fully manage their own business without involvement [...] of A.L. Industrier AS. A.L. Industrier AS did not take part in the management of the individual business units or legal entities other than through the appointment of board members."²¹³⁶ However, the General Court clarified in this respect 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."²¹³⁷ The Commission notes that A.L. Industrier AS was until 1994 a pharmaceutical company actively managing its own business, and its shareholdings. In 1994, it merged this business into its former subsidiary Alpharma, Inc. Unlike a financial investor, therefore, it strategically bundled all its pharmaceutical assets in Alpharma, Inc. to achieve more growth and synergies under the management of its own former and future management. First, an important personal link consisted of [...]*, which signed the agreement with Lundbeck.²¹³⁸ Secondly, the nomination of directors to Alpharma, Inc.'s Board of Directors, [...]*, showed that A.L. Industrier AS clearly did not act as a mere financial investor by refraining from any involvement in Alpharma Inc.'s management and control.²¹³⁹
- (1280) In this respect, it is irrelevant that A.L. Industrier AS' Board of Directors generally did not give any specific instructions, issue guidelines or exercise any right of co-determination regarding Alpharma, Inc.'s market conduct.²¹⁴⁰ The General Court confirmed in this respect that "...greater or lesser – degree of autonomy of a subsidiary in its own commercial management is not necessarily incompatible with the parent company's decisive influence..."²¹⁴¹ In fact, unlike for a financial investor, the exercise of control was an important issue for A.L. Industrier AS: when A.L. Industrier AS risked losing its control over Alpharma, Inc. in 2000 in view of a

²¹³³ See recital (45).

²¹³⁴ ID 2561, page 1.

²¹³⁵ See recital (43).

²¹³⁶ ID 2555, page 9.

²¹³⁷ Case T-392/09 *I. garantovaná a.s. v Commission*, judgment of 12 December 2012, paragraph 52.

²¹³⁸ See recital (45).

²¹³⁹ In view of these appointments, it is irrelevant that A.L. Industrier AS had just one [employee function]* left working for A.L. Industrier AS [...]*. That [employee function]*, as explained, created another personal link, because was at the same time [employee function]*, see recital (46). For A.L. Industrier AS' argument see ID 4921, page 4.

²¹⁴⁰ AG Kokott's opinion in Case C-440/11 P *Commission v Stichting Administratiekantoor Portielje and Gosselin Group NV* of 29 November 2012, paragraph 55.

²¹⁴¹ Case T-392/09 *I. garantovaná a.s. v Commission européenne*, judgment of 12 December 2012, paragraphs 48.

possible dilution of voting rights in relation to an envisaged take-over of another company by Alpharma Inc., it "*instruct[ed] the board members of Alpharma Inc appointed by the B-shares to consult the board of A.L. Industrier before they decided to issue so many A shares that A.L Industrier lost the majority vote.*"²¹⁴² Clearly, therefore, A.L. Industrier AS did not abstain from *any* involvement in controlling Alpharma, Inc.

- (1281) Moreover, Alpharma, Inc. continuously reported to the SEC and its shareholders that "*A.L. Industrier, and ultimately [...]*, can control the Company*".²¹⁴³ Secondly, it informed that in its "*various transactions*" with A.L. Industrier AS "*from time to time*", "*conflicts of interest are present*", although admittedly these transactions appear to have been very few and only of minor commercial importance.²¹⁴⁴ However, as concerns A.L. Industrier AS' purchase of a convertible subordinated note which was converted into Class B-shares in 2001,²¹⁴⁵ although it is certainly correct that Alpharma, Inc. could have raised debts "*by using various methods*", as A.L. Industrier AS argued, in the present case it chose the specific way [...]*. That privilege can only be explained by the fact that A.L. Industrier AS controlled Alpharma Inc. already, because it held the other controlling Class B-shares. This way, it would continue to control Alpharma, Inc. Thirdly, the transfer of assets between Alpharma, Inc. and A.L. Industrier AS including its subsidiaries was reported as "*a transfer and exchange between companies under common control*".²¹⁴⁶ Finally, the financial accounts of Alpharma Inc. were in the period concerned consolidated into the financial accounts of A.L. Industrier AS.²¹⁴⁷ As confirmed by the General Court, the consolidation of financial accounts "*certainly corroborates*" that a company exerted decisive influence "*even if that consolidation is [...] mandatory under the national law applicable*".²¹⁴⁸ This is all the more true for the conclusion of "*various transactions*", where "*conflicts of interest are present*" and the implementation of transactions "*under common control*".
- (1282) A.L. Industrier AS further argued with reference to *Alliance One*, paragraph 27 that the Commission must prove that A.L. Industrier AS was constantly informed about Alpharma, Inc.'s practices, which A.L. Industrier AS alleged did not happen. However, A.L. Industrier AS misreads the Commission's arguments in that case.²¹⁴⁹ In fact, paragraph 27 makes clear that "*an assumption*" of an economic unit "*can be further strengthened by 'specific factors arising in individual cases'*" including by the fact that a parent company is constantly informed about the subsidiaries practices or that the parent company "*holds the majority of the capital of that subsidiary at the*

²¹⁴² See recital (44).

²¹⁴³ See recital (46).

²¹⁴⁴ See recital (44).

²¹⁴⁵ See recital (44).

²¹⁴⁶ See recitals (43).

²¹⁴⁷ ID 2555, page 8.

²¹⁴⁸ Case T-392/09 *I. garantovaná a.s. v Commission*, judgment of 12 December 2012, paragraph 57.

²¹⁴⁹ Moreover, as explained by Advocate General Kokott, "*...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.*" See AG Kokott's opinion in Case C-97/08, *Akzo Nobel v Commission* of 23 April 2009, paragraphs 89 and 91. See also Case C-97/08P, *Akzo Nobel NV and others (Choline Chloride) v Commission*, [2009] ECR, I-8237, paragraph 73.

time when the infringement is committed".²¹⁵⁰ This latter condition is economically met in the present case, because A.L. Industrier AS held the majority of voting rights in Alpharma, Inc., which created economic unity comparable to holding the majority of capital. Moreover, the personal link created through [...] must be taken into consideration, as explained in recital (1276) above.²¹⁵¹ The economic unit results in particular from this personal link between A.L. Industrier AS and Alpharma.

(1283) A.L. Industrier AS claimed that "*the Commission seems to introduce a new legal concept: Actual (de facto) control at the shareholders meeting.*" Also, the Commission would have misunderstood Norwegian and U.S. corporate law.²¹⁵² The Commission observes that decisive for whether or not two legal entities form together an economic unit is, as explained in recital (1274), economic reality.²¹⁵³ Advocate General Kokott showed in her opinion on the Case C-440/11 P²¹⁵⁴ that the economic unit may also have an informal basis consisting of personal links between the two companies. Economic reality controls not company law. The personal link between A.L. Industrier AS and Alpharma, Inc. has several components:

- [...] *;
- The shareholder meetings of A.L. Industrier AS were under the control of [...] *. A.L. Industrier AS had the right to appoint 6 out of 9 members of Alpharma, Inc.'s board. [...] *.
- According to the Court in Case C-508/11 P²¹⁵⁵, the appointment of member of the board is at the core of the prerogatives of a parent company which enables the parent company to exercise decisive influence;
- The then [employee function] * of A.L. Industrier AS was at the same time a [employee function] * of Alpharma ApS.

²¹⁵⁰ See Case T-24/05 *Alliance One International, Inc., formerly Standard Commercial Corp. and Others v Commission*, paragraph 27:

"– according to settled case-law, where the subsidiary is wholly owned by the parent company, it can legitimately be assumed that the parent company in fact exercises decisive influence over its subsidiary's conduct (Case 107/82 *AEG-Telefunken v Commission* [1983] ECR 3151, paragraph 50; Case C-286/98 P *Stora Kopparbergs Bergslags v Commission* [2000] ECR I-9925, paragraph 29; Joined Cases T-305/94 to T-307/94, T-313/94 to T-316/94, T-318/94, T-325/94, T-328/94, T-329/94 and T-335/94 *Limburgse Vinyl Maatschappij and Others v Commission* ('PVC II') [1999] ECR II-931, paragraphs 961 and 984);

– such an assumption can be further strengthened by 'specific factors arising in individual cases';

– in the case of subsidiaries which are not wholly owned, the Court of Justice has ruled that a parent company can influence its subsidiary's policy if it holds the majority of the capital of that subsidiary at the time when the infringement is committed (*Imperial Chemical Industries v Commission*, paragraph 136) or where it is 'constantly' informed about the subsidiary's practices and directly determines its conduct (*AEG-Telefunken v Commission*, paragraph 52);"

²¹⁵¹ The General Court has confirmed in Case T-197/06 *FMC Corp v Commission*, judgment of 16 June 2011, paragraph 146, that no specific information policy is required, when a "chairman and managing director" in one company is at the same time "vicepresident" of the other. In that case, the same individual "was therefore in a position to inform the latter about the commercial policy of the subsidiary".

²¹⁵² See ID 6974, in particular page 6.

²¹⁵³ See recital (1274).

²¹⁵⁴ AG Kokott's opinion in Case C-440/11 P *Commission v Stichting Administratiekantoor Portielje and Gosselin Group NV* of 29 November 2012, paragraph 50.

²¹⁵⁵ Case C-508/11 P *Eni SpA v Commission*, paragraphs 65-67, not yet reported.

- (1284) For these reasons, A.L. Industrier AS and Alpharma constituted an economic unit at the relevant time.

The independence of several members of the Board of Alpharma is irrelevant

- (1285) A.L. Industrier AS finally argued that "[t]he crucial issue [...] is whether [...] Alpharma, Inc.'s] board members managed the business as independent board members or whether they were under the instruction of A.L. Industrier."²¹⁵⁶ A.L. Industrier AS submitted that the majority of them were independent "under Delaware Company law". In its view, "[t]he parent, once having elected directors, does not have a right thereafter to interfere... The parent thus lacks the right to control through interim instructions." Under these rules, two thirds of the board members were found to be independent.²¹⁵⁷ The Commission notes that Alpharma, Inc.'s [employee function]*, who was both [employee function]* of A.L. Industrier AS and [employee function]*, was not considered independent by Alpharma, Inc.'s board because of the "material relationship with the listed company".²¹⁵⁸ [Employee function]* therefore created economic unity between both companies irrespective of the other board members. Industrier AS' argument fails to consider this personal link which is key. Again, references to Norwegian or U.S. corporate law, which A.L. Industrier AS referred to, are irrelevant in this respect. Decisive is whether A.L. Industrier AS, and [employee function]*, "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",²¹⁵⁹ considering those personal links between the two companies.²¹⁶⁰ As explained, contrary to A.L. Industrier AS, personal links based on [...] of [employee function]* of both companies, [...] created an economic unit between A.L. Industrier AS and Alpharma, Inc.

Conclusion

- (1286) A.L. Industrier AS is therefore held jointly and severally liable for the infringement committed by Alpharma.
- (1287) For the infringement committed by the undertaking Alpharma, this Decision is therefore addressed both to Zoetis Products LLC, Xellia Pharmaceuticals ApS and A.L. Industrier AS.

15.6. Ranbaxy

- (1288) Ranbaxy's agreement with Lundbeck regarding the EEA was signed by the Indian company Ranbaxy laboratories Limited, the then parent company of the Ranbaxy group of companies. Ranbaxy's United Kingdom subsidiary, Ranbaxy (UK) Limited, which had originally been mentioned in drafts of the agreement as co-signatory, did

²¹⁵⁶ ID 6788, page 2.

²¹⁵⁷ ID 6788, page 3.

²¹⁵⁸ ID 6559, pages 13-14; ID 6788, page 3; ID 6974, page 6. In total in 2003, 4 out of the 6 directors that A.L. Industrier AS had nominated in May 2003 were found to be independent under the proposed New York Stock Exchange Corporate Governance Standards (Rule 303A-01, which was later approved by the SEC on 4 November 2003, see <http://www.nyse.com/pdfs/finalcorpgovrules.pdf>). ID 6559, pages 13-14, 17-18 and 23. The Commission notes that even if [...] (see, for instance, ID 6788, page 15: vote of 1 April 2001 of A.L. Industrier AS' board regarding financing of Alpharma, Inc.'s envisaged acquisition of Faulding), fact remains that [...]*.

²¹⁵⁹ AG Kokott's opinion in Case C-97/08, *Akzo Nobel v Commission* of 23 April 2009, paragraph 93.

²¹⁶⁰ AG Kokott's opinion in Case C-440/11 P *Commission v Stichting Administratiekantor Portielje and Gosselin Group NV* of 29 November 2012, paragraph 74.

not in the end sign the agreement. As the facts described in section 7.7 indicate, it did, however, play a prominent role in the negotiation and implementation of the agreement.

- (1289) As described in section 3.6, since June 2008, the undertaking Ranbaxy has been a member of the Japanese Daiichi Sankyo Group. However, Ranbaxy Laboratories Limited has kept its legal personality within that group. As the company Ranbaxy Laboratories Limited still exists, the Commission considers it appropriate to hold Ranbaxy Laboratories Limited, as the parent company of the undertaking Ranbaxy at the time of the infringement, responsible for the infringement which the undertaking Ranbaxy committed in this case.
- (1290) Moreover, given that Ranbaxy (UK) Limited played a prominent role in the negotiation and implementation of the agreement with Lundbeck, and taking into account that Ranbaxy Laboratories Limited is not located in the EEA, the Commission considers it appropriate to hold Ranbaxy (UK) Limited jointly and severally liable for the infringement committed by the undertaking Ranbaxy in this case.
- (1291) For the infringement committed by the undertaking Ranbaxy, this Decision is therefore addressed both to Ranbaxy Laboratories Limited and Ranbaxy (UK) Limited.

16. DURATION OF THE INFRINGEMENTS

- (1292) For each of the four infringements identified in this Decision²¹⁶¹, the infringement lasted at least from the date of conclusion of the (first) agreement until the expiry date of the (longest lasting) agreement, as follows:
- the set of agreements between Lundbeck and Merck: from 24 January 2002 (the date of conclusion of the agreement regarding the United Kingdom) until at least 1 November 2003 (the date of expiry of the agreement regarding the United Kingdom), a period of one year and nine months²¹⁶²;
 - the set of agreements between Lundbeck and Arrow: from 24 January 2002 (the date of conclusion of the agreement regarding the United Kingdom) until at least 20 October 2003 (the date of expiry of the agreement regarding the United Kingdom)²¹⁶³, a period of one year and eight months;
 - the agreement between Lundbeck and Alpharma: from 22 February 2002 until at least 30 June 2003, a period of one year and four months;
 - the agreement between Lundbeck and Ranbaxy: from 16 June 2002 until at least 31 December 2003, a period of one year and six months.
- (1293) With respect to the limitation period for the imposition of fines mentioned in Article 25 of Council Regulation (EC) No 1/2003, the Commission notes, firstly, that each

²¹⁶¹ See section 12.8 above.

²¹⁶² The agreement between Lundbeck and Merck (GUK) regarding other EEA countries than the United Kingdom lasted from 22 October 2002 until 22 October 2003 and therefore fell entirely within the period of operation of the agreement regarding the United Kingdom.

²¹⁶³ The agreement between Lundbeck and Arrow regarding Denmark lasted from 3 June 2002 until 1 April 2003 and therefore fell entirely within the period of operation of the agreement regarding the United Kingdom.

of the four infringements covered by this Decision is a single and continuous infringement. Therefore, in accordance with paragraph 2 of Article 25, time begins to run on the day on which the infringement ceased. Secondly, as the Commission conducted inspections regarding the four infringements in question in October 2005, followed by requests for information in 2006, new inspections in 2009 and the initiation of proceedings in 2010²¹⁶⁴, the limitation period for the imposition of fines was repeatedly interrupted. In accordance with paragraph 4 of Article 25, this interruption applies to all undertakings that participated in the infringements. As a result, in accordance with paragraph 5 of Article 25, the limitation period for the imposition of fines expires for each infringement ten years after the infringement ceased.

17. REMEDIES

17.1. Article 7(1) of Regulation (EC) No 1/2003

(1294) Where the Commission finds that there is an infringement of Article 101 of the Treaty and Article 53 of the EEA Agreement²¹⁶⁵, it may by decision require the undertakings concerned to bring such infringement to an end, in accordance with Article 7(1) of Regulation (EC) No 1/2003.²¹⁶⁶ The four infringements found in this Decision have ceased.²¹⁶⁷ Therefore, there is no need to require the undertakings concerned to bring the infringements to an end. However, there is a need to expressly confirm the addressees' obligation not to enter into new agreements having the same or a similar object or effect, given that several of the addressees of this Decision expressed, during these proceedings, that they do not regard the agreements under review to be anticompetitive.²¹⁶⁸ In these circumstances, there is a real danger that the undertakings concerned might commit similar practices as those considered in this Decision in the future.

17.2. Article 23 of Regulation (EC) No 1/2003

(1295) Under Article 23(2) of Regulation (EC) No 1/2003, the Commission may by decision impose fines upon undertakings where, either intentionally or negligently, they infringe Article 101 of the Treaty and Article 53 of the EEA Agreement. In accordance with the same provision, for each undertaking participating in an

²¹⁶⁴ See section 2.1.

²¹⁶⁵ With respect to Article 53 of the EEA Agreement, Article 5 of Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements of implementing the Agreement on the European Economic Area provides that “*the Community rules giving effect to the principles set out in Articles 85 and 86 [now Articles 101 and 102 TFEU] of the EC Treaty [...] shall apply mutatis mutandis.*” (OJ L 305, 30.11.1994, page 6).

²¹⁶⁶ 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, OJ L1 of 4.1.2003, page 1.

²¹⁶⁷ See chapter 16.

²¹⁶⁸ Notably, in the parties' replies to the Statement of Objections: for Lundbeck see ID 5394, page 322; for Merck KGaA see ID 5960, page 409; for GUK see ID 6026, page 6; for Arrow see ID 6082, page 4; for Alpharma see ID 6056, page 10; for A.L. Industrier AS see ID 4891, page 1; for Ranbaxy see ID 5176, page 3. See also chapter 11. See in this context, for instance, Case 7/82, *GVL v Commission*, [1983] ECR 483, paragraph 27; Case T-456/05 and T-47/05; *Güterman and Zwicky AG v Commission*, [2010] II-1443, paragraphs 66-67; Case T-410/03; *Hoechst v Commission*, [2008] ECR II-881, paragraphs 199-200.

infringement, the fine shall not exceed 10% of its total turnover in the preceding business year.

- (1296) The Commission considers that, based on the facts described in this Decision, the infringements have been committed intentionally. As described in chapter 7 and legally assessed in chapter 12, the infringements consisted of explicit, written agreements between the parties concerned, aimed at preventing or stopping the generic undertaking from selling generic citalopram in one or more markets in the EEA in exchange for a transfer of value from the originator undertaking. The legal assessment of the agreements concluded between the originator undertaking Lundbeck and the generic undertakings Merck, Arrow, Alpharma and Ranbaxy, respectively, also analysed the intentions underlying each agreement. The conclusion for each agreement was that the contractual parties knew or should have known that the respective agreements had the object and necessary consequence of restricting competition.²¹⁶⁹ However, even if the parties had not deliberately infringed Article 101 of the Treaty and Article 53 of the EEA Agreement, at the very least they acted negligently in entering into such anti-competitive agreements. The Commission therefore intends to impose fines on the undertakings to which this Decision is addressed.
- (1297) Pursuant to Article 23(3) of Regulation (EC) No 1/2003, the Commission shall, in fixing the amount of the fines, have regard to all relevant circumstances, 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 party to the infringement(s) will be assessed on an individual basis.
- (1298) In setting the fines to be imposed in this case, the Commission will also refer to the principles laid down in its Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation (EC) No 1/2003 ("the Guidelines on fines").²¹⁷⁰

17.3. General arguments of the parties against the imposition of fines

17.3.1. Novelty and lack of intention of negligence

- (1299) In its reply to the Statement of Objections, Lundbeck argued that imposing fines would not be justified in light of the novelty of the case. Lundbeck argued that it could not have been aware that the conduct at issue violated Union competition law because *"the relevant facts raise complex and novel legal issues and no guidance can be derived from existing legal precedent."* According to Lundbeck, *"Under these circumstances, the long-standing practice of the EU Courts and of the Commission is not to impose any fine or to impose a symbolic fine only."*²¹⁷¹ Lundbeck also relied on statements of both the Commission²¹⁷² and the Danish Competition Authority²¹⁷³ in

²¹⁶⁹ See recitals (812), (865), (954), (1005), (1079) and (1166).

²¹⁷⁰ 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.

²¹⁷¹ ID 5394, page 309.

²¹⁷² Lundbeck made reference to recital 836 of the Statement of Objections, stating that this case represents one of the first concrete proceedings of the Commission dealing with reverse payment agreements.

²¹⁷³ Lundbeck referred to the press release of the Danish Competition Authority of 28 January 2004. See also ID 6057, page 6.

an effort to demonstrate such uncertainty at the time of events. Finally, Lundbeck concluded from the novelty of the case that "*even if Lundbeck had infringed Article 101(1) of the Treaty by entering into the Agreements (quod non), it did so neither intentionally nor negligently.*"²¹⁷⁴ Other parties raised similar arguments.²¹⁷⁵ Merck KGaA, for instance, argued that in the past, undertakings were considered not to have been negligent where their practice was found to infringe competition rules for the first time.²¹⁷⁶

- (1300) 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.*"²¹⁷⁷

The Commission considers that as established throughout this Decision, Lundbeck was perfectly aware that the examined agreements were aimed at excluding competitors. It was the very purpose of Lundbeck'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.

There may not be any established precedents specifically in relation to reverse payment agreements²¹⁷⁸, however, the notion that such agreements which are aimed at market exclusion in exchange for a payment are likely to constitute a restriction by object under Article 101 of the Treaty is well established and cannot be seen as novel.

²¹⁷⁴ ID 5394, page 314.

²¹⁷⁵ Arrow, for instance, argued that there is no evidence to demonstrate that Arrow intended to restrict competition and that it was not in a position to enter the market when it entered into the agreement with Lundbeck. Arrow further argued that there was no legal precedent concerning these issues and the legal position surrounding settlement agreements was therefore at best unclear. See ID 6082, pages 75-77. Both GUK and Alpharma argued that the agreements in question were not clearly anti-competitive. See ID 6026, page 91 and ID 6056, pages 53-55 respectively. Ranbaxy argued that it did not participate in a practice that had market exclusion as its object or effect and that its sole purpose was to strike a deal with Lundbeck that would facilitate its market entry, not to delay it. See ID 5176, p. 55.

²¹⁷⁶ ID 5960, pages 355 and 357-359. In support, Merck KGaA invoked the following cases: Case COMP/38.096 *Clearstream*, paragraphs 342, 344 and 345; Case IV/29.176 *Vegetable parchment*, paragraph 83, and Cases IV/34.073, IV/34.295 and IV/35.426 *Van Den Bergh Foods Limited*. Merck KGaA also argued that Merck (GUK) acted neither negligently nor intentionally, because the agreements did not restrict competition by object. Merck (GUK) considered the agreements to be within the scope of Lundbeck's patents and Merck (GUK) was not aware of the possibility of delaying generic entry. Merck (GUK) would have not entered at risk in any case and used the agreements to clear the way, which allowed for earlier entry than absent the agreements. There was no precedent and the practice concerned is now assessed as an infringement of Union competition law for the first time. See ID 5960, pages 351-359. See in this respect also sections 12.2 and 12.3.

²¹⁷⁷ Case C-457/10 P, *AstraZeneca v Commission* [not yet reported], judgment of 6 December 2012, paragraph 164.

²¹⁷⁸ This explains the statements of Commissioner Monti quoted in Lundbeck's reply to the Statement of Objections, ID 5394, page 311.

- (1301) Regarding the alleged lack of intent or negligence, the Commission rejects the arguments raised by the parties for several reasons. First, according to well-established jurisprudence 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".²¹⁷⁹ In reply to the Statement of Objections, Merck KGaA argued that this jurisprudence would impose a requirement that "a rule existed at the relevant time and that it had been correctly published".²¹⁸⁰ However, 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 thus not required. As stated in recital (1296) above, the Commission regards explicit, written agreements aimed at preventing or stopping generic suppliers from selling generic citalopram in markets in the EEA in return for payments as constituting an intentional or at least negligent infringement. Lundbeck 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 at the time. Lundbeck acknowledged the following at the time: "*It is illegal to block competition.*"²¹⁸¹ For the same reasons, the generic undertakings concerned should have realised that the value transfers which they accepted from Lundbeck served the purpose of making them accept the limitations on their commercial autonomy in the agreements and deprived them of any incentive to continue their independent efforts to enter with generic citalopram in concerned markets in the EEA 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.*"²¹⁸² 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.
- (1302) Second, where intention or negligence is established, the Commission has discretion whether or not to impose a fine or a symbolic fine. 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 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 fact that the Commission may not have imposed fines in certain other cases is immaterial. 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 sanction.

²¹⁷⁹ Case T-11/06 *Romana Tabacchi Srl v Commission* [not yet reported], paragraph 227; Case T-348/94 *Enso Española SA v Commission*, paragraph 277.

²¹⁸⁰ See ID 5960, page 355.

²¹⁸¹ See recital (191).

²¹⁸² See recital (647).

- (1303) Third, the Commission cannot accept that statements made by the Commission and cited by Lundbeck gave rise to a level of uncertainty which precludes the imposition of fines. It must be noted that the statements of the Commission and of the Danish Competition Authority which Lundbeck referred to were made long after the agreements were concluded. Also, in the absence of analysis of the particular factual situation it would not be appropriate for a competition authority to make statements beyond the fact that certain practices ‘may’ breach competition rules or are ‘potentially’ anti-competitive. The statements selected by Lundbeck illustrate that the Commission had clear concerns about agreements limiting generic entry and in particular those involving value transfers. Finally, the Commission cannot be held responsible for statements made by the Danish Competition Authority and this point is explored further in section 17.3.2 dealing with legitimate expectations.
- (1304) Alpharma argued the following in its reply to the Statement of Objections: *"If a court would have upheld Lundbeck's patents, logically the Settlement Agreement would not have restricted competition. On the other hand, if a court would not have upheld Lundbeck's patents, then the Settlement Agreement may indeed have had a restrictive effect. As discussed above, Alpharma did not know which of these outcomes would occur. Thus, it is clear that Alpharma could not have determined whether its conduct was anti-competitive."*²¹⁸³ This argument misinterprets the anti-competitive character of the agreements in question: What matters from a competition policy perspective is whether that 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 payments, that is to say the fact that Lundbeck made sure by the payments that the generic companies in question would not try to enter the market for the duration of the agreement, which characterises the agreements in question as anti-competitive. As analysed in chapter 12, the parties knew or should have known that such agreements could amount to an infringement of Article 101 of the Treaty.

17.3.2. Legitimate expectations

- (1305) Lundbeck also argued that imposing fines would run counter to the principle of legitimate expectations.²¹⁸⁴ In particular Lundbeck argued the following: *"the Commission took almost ten years to form a view on the Agreements..."*²¹⁸⁵ Lundbeck also referred to a press statement of the Danish Competition Authority saying that *"the Commission does not want to initiate proceedings against Lundbeck"* and various press reports at the time.²¹⁸⁶ Other parties made similar arguments.²¹⁸⁷
- (1306) The principle of legitimate expectations has been claimed in two respects. First, the press release of Danish Competition Authority has allegedly created legitimate expectations that the Commission would not take a decision based on Article 101 of the Treaty in such circumstances. This claim has been addressed above in section 11.10 to which the Commission refers. Second, the fact that the Commission *"took almost ten years to form a view on the agreements"* would have allegedly created legitimate expectations that no fines would be imposed.

²¹⁸³ ID 6056, page 57.

²¹⁸⁴ For Lundbeck, see ID 5394, page 315.

²¹⁸⁵ ID 5394, page 315.

²¹⁸⁶ ID 5394, page 316.

²¹⁸⁷ For instance, for Merck KGaA, see ID 5960, page 404. See also section 11.10.

This latter claim has no merit. Article 25 of Regulation (EC) No 1/2003 and Regulation (EEC) No 2899/74 of the Council of 26 November 1974 concerning limitation periods in proceedings and the enforcement of sanctions under the rules of the European Economic Community relating to transport and competition²¹⁸⁸ lay down a limitation period for the Commission to impose a fine. According to Regulation (EEC) No 2899/74, second recital of the Preamble, the limitation period was introduced to ensure legal certainty.²¹⁸⁹ Therefore, there can be no legitimate expectations that no fines will be imposed within the limitation period.

However, the length of the Commission's investigation can be taken into account for the assessment of potential mitigating circumstances for the purpose of the calculation of the fine (see recitals (1349) and (1380) below).

- (1307) Furthermore, the absence of any legitimate expectations from the Commission's conduct is even more evident given that, as Lundbeck has noted in its own response²¹⁹⁰, the Commission previously expressed concerns over the practices subject to this Decision and took a number of investigative measures, including inspections at Lundbeck's premises, prior to the initiation of proceedings.

17.3.3. Legal certainty

- (1308) Arrow²¹⁹¹ and GUK²¹⁹² argued that the principle of legal certainty would be breached by the findings of this Decision that the agreements in question constituted restrictions of competition by object. They cited the absence of established precedents as a basis for this argument. Arrow also argues that the principle of *nullum crimen, nulla poena sine certa* was breached on the basis that the Commission had developed a new interpretation of a restriction by object in relation to patent settlements and sought to apply this retrospectively.²¹⁹³ These parties argue the breach of these principles precluded the imposition of fines.
- (1309) It is settled case law that the principle of legal certainty requires that rules such as Article 101 of the Treaty enable those concerned to know precisely the extent of the obligations which are imposed on them, and that these persons must be able to ascertain unequivocally what their rights and obligations are and take the appropriate steps accordingly.²¹⁹⁴

Agreements explicitly prohibited by Article 101, paragraph 1, of the Treaty include those which "*limit or control production, markets, technical development, or investment*" or "*share markets or sources of supply*".

The parties to the agreements in question could not ignore that these agreements were injurious to the proper functioning of normal competition since they barred

²¹⁸⁸ OJL 319, 29/11/1974 p. 1.

²¹⁸⁹ Case T-213/00 *CMA-CGM*, [2008] ECR II-913, paragraph 324: "... *Regulation No 2988/74 established a complete system of rules covering in detail the periods within which the Commission is entitled, without undermining the fundamental requirement of legal certainty, to impose fines on undertakings which are the subject of procedures under the Community competition rules.*"

²¹⁹⁰ ID 5394, page 316.

²¹⁹¹ ID 6082, page 76.

²¹⁹² ID 6026, page 89.

²¹⁹³ ID 6082, pages 76-77.

²¹⁹⁴ Case C-345/6, *Gottfried Heinrich*, [2009] ECR I-1659, paragraph 44. See also C-352/09 P, *Thyssen* [not yet reported], paragraph 81.

market entry and allowed for the incumbent to keep unaltered its prominent position on the market in exchange for a payment. The agreements in question restricted not just generic suppliers' commercial behaviour but their ability to enter the market.

It is longstanding and well-established case law that any practice or agreement which substitutes practical cooperation for the risk of competition may fall within the scope of Article 101 of the Treaty²¹⁹⁵, particularly when the agreements have an anticompetitive object consisting of hindering current and future competition from new entrants.²¹⁹⁶

Whilst there may not be any established precedents specifically in relation to reverse payment agreements, the notion that agreements aimed at market exclusion in exchange for a payment are likely to constitute a restriction by object under Article 101 of the Treaty is one that is well established and therefore enshrined in the Treaty.

Moreover, internal evidence shows that Lundbeck and its counterparts had no doubt about the aim of their agreements, namely money in exchange for the generic producer not to compete with Lundbeck.²¹⁹⁷ Lundbeck also thought that such a deal would be "*difficult – antitrust wise*". Lundbeck was aware that "*it is illegal to block competition*".²¹⁹⁸ Nevertheless, Lundbeck proceeded.²¹⁹⁹ Moreover, NM Parma warned Lundbeck against antitrust issues.²²⁰⁰

Therefore, the alleged breach of the principle of legal certainty does not exist.

17.3.4. *Nullum crimen, nulla poena sine lege*

- (1310) The principle of legality in relation to crime and punishment ("*nullum crimen, nulla poena sine lege*") 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). This principle applies to fines imposed by the Commission pursuant to Article 7 of Regulation (EC) No 1/2003.
- (1311) 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.²²⁰¹ 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*

²¹⁹⁵ See Case T-14/89, *Montedipe SpA v Commission*, [1992] ECR II-1155, paragraph 209.

²¹⁹⁶ Commission Decision of 17 October 2007, COMP/D1/38.606 *Groupeement des cartes bancaires*, paragraph 251, upheld by the General Court in Case T-491/07 *Groupeement des cartes bancaires v Commission* [not yet reported], judgment of 29 November 2012.

²¹⁹⁷ See for instance recitals (255), (345) and (558) above.

²¹⁹⁸ See recitals (188) and (191).

²¹⁹⁹ See, for instance, recitals (188), (190) and (558).

²²⁰⁰ See recital (190) and footnote 1546.

²²⁰¹ See Case T-99/04 *AC-Treuhand AG v Commission*, [2008] ECR II-1501, paragraph 141.

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..."²²⁰²

- (1312) First, for the reasons set out in section 17.3.1 above, the type of infringement at stake in this case, exclusion from the market in return for a payment, was not new and its illegality was foreseeable for the parties. The literal wording of the prohibition laid down in Article 101 of the Treaty²²⁰³ itself did suggest that these agreements were infringing Union competition law.
- (1313) Second, the above mentioned pieces of evidence establish that Lundbeck and the generic suppliers took the decision to enter into the examined agreements after having weighed up the pros and cons of the consequences of this type of agreement. Nothing suggests that they could not have known that their conduct was infringing Article 101 of the Treaty and were taken by surprise in this respect.
- (1314) Moreover, in adopting this Decision, the Commission does not make a new interpretation of Article 101 of the Treaty in relation to settlement agreements. The Commission recalls (see section 11.10 above) that at the time of the Commission's contacts with the Danish Competition Authority, the Commission had not investigated the agreements and did not say that settlement agreements of this type would not infringe Article 101 of the Treaty. In the Commission's report on the sector inquiry into the pharmaceutical sector, it concluded that patent settlement agreements deserve close scrutiny as they could potentially infringe competition.
- (1315) Therefore, the allegation of breach of the principle of *nullum crimen* does not hold.

17.4. The calculation of the fines for Lundbeck

17.4.1. General methodology

- (1316) In applying the Guidelines on fines, the basic amount results from the sum of an additional amount and a variable amount. The additional amount is calculated as a proportion of the value of sales of goods or services to which the infringement relates in a given year, normally, the last year of the infringement. The variable amount results from a proportion of the value of sales multiplied by the number of years of the undertaking's participation in the infringement. The resulting basic amount can then either be increased or reduced for each undertaking, depending on aggravating or mitigating circumstances. The Commission observes that Lundbeck is to receive a fine for each infringement in which it was involved.
- (1317) The Commission will apply the limit set forth in Article 23(2) of Regulation (EC) No 1/2003 to Lundbeck.
- (1318) Lundbeck made a number of points on the general methodology for the calculation of fines.²²⁰⁴ It argued that if the Commission were to impose separate fines for each of the four infringements this would: (i) lead to multiple counting, which it asserted the

²²⁰² *Ibidem*, paragraph 142.

²²⁰³ Article 81 EC in the relevant period.

²²⁰⁴ ID 5394, page 317.

Commission has striven to avoid in previous decisions; (ii) violate the principle of equal treatment; and (iii) indirectly violate the principle of *ne bis in idem*.

- (1319) The Commission rejects these arguments. Regarding multiple counting resulting from separate fines, it is established in section 12.8 that the agreements in question constitute four separate infringements. It follows from Article 23(2) of Regulation (EC) No 1/2003 and is consistent with the Guidelines on fines that four separate fines should be imposed. The Commission is not prevented from sanctioning separate infringements by separate fines even if in part the same turnover is used to calculate the fines. The Commission's Decision of 9 November 2010 in Case No COMP/39258 - *Airfreight*, which Lundbeck solely invoked on this point, does not substantiate Lundbeck's arguments on this point. The position in *Airfreight* was substantially different as it only involved a single cartel, whereas there are four infringements found with temporal overlaps in this Decision. The *Airfreight* cartel involved in part flights into and out of the EEA. Inbound and outbound turnover were both taken into consideration but a reduction of 50% was granted to take into account the fact that some of the affected turnover was created outside the EEA²²⁰⁵. This is not the position in the case in hand where all of the affected turnover was created within the EEA. The Commission's Decision of 28 March 2012 in Case No COMP/39462 - *Freight Forwarding*²²⁰⁶ would be a better analogy to the present case. Four separate infringements were found in that case and four separate fines imposed without any discount for simultaneity for those parties that were involved in more than one cartel. This case is also similar to the Commission's Decision 2003/2/EC in Case COMP/E-1/37.5122 - *Vitamins*²²⁰⁷, upheld by the Courts²²⁰⁸, where 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.
- (1320) There is equally no breach of the principle of equal treatment for Lundbeck compared to the position of the generic undertakings. Lundbeck's relevant sales are taken into account four times because it entered into a number of agreements with four generic undertakings which constitute four infringements. However, each of the generic undertakings only committed one infringement, which consisted in the case of Merck (GUK) and Arrow of two agreements, respectively. Therefore, each party is simply sanctioned for the number of infringements it committed. This is the approach adopted in respect of Lundbeck and the other parties, and is based on the applicable rules.
- (1321) There is no breach of the principle of *ne bis in idem*. This was implicitly admitted by Lundbeck's own qualification that this could only be 'indirect' in any event, although this was not explained further. In essence, the principle of *ne bis in idem*, which was developed in the context of criminal law, constitutes the right not to be tried or punished twice for the same facts. The Courts of the European Union have defined the principle of *ne bis in idem* in competition cases to "preclude an undertaking from

²²⁰⁵ See Commission press release, 09/11/2010, IP/10/1487.

²²⁰⁶ Commission Decision of 28.03.2012, Case COMP/39462 *Freight Forwarding*.

²²⁰⁷ *Vitamins*, Commission Decision 2003/2/EC [2003] OJ L 6/1, 10.1.2003.

²²⁰⁸ See, for instance, Case T-15/02 *BASF v Commission*, [2006] ECR II-00497.

being sanctioned by the Commission or made the defendant to proceedings brought by the Commission a second time in respect of anti-competitive conduct for which it has already been penalised or of which it has been exonerated by a previous decision of the Commission that not amenable to challenge."²²⁰⁹ The Courts of the European Union have further clarified that this principle is subject to the following three conditions: (i) identity of the facts; (ii) unity of the offender; (iii) unity of the legal interest protected. In this case, which involves four infringements in respect of agreements with four separate parties there is no identity of the facts.

- (1322) Lundbeck also argued that a single fine should be imposed and that this is consistent with the Commission's earlier practice in *AstraZeneca*.²²¹⁰ The Commission notes that *AstraZeneca* involved an Article 102 abuse of dominance case rather than an Article 101 infringement. While it would be lawful for the Commission to impose a single fine on a legal entity involved in several infringements, the Commission can also apply several fines in such cases. Previous cases where a single fine was imposed for several infringements are not a binding legal framework in this case. Moreover, as noted in recital (1319), in previous Article 101 decisions involving multiple infringements, namely *Vitamins*²²¹¹ and *Freight Forwarding*²²¹², fines were imposed for each of the separate infringements. As this case involves four separate infringements rather than one infringement four separate fines are imposed.
- (1323) Lundbeck also made the general argument that the Commission's approach would lead to a disproportionate fine. The Commission is aware of the impact of imposing multiple fines in parallel in this case. Thus, having regard to the particular circumstances of the case and the need to avoid a potentially disproportionate outcome, the Commission will, as indicated in recital (1329) below, apply a correction factor to Lundbeck for the four infringements.

17.4.2. The value of sales

- (1324) The basic amount of the fine to be imposed on the undertakings concerned is to be set by reference to the value of sales²²¹³, that is to say, the value of the undertakings' sales of goods or services to which the infringement directly or indirectly related in the relevant geographic area in the EEA.
- (1325) Through the infringements in question Lundbeck protected its citalopram sales in the geographic area concerned by each agreement. Therefore, the Commission intends to take Lundbeck's citalopram sales in the respective geographic areas for each infringement into account.
- (1326) 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.²²¹⁴ However, if the last year is not sufficiently representative, the Commission may take into account another period for the determination of the annual value of sales. In this

²²⁰⁹ Case T-224/00 *Archer Daniel Midland and Archer Daniel Midlands Ingredients v. Commission*, [2003], ECR II-2597, at Para 86. See also Case C-397/03 P, *Archer Daniel Midland and Archer Daniel Midlands Ingredients v. Commission*, Judgment of 18.5.2006; Case C-308/04 P, *SGL Carbon AG v. Commission*, etc.

²²¹⁰ See Lundbeck's reply to the Statement of Objections, ID 5394, page 317.

²²¹¹ *Vitamins*, Commission Decision 2003/2/EC [2003] OJ L 6/1, Case COMP E-137.512.

²²¹² *Freight Forwarding*, Commission Decision, Case 39.462.

²²¹³ Point 12 of the Guidelines on fines.

²²¹⁴ Point 13 of the Guidelines on fines.

case, because Lundbeck's sales of citalopram gradually decreased during the course of the agreements, and the agreements lasted less than two years, which period neither covered the full business year of 2002 nor the full business year of 2003, the Commission calculated an annual average value of sales on the basis of Lundbeck's actual sales during the relevant period.²²¹⁵

- (1327) The Commission therefore rejects Lundbeck's argument that the Commission should base its calculations on the last 12 months of each agreement or any appropriate shorter period. Whilst this approach would clearly be to the advantage of Lundbeck it would not constitute a representative period for each infringement for the reasons set out in recital (1326) above.
- (1328) In view of this and based on the information provided by Lundbeck²²¹⁶, the annual average values of sales that are taken into consideration are the following:
- for the infringement with Merck: EUR [0-100]* million for the United Kingdom and EUR [200-400]* million for the other EEA Contracting Parties²²¹⁷;
 - for the infringement with Arrow: EUR [0-100]* million for the United Kingdom and EUR [0-50]* million for Denmark;
 - for the infringement with Alpharma: EUR [300-500]* million for the EEA.
 - for the infringement with Ranbaxy: EUR [200-400]* million for the EEA.
- (1329) The Commission recognises that this Decision establishes that Lundbeck committed a number of infringements of Article 101 of the Treaty and of Article 53 of the EEA Agreement which relate to the same product, citalopram, and largely to the same geographic areas and periods of time. Having regard to these similar and parallel agreements and 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 that is appropriate to achieve deterrence in the specific circumstances of this case, of an average figure of -48% to the annual average values of sales to Lundbeck for each of the four infringements, based on an objective method reflecting the degree of temporal and geographic overlaps between the infringements.²²¹⁸

17.4.3. Determination of the basic amounts of the fines

- (1330) The basic amount consists of a variable amount of up to 30% of an undertaking's relevant sales in the EEA, 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 the value of an undertaking's relevant sales, irrespective of duration.²²¹⁹

²²¹⁵ For this purpose, the Commission has first calculated a monthly average value of Lundbeck's sales of citalopram in the period of operation of each agreement. This monthly average value of sales has then been multiplied by twelve to arrive at an annual average value of Lundbeck's sales of citalopram for the geographic area(s) covered by the agreement.

²²¹⁶ See ID 4234.

²²¹⁷ The value of EUR [200-400]* million excludes sales in the United Kingdom.

²²¹⁸ The method reduces the variable amount to [...] % for each additional infringement as far as it is overlapping both in time and space.

²²¹⁹ See points 19 to 26 of the Guidelines on fines.

Gravity

- (1331) The gravity of the infringement determines the percentage of the value of sales taken into account when setting the fine. When assessing the gravity of the infringement, the Commission will have 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 are assessed as follows:
- (a) Nature
 - the anti-competitive nature and objective of the infringements, in particular the fact that, despite Lundbeck's assertions to the contrary, the Commission considers the infringements to constitute market exclusion, which must be regarded as serious infringements of Article 101 of the Treaty and of Article 53 of the EEA Agreement;
 - (b) Market share
 - the fact that at the time when it concluded the agreements Lundbeck possessed a very high market share of the product to which the infringements relate for the geographic areas concerned;
 - (c) Geographic scope
 - the wide geographic scope of the infringements; except for the infringement with Arrow, all infringements covered the entire EEA;
 - (d) Implementation
 - the fact that all of the agreements were implemented.

Conclusion on Gravity

- (1332) In conclusion on gravity, the Commission has taken into account the criteria discussed above in recital (1331) namely nature, market share, geographical scope and implementation. It must be recalled that the arrangements constitute a restriction by object and the market exclusion described is considered to be a serious infringement. 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 chapters 11 and 12. 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 three infringements with the EEA wide scope (that is to say the infringements with Merck, Alpharma and Ranbaxy). Taking into account the criteria discussed in recital (1331), namely nature, market share and implementation, the proportion of the value of sales to be taken into account should be 10% for the infringement with Arrow (which related only to the United Kingdom and to Denmark).
- (1333) The Commission rejects Lundbeck's argument that the gravity coefficient should be set at the lowest possible end of the scale as the agreements allegedly fell within the scope of Lundbeck's patents.²²²⁰ Firstly, the Commission does not accept Lundbeck's argument that the agreements fell within the scope of Lundbeck's patents as explained in section 11.4 and, for each agreement, in chapter 12. Secondly, as

²²²⁰

See Lundbeck's reply to the Statement of Objections, ID 5394, page 318.

indicated in recital (660) above, decisive for the legal assessment of the gravity in this case is that the agreements limited generic entry and that those limitations were paid for by the originator undertaking. This applies as much to restrictions agreed in exchange for a payment that fall within the scope of the patent as to those restrictions exceeding that scope.

Duration

(1334) In its assessment of the duration of the infringements the Commission considers that the agreements lasted as follows:

- the infringement with Merck: one year and nine months for the agreement regarding the United Kingdom and one year for the agreement regarding the other EEA Contracting Parties;
- the infringement with Arrow: one year and eight months for the agreement regarding the United Kingdom and nine months for the infringement regarding Denmark;
- the infringement with Alpharma: one year and four months; and
- the infringement with Ranbaxy: one year and six months.²²²¹

(1335) The Commission rejects Lundbeck's arguments that the Commission should take into account that the agreements could not have had any anti-competitive effect prior to the generics' actual readiness to enter the market.²²²² In a case involving a restriction by object the start date for the purposes of calculating duration is determined by the date of entering into the agreement irrespective of effects.

(1336) However, as argued by Lundbeck, rather than rounding up periods as indicated in point 24 of the Guidelines on fines the Commission, in its discretion, will instead take into account the actual duration of participation in the infringements of Lundbeck based on full months.

(1337) This leads to the following calculation of the multiplier for duration:

Infringement	Duration Multiplier
Merck (United Kingdom)	1.75
Merck (Other EEA Contracting Parties excluding United Kingdom)	1
Arrow (United Kingdom)	1.66
Arrow (Denmark)	0.75
Alpharma	1.33
Ranbaxy	1.5

²²²¹ See recital (1292) and footnotes 2162 and 2163. See also chapter 7.

²²²² See Lundbeck's reply to the Statement of Objections, ID5394, page 318.

Additional amount

- (1338) As the infringements consist of horizontal market-exclusion agreements which are restrictions of competition by their very nature, the Commission intends to apply the provisions of the Guidelines on fines on the additional amount.²²²³
- (1339) Accordingly, the Commission rejects Lundbeck's argument that an additional amount should not be imposed²²²⁴ and notes that irrespective of whether the agreements in question fall within the examples cited in paragraph 25 of the Guidelines on fines the Commission has discretion on whether or not to impose an additional amount. Furthermore, in response to the argument that the alleged short duration of the infringements should have an impact on the application of the additional amount, the Commission refers to point 25 which explicitly states that the additional amount applies irrespective of duration. Indeed the rationale behind the additional amount is to discourage undertakings from even entering into anti-competitive arrangements and in this respect can be seen as being particularly relevant to infringements of short duration.
- (1340) Taking into account the criteria discussed in recital (1331) above, the Commission concludes that an additional amount of 10% of the average annual value of sales should be included in the basic amount for Lundbeck for one of the first infringements that occurred, that is to say the infringement with Arrow. This 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.

Calculation and conclusion on the basic amount

- (1341) Based on the criteria explained in this section, the basic amount of the fine for Lundbeck calculated for each of the infringements is as follows:

<u>Infringement</u>	<u>Basic Amount</u>
<u>Merck</u>	H. Lundbeck A/S: EUR 22 104 000 of which jointly and severally with Lundbeck Limited ²²²⁵ : EUR 5 896 000
<u>Arrow</u>	H. Lundbeck A/S: EUR 14 391 000
<u>Alpharma</u>	H. Lundbeck A/S: EUR 35 520 000
<u>Ranbaxy</u>	H. Lundbeck A/S: EUR 32 172 000

²²²³ See point 25 of the Guidelines on fines.

²²²⁴ See Lundbeck's reply to the Statement of Objections, ID 5394, page 316.

²²²⁵ As indicated in section 15.2, Lundbeck Limited is held jointly and severally liable for the United Kingdom agreement with Merck (GUK) only.

17.4.4. Adjustments to the basic amount of the fine

Aggravating Circumstances

- (1342) No aggravating circumstances have been found.

Mitigating circumstances

- (1343) Lundbeck argued that the Commission should take into account as a mitigating factor that there was reasonable doubt as to the existence of the infringement and referred to point 29, second indent of the Guidelines on fines.²²²⁶

The Commission does not accept this argument. The Commission does not regard explicit, written agreements aimed at preventing or stopping market entry in return for payments as giving rise to reasonable doubt as to the existence of an infringement. In any event, as Lundbeck recognised, the mitigating circumstance of reasonable doubt as to the existence of the infringement only formed part of the former 2002 Guidelines on fines but was removed from the version currently in force. In the current version of the Guidelines on fines at point 29, second indent, it is stated that where the undertaking concerned provides evidence that the infringement has been committed as a result of negligence, the Commission may reduce the basic amount. As shown in recital (1296), the Commission considers that, based on the facts described in the Decision, the infringements have been committed intentionally.

- (1344) The submissions of Lundbeck did not provide evidence sufficient to establish that the infringement was committed as a result of negligence.
- (1345) Lundbeck also argued that its exemplary cooperation outside the Leniency Notice²²²⁷ should give rise to a mitigating circumstance under point 29, fourth indent of the Guidelines on fines.²²²⁸
- (1346) 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."*
- (1347) 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 Lundbeck enabled the Commission to establish the infringements more easily.²²²⁹ The Commission considers the award of such a reduction could only be of an exceptional nature.²²³⁰
- (1348) Furthermore, cooperation when answering requests for information cannot constitute an attenuating circumstance. Undertakings are required to answer requests for information and are subject to penalties if they provide the Commission with

²²²⁶ See Lundbeck's reply to the Statement of Objections, ID 5394, pages 318-319.

²²²⁷ Commission Notice on Immunity from fines and reduction of fines in cartel cases (OJ C 298/17, 8.12.2006).

²²²⁸ See Lundbeck's reply to the Statement of Objections, ID 5394, pages 319.

²²²⁹ Case T-48/02 *Brouwerij Haacht v. Commission*, [2005] ECR II-5259 paragraph 104 and the case law cited therein.

²²³⁰ Commission Decision of 20.10.2005, Case COMP/38.281 *Italian Raw Tobacco*, paragraphs 385 ff.

incorrect or misleading answers to a request for information.²²³¹ Lundbeck has in its replies to requests for information not gone substantially further than it was required under Article 18(4) of Regulation (EC) No 1/2003. Equally in terms of inspections Lundbeck has gone no further than its duty to cooperate as specified in Article 20(4) of Regulation No 1/2003. Lundbeck has not voluntarily 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 Lundbeck.

- (1349) Lundbeck argued that in view of the length of the Commission's investigation it should be granted a reduction.²²³² In this case, the Commission, in its discretion, decided to grant Lundbeck a reduction of 10% of the basic amount in view of the long duration.
- (1350) Lundbeck also argued for a reduction in view of alleged procedural irregularities.²²³³ The Commission does not accept Lundbeck's argument of procedural irregularities. In any case, such matters are not relevant to the determination of fines.

Conclusion on the adjustments to the basic amounts

- (1351) Based on the adjustment described in recital (1349) above, the adjusted basic amount of the fine to be applied to Lundbeck for the respective infringements is as follows

Infringement	Adjusted Basic Amount
Merck	H. Lundbeck A/S: EUR 19 893 600 of which jointly and severally with Lundbeck Limited ²²³⁴ : EUR 5 306 400
Arrow	H. Lundbeck A/S: EUR 12 951 900
Alpharma	H. Lundbeck A/S: EUR 31 968 000
Ranbaxy	H. Lundbeck A/S: EUR 28 954 800

17.4.5. Deterrence

- (1352) When determining the amount of the fines, the Commission pays particular attention to the need to ensure that fines have a sufficiently deterrent effect. To that end, the Commission may increase the fines to be imposed on undertakings which have a particularly large turnover beyond the sales of goods or services to which the infringement relates.²²³⁵
- (1353) In this case, the Commission does not apply any specific increase for deterrence to Lundbeck.

²²³¹ Article 20(4) and Article 23(1)(a) and (c) of Regulation No 1/2003.

²²³² See Lundbeck's reply to the Statement of Objections, ID 5394, page 319.

²²³³ See Lundbeck's reply to the Statement of Objections, ID 5394, page 319.

²²³⁴ As indicated in section 15.2, Lundbeck Limited is held jointly and severally liable for the United Kingdom agreement with Merck (GUK) only.

²²³⁵ Point 30 of the Guidelines on fines.

17.4.6. Application of the 10% turnover limit

- (1354) 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.
- (1355) Lundbeck considers the overall amount of fines should not exceed 10% of Lundbeck annual turnover. Moreover, Lundbeck argues that the turnover to be taken into account should be that of 2005, when the Commission made its first investigatory measures, rather than its 2011 turnover.²²³⁶
- (1356) The legal maximum fine, laid down in Article 23(2) of Regulation 1/2003, specifically provides that per undertaking the fine shall not exceed 10% of its total turnover in the *preceding business year* and the strict conditions under the case law for deviating from this rule are not present.²²³⁷ Furthermore, it is clear from the Guidelines on fines that the legal maximum applies per infringement. On this basis the Commission cannot accept Lundbeck's arguments.
- (1357) The adjusted basic amounts set out in recital (1351) above do not exceed 10% of the total turnover of H. Lundbeck A/S, the parent company of the undertaking Lundbeck, in 2012.²²³⁸

17.4.7. Conclusion: final amount of fines for Lundbeck

- (1358) Therefore the fines to be imposed on H. Lundbeck A/S and Lundbeck Limited pursuant to Article 23(2) of Regulation (EC) No 1/2003 should be as follows²²³⁹;

Infringement	Fine
Merck	H. Lundbeck A/S: EUR 19 893 000 of which jointly and severally with Lundbeck Limited ²²⁴⁰ : EUR 5 306 000
Arrow	H. Lundbeck A/S: EUR 12 951 000
Alpharma	H. Lundbeck A/S: EUR 31 968 000

²²³⁶ See Lundbeck's reply to the Statement of Objections, ID 5394, page 319.

²²³⁷ See Case T-33/02 *Britannia Alloys & Chemicals v Commission* [2005] ECR II-4973, paragraph 49: "The Court would point out that, even in a year of normal business activity, the turnover of an undertaking may fall significantly, or indeed substantially, as compared with previous years, for various reasons, such as a difficult economic context, a crisis in the sector concerned, an accident or a strike. However, as long as an undertaking has in fact achieved a turnover during a complete year in which economic activities, albeit on a reduced scale, have been carried on, the Commission must take the undertaking as it stands when setting the upper limit provided for in Article 15(2) of Regulation No 17. Accordingly, at least in situations where there is no indication that an undertaking has ceased its commercial activities or has diverted its turnover in order to avoid the imposition of a heavy fine, the Court considers that the Commission is obliged to fix the maximum limit of the fine by reference to the most recent turnover corresponding to a complete year of economic activity." This ruling was upheld on appeal in Case C-76/06 P *Britannia Alloys & Chemicals / Commission* [2007] ECR I-4405, paragraph 27. See also Case T-410/09 *Almamet v Commission*, judgment of 12 December 2012, paragraph 216.

²²³⁸ See ID 6970.

²²³⁹ The final amount of the fine is rounded down.

²²⁴⁰ As indicated in section 15.2, Lundbeck Limited is held jointly and severally liable for the United Kingdom agreement with Merck (GUK) only.

Ranbaxy	H. Lundbeck A/S: EUR 28 954 000
Total	H. Lundbeck A/S: EUR 93 766 000 of which jointly and severally with Lundbeck Limited: EUR 5 306 000

17.5. The calculation of the fines for Merck, Arrow, Alpharma and Ranbaxy

- (1359) The generic undertakings agreed not to sell generic citalopram in the geographic area concerned by each agreement and therefore do not have any, or only have very limited, sales in the geographic areas concerned. The Commission therefore intends to apply point 37 of the Guidelines on fines to the generic undertakings. Point 37 of the Guidelines on fines allows the Commission to depart from the normal methodology of the Guidelines on fines depending on the particularities of a given case or the need to achieve deterrence in a particular case.
- (1360) The Commission takes the following elements into account when calculating the fines for the generic undertakings in this case.

17.5.1. Gravity

- (1361) When assessing the gravity of each infringement²²⁴¹, the Commission will have 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 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 Merck, Arrow, Alpharma and Ranbaxy corresponding to the value transferred to the generic undertaking in each infringement.²²⁴² 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:

(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 and of Article 53 of the EEA Agreement;

(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 Lundbeck, Lundbeck possessed a very high market share of the product to which the infringements relate for the geographic area concerned;

²²⁴¹ See Article 23(3) of Regulation No 1/2003.

²²⁴² The values are summarised in the footnotes attached to recital (1374) below.

- (c) Geographic scope
 - the wide geographic scope of the infringements (except for the infringement with Arrow, all infringements covered the entire EEA);
 - (d) Implementation
 - the fact that all of the agreements were implemented.
- (1362) The Commission does not accept the arguments advanced by Arrow²²⁴³ and Alpharma²²⁴⁴ that the infringement should not be treated as a serious breach of the competition rules given its novelty. The Commission regards the infringement as constituting market exclusion; as such this must be regarded as being serious. Whilst the Commission may not have previously sanctioned this specific type of agreement between an originator and generics undertakings in the pharmaceutical sector it is well established that excluding competitors from the market is likely to constitute an infringement of Union competition law.
- (1363) Arrow also claimed that its conduct had no impact.²²⁴⁵ This argument goes to an effects analysis, which is irrelevant in a case such as the present one which involves the finding of a restriction of competition by object.
- (1364) The Commission also rejects Alpharma's argument that the Commission should disregard Lundbeck's high share of the product to which the infringements relate when assessing the gravity of the infringement as the market would not have been properly defined.²²⁴⁶ The fact that the generic undertakings knew or should have known that through the agreements and payments Lundbeck extended, or at least maintained, its exclusive position on citalopram is an important factor for the assessment of gravity of the anti-competitive conduct in question. The fact that the market is not specifically defined is irrelevant in this context as this case involves a restriction of competition by object.
- (1365) The Commission does not accept Alpharma's argument that the geographic scope should only extend to those countries for which Alpharma held a marketing authorisation.²²⁴⁷ In a case involving a restriction by object the geographic scope of the infringement is determined by the scope of the agreement irrespective of effects.

17.5.2. Duration

- (1366) The Commission takes the duration of each infringement into account²²⁴⁸, namely
- for Merck: one year and nine months for the agreement regarding the United Kingdom and one year for the agreement regarding the other EEA Contracting Parties;
 - for Arrow: one year and eight months for the agreement regarding the United Kingdom and nine months for the infringement regarding Denmark;
 - for Alpharma: one year and four months; and

²²⁴³ ID 6082, page 79.

²²⁴⁴ ID 6056, page 58.

²²⁴⁵ ID 6082, page 79.

²²⁴⁶ ID 6056, page 59.

²²⁴⁷ ID 6056, pages 59-60.

²²⁴⁸ See Article 23(3) of Regulation No 1/2003.

– for Ranbaxy: one year and six months.²²⁴⁹

- (1367) Arrow argued that the Commission should take into account that it could not have entered the market at the time the agreements in question were concluded and that Arrow was not able to compete in any of the relevant markets.²²⁵⁰ Similarly, Alpharma argued that the duration of the infringement should be limited to the period during which Alpharma and Lundbeck were potential competitors and that duration should start on the date that Alpharma could actually have launched the relevant products in each Contracting Party of the EEA.²²⁵¹
- (1368) The Commission rejects these arguments as, in a case involving a restriction by object, the start date for the purposes of calculating duration is determined by the occasion of entering into the agreement irrespective of the potential lack of effects. The difference with the *E.ON Ruhrgas*²²⁵² is that in paragraph 251 of that judgement invoked by Alpharma, the Court did not deal with the question of whether the infringement took place during the period when the agreement was in force, but rather with the issue whether the infringement continued after the formal revocation of the agreement. However, even in that context the Court explained the following: *"In so far as the existence of the infringement and [...] the continuation of the agreement in spite of its formal revocation are established by documentary evidence, it is not necessary to examine the conduct of the undertakings in question in respect of the abovementioned periods and markets. 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)."*²²⁵³
- (1369) In response to Arrow's point that the agreements were in force only for a short period²²⁵⁴ the Commission notes that this is already taken into account in the duration calculation.

17.5.3. Deterrence

- (1370) The Commission has taken into account the need to ensure deterrence in each infringement²²⁵⁵ by using as a basis for the calculation of the fine the value transferred to the generic undertaking in each infringement.
- (1371) The Commission rejects the arguments advanced by Alpharma that the amount of the fine should not be based upon the amount of value transferred from Lundbeck to Alpharma.²²⁵⁶ First, Alpharma argued that the fine should not reflect any value transferred for the purchase of the products within the scope of Lundbeck's patents. As indicated in recital (660) above, what is decisive for the legal assessment in this

²²⁴⁹ See recital (1292). See also chapter 7.

²²⁵⁰ ID 6082, page 79.

²²⁵¹ ID 6056, pages 60-61.

²²⁵² Case T-360/09, *E.ON Ruhrgas AG and E.ON AG v Commission*, judgment of 29 June 2012.

²²⁵³ Case T-360/09, *E.ON Ruhrgas AG and E.ON AG v Commission*, judgment of 29 June 2012, paragraph 252.

²²⁵⁴ ID 6082, page 79.

²²⁵⁵ See also point 31 of the Guidelines on fines.

²²⁵⁶ ID 6056, page 62.

case is whether the agreements limited generic entry and whether those limitations were paid for by the originator undertaking. This applies as much to restrictions agreed in exchange for a payment that fall within the scope of the patent as to restrictions exceeding that scope. Second, the Commission rejects Alpharma's argument that any fine imposed should take Alpharma's costs into account. The costs that Alpharma indicated in its reply to the Statement of Objections were not incurred directly as a result of the implementation of the agreement with Lundbeck. Third, the Commission also rejects Alpharma's argument that the Commission should exclude any profits that Alpharma would have made had it entered the market. The Guidelines on fines refer to the need to increase the fine in order to exceed the gains "*improperly made as a result of the infringement*".²²⁵⁷ This is exactly the case of the value transferred to Alpharma by Lundbeck.

- (1372) Alpharma also argued that, for the purposes of the calculation of the fine, the Commission should apply the applicable USD/EUR exchange rate at the current exchange rate.²²⁵⁸ The Commission, as a general rule, applies the contemporary exchange rate, that is to say the exchange rate applicable at the time of the events in question, as this exchange rate best reflects the value of the amount or transaction concerned.
- (1373) Ranbaxy²²⁵⁹ and GUK²²⁶⁰ argued that the amount of the value transferred to the generic undertaking should take the company's distribution costs incurred in relation to the distribution of Lundbeck's product into account. However, both parties failed to substantiate with sufficient evidence the actual distribution costs they claimed to have incurred. Nevertheless, for the purpose of the calculation of the fine the Commission reduced the amount of value transferred to Ranbaxy and Merck to take account of distribution costs by 10% of turnover, as explained in footnotes 2261 and 2264.
- (1374) In conclusion, 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 Merck's infringement: EUR 23.8 million²²⁶¹;
 - for Arrow's infringement: EUR 11.1 million²²⁶²;
 - for Alpharma's infringement: EUR 11.7 million²²⁶³;
 - for Ranbaxy's infringement: EUR 11.5 million²²⁶⁴.

²²⁵⁷ Point 31 of the Guidelines on fines.

²²⁵⁸ ID 6056, pages 61-62.

²²⁵⁹ ID 5176, pages 56-57.

²²⁶⁰ ID 6026, page 79.

²²⁶¹ This amount consists of EUR 19.4 million for the United Kingdom agreement and EUR 12 million for the agreement regarding the other EEA Contracting Parties. See sections 7.2 and 7.3. The Commission applies 10% reduction to the turnover from the distribution of citalopram obtained by GUK under the agreement with Lundbeck, in view of GUK's additional costs.

²²⁶² This amount consists of EUR 10.4 million for the United Kingdom agreement and EUR 0.7 million for the agreement regarding Denmark. See sections 7.4 and 7.5.

²²⁶³ See section 7.6.

17.5.4. Aggravating circumstances

(1375) No aggravating circumstances have been found.

17.5.5. Mitigating circumstances

- (1376) Arrow argued that it was merely a start-up company with no manufacturing capability and that it entered into the agreements with Lundbeck to protect this fledgling business.²²⁶⁵ The Commission cannot accept these arguments. First, undertakings are responsible for their conduct at whatever stage of their development. Second, as indicated in recital (1368) above, arguments concerning Arrow's ability to compete in the market go to an effects analysis, which is irrelevant in a case such as this which involves the finding of a restriction of competition by object.
- (1377) Alpharma argued reasonable doubt as to whether the agreement constituted an infringement of Union competition law as at the time of the settlement agreement there was no precedent.²²⁶⁶ As indicated in section 17.3.1 above the Commission does not regard explicit, written agreements aimed at preventing or stopping market entry in return for payments as giving rise to reasonable doubt as to the existence of an infringement. In any event, the mitigating circumstance of reasonable doubt as to the existence of the infringement formed part of the former 2002 Guidelines on fines but was removed from the version currently in force.
- (1378) Alpharma further argued that the Commission should reduce the level of the fine on the grounds that Alpharma acted negligently.²²⁶⁷ The submissions of Alpharma, however, do not provide evidence sufficient to establish that the infringement was committed as a result of negligence as required by the Guidelines on fines. As shown in recital (1296), the Commission considers that, based on the facts described in the Decision, the infringements have been committed intentionally.
- (1379) Resolution argued that any involvement in the infringement by Resolution was substantially limited and arose out of the direct control by Arrow's former [employee function]*. Resolution therefore argued that it did not intentionally enter into any unlawful agreements with Lundbeck and, at most, any involvement in the infringement would have been committed negligently.²²⁶⁸ As indicated in section 15.4, Resolution was a party to the United Kingdom agreement in its own right and accepted obligations under the agreement which pertained only to itself. Resolution did not provide sufficient evidence that the infringement was committed as a result of negligence and the Commission therefore does not accept this argument.
- (1380) In this case the Commission, in its discretion, decided to grant the generic undertakings a reduction of 10% of the amount of fine in view of the long duration of the Commission's investigation.

²²⁶⁴ See section 7.7. The Commission applies 10% reduction to the turnover from the distribution of citalopram obtained by Ranbaxy under the agreement with Lundbeck, in view of Ranbaxy's additional costs.

²²⁶⁵ ID 6082, page 78.

²²⁶⁶ ID 6056, page 63.

²²⁶⁷ ID 6056, page 65.

²²⁶⁸ ID 4937, pages 14-15.

17.5.6. Application of the 10% turnover limit

- (1381) The Commission has had regard for each of the generic undertakings to the limit set forth in Article 23(2) of Regulation (EC) No 1/2003, which 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.

Merck

- (1382) As described in section 3.3, Generic [UK] Limited and Merck KGaA are held jointly and severally liable. As mentioned in recital (33) above, in October 2007 Merck KGaA sold the Merck Generics business, including Generics [UK] Limited, and Generics [UK] Limited has continued to exist as a separate legal entity within the United States undertaking Mylan. In accordance with the settled case-law²²⁶⁹, the 10% limit set forth in Article 23(2) of Regulation (EC) No 1/2003 is therefore calculated and applied separately for Merck KGaA and Generics [UK] Limited.

Arrow

- (1383) As indicated in section 15.4, Resolution Chemicals Limited signed the United Kingdom agreement on behalf of the Arrow Group of companies and is therefore held jointly and severally liable for this agreement with Arrow Group ApS and Arrow Generics Limited. As also indicated in section 15.4, Resolution Chemicals Limited no longer belongs to the Arrow group of companies. The 10% limit set forth in Article 23(2) of Regulation (EC) No 1/2003 is therefore calculated and applied separately for Arrow Group ApS and Arrow Generics Limited on the one hand, which still belong to the Arrow group of companies, and for Resolution Chemicals Limited on the other hand.²²⁷⁰

Alpharma

- (1384) As indicated in section 15.5, Zoetis Products LLC, Xellia Pharmaceuticals ApS and A.L. Industrier AS are held jointly and severally liable. These three companies no longer belong to the same group of companies. The 10% limit set forth in Article 23(2) of Regulation (EC) No 1/2003 is therefore calculated and applied separately for Zoetis Products LLC, Xellia Pharmaceuticals ApS and A.L. Industrier AS.²²⁷¹
- (1385) Alpharma argued that the 10% fine ceiling applicable to A.L. Industrier AS should be based upon A.L. Industrier AS' turnover in the last financial year in which it had real economic operations that is to say the year 2005.²²⁷² However, the Commission rejects this argument based on the following considerations.

²²⁶⁹ See Joined cases T-71/03, T-74/03, T-87/03 and T-91/03 *Tokai Carbon and others v Commission*, paragraph 390; Case T-377/06 *Comap v Commission*, paragraph 111; Case T-385/06, *Aalberts v Commission*, paragraph 125; Case T-191/06, *FMC Forest v Commission*, paragraph 324; Case T-54/06 *Kendrion v Commission*, paragraph 91.

²²⁷⁰ See Joined cases T-71/03, T-74/03, T-87/03 and T-91/03 *Tokai Carbon and others v Commission*, paragraph 390; Case T-377/06 *Comap v Commission*, paragraph 111; Case T-385/06, *Aalberts v Commission*, paragraph 125; Case T-191/06, *FMC Forest v Commission*, paragraph 324; Case T-54/06 *Kendrion v Commission*, paragraph 91.

²²⁷¹ See Joined cases T-71/03, T-74/03, T-87/03 and T-91/03 *Tokai Carbon and others v Commission*, paragraph 390; Case T-377/06 *Comap v Commission*, paragraph 111; Case T-385/06, *Aalberts v Commission*, paragraph 125; Case T-191/06, *FMC Forest v Commission*, paragraph 324; Case T-54/06 *Kendrion v Commission*, paragraph 91.

²²⁷² ID 6056, pages 66-68.

- (1386) According to the information provided by A.L. Industrier AS, the total worldwide consolidated turnover, including financial income²²⁷³, of A.L. Industrier AS for the business year 2011 was EUR 432,161.²²⁷⁴ In 2012, A.L. Industrier AS was in the process of unwinding its assets leading to a decrease of its turnover to zero.²²⁷⁵
- (1387) According to the settled case-law, if the turnover in the business year preceding the adoption of the Commission's decision does not represent a full year of normal economic activity and does not provide any useful indication as to the actual economic situation of the undertaking concerned and the appropriate level of any fine to be imposed on it, the Commission is obliged, for the purposes of calculating the upper limit of the fine, to refer to the last full business year corresponding to a full year of normal economic activity.²²⁷⁶ AL Industrier AS' annual report for 2012 showed that the company was in the process of winding down its assets²²⁷⁷, therefore making 2012 an unsuitable basis for the calculation of the company turnover. In light of the above, the Commission considers the business year 2011 to be the last year of A.L. Industrier AS' normal business activity and therefore takes that business year as a basis for the calculation of the 10% limit set forth in Article 23(2) of Regulation No 1/2003.

Ranbaxy

- (1388) As indicated in section 15.6, Ranbaxy (UK) Limited and Ranbaxy Laboratories Limited are held jointly and severally liable. The amount of fine set out in recital (1396) below does not exceed 10% of the total turnover of Ranbaxy Laboratories Limited, the parent company of the undertaking Ranbaxy, in 2012.

17.5.7. Ability to pay

- (1389) According to point 35 of the 2006 Guidelines on fines, "[i]n exceptional cases, the Commission may, upon request, take account of the undertaking's inability to pay in a specific social and economic context. It will not base any reduction granted for this reason in the fine on the mere finding of an adverse or loss-making financial situation. A reduction could be granted solely on the basis of objective evidence that the imposition of the fine as provided for in these Guidelines would irretrievably jeopardise the economic viability of the undertaking concerned and cause its assets to lose all their value."

²²⁷³ A.L. Industrier AS argued that "the normal economic activity of A.L. Industrier has been to be a financial holding company involved in investment activities." (ID 6979, page 2) Articles 5.1 and 5.3 of the Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings provide for the types of revenue that can be taken into account in the case of "other financial institutions". See also recitals (217) to (220) of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings on the calculation of turnover for financial holdings, which categorizes them as other financial institutions.

²²⁷⁴ ID 7057, page 1, using an exchange rate for 2011 of 1EUR = 7.7934 NOK. Source European Central Bank.

²²⁷⁵ See A.L. Industrier AS' Annual Report for 2012, showing that "the Board believes that significant parts of the company assets should be returned to the shareholders as soon as possible." (ID 7064, page 3, translated from the Norwegian). See also IDs 7058 and 7061.

²²⁷⁶ See the case law quoted in footnote 2237, confirmed in Case T-392/09 *I. Garantovana v Commission*, paragraph 86.

²²⁷⁷ See ID 7064, page 3.

- (1390) In exercising its discretion under point 35 of the 2006 Guidelines on fines, the Commission carries out an overall assessment of the undertaking's financial situation, with the primary focus on the undertaking's capacity to pay the fine in a specific social and economic context.
- (1391) Among the undertakings addressed in the Decision, Resolution Chemicals Limited made an application claiming inability to pay the fine under point 35 of the 2006 Guidelines on fines. The Commission has considered this claim and carefully analysed the available financial data of this undertaking. Resolution Chemicals Limited received requests for information pursuant to Article 18(1) and (2) of Regulation (EC) No 1/2003 asking it to submit details about its individual financial situation and the specific social and economic context it operates in.
- (1392) Insofar as the undertaking argues that the estimated fine would have a negative impact on its financial situation, without adducing credible evidence demonstrating its inability to pay the expected fine, the Commission points to settled case law according to which the Commission is not required, when determining the amount of the fine to be imposed, to take into account the poor financial situation of an undertaking, since recognition of such an obligation would be tantamount to giving unjustified competitive advantages to undertakings which are the least well adapted to the conditions of the market.²²⁷⁸
- (1393) Accordingly, in recitals (1395) to (1395), the financial position of Resolution Chemicals Limited and the impact of the fine imposed upon it are assessed in the specific social and economic context. The financial situation of the undertaking concerned is assessed at the time the Decision is adopted and on the basis of the financial data and information submitted by the undertaking.
- (1394) In assessing the undertaking's financial situation, the Commission considers the financial statements, for example annual reports, consisting of a balance sheet, an income statement, a statement of changes in equity, a cash-flow statement and notes, usually of the last five financial years, as well as their forecasts for 2013 to 2016. The Commission takes into account and relies upon a number of financial ratios measuring the solidity (in this case, the proportion which the expected fine would represent of the undertaking's equity and assets), its profitability, solvency and liquidity, all of which are commonly used when evaluating risks of bankruptcy. In addition, the Commission takes into account relations with outside financial partners such as banks, on the basis of copies of contracts concluded with those partners in order to assess the undertaking's access to finance and, in particular, the scope of any undrawn credit facilities it may have. The Commission also includes in its analysis the relations with shareholders in order to assess their confidence in the undertaking's economic viability (shareholder relations may be illustrated by recent dividend payments and other outflows of cash paid to the shareholders), as well as the ability of the shareholders to assist the undertaking concerned financially.²²⁷⁹ Attention is

²²⁷⁸ See Joined Cases 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82, *IAZ International Belgium and Others v Commission* [1983] ECR 3369, paragraphs 54 and 55, and Joined Cases C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, *Dansk Rørindustri and Others v Commission* [2005] ECR I-5425, paragraph 327, Case C-308/04 P, *SGL Carbon AG v Commission* [2006] ECR I-5977, paragraph 105.

²²⁷⁹ By analogy to the assessment of "serious and irreparable harm" in the context of interim measures, the Commission bases its assessment of the undertaking's ability to pay on the financial situation of the

paid both to the equity and profitability of the undertaking and, above all, to its solvency, liquidity and cash flow. The analysis is both prospective and retrospective but with a focus on the present and immediate future of the undertaking. The analysis is not purely static but rather dynamic, whilst taking consistency over time of the submitted forecasts into account. The analysis takes possible restructuring plans and their state of implementation into account.

- (1395) The inability to pay claim submitted by Resolution Chemicals Limited should be rejected for the reasons set out in confidential annex 1, which is accessible only to Resolution Chemicals Limited.

17.6. Conclusion: final amount of fines for Merck, Arrow, Alpharma and Ranbaxy

- (1396) The final amounts of the fines to be imposed pursuant to Article 23(2) of Regulation (EC) No 1/2003 on Merck, Arrow, Alpharma and Ranbaxy are as follows:

Undertaking	Amount of Fine
Merck	Merck KGaA: EUR 21 411 000 of which jointly and severally with Generics [UK] Limited: EUR 7 766 843 Total amount: EUR 21 411 000
Arrow	Arrow Group ApS: EUR 9 975 000 of which jointly and severally with Arrow Generics Limited ²²⁸⁰ : EUR 9 360 000 of the latter amount of which jointly and severally with Resolution Chemicals Limited ²²⁸¹ : EUR 823 735 Total amount: EUR 9 975 000
Alpharma	Zoetis Products LLC and Xellia Pharmaceuticals ApS jointly and severally: EUR 10 530 000 of which jointly and severally with A.L. Industrier AS: EUR 43 216 Total amount: EUR 10 530 000

undertaking as a whole, including its shareholders, irrespective of the finding of liability. (Case C-335/99 P (R), *HFB v. Commission*, [1999] ECR I-8705; Case C-7/01 P(R), *FEG v. Commission*, [2001] ECR I-2559), and Case T-410/09 R *Almamet v. Commission* (not yet reported), at paragraphs 47 *et seq.*)

²²⁸⁰ Arrow Generics Limited is held jointly and severally liable for the United Kingdom agreement only.

²²⁸¹ Resolution Chemicals Limited is held jointly and severally liable for the United Kingdom agreement only.

Ranbaxy	Ranbaxy Laboratories Limited and Ranbaxy (UK) Limited, jointly and severally: EUR 10 323 000. Total amount: EUR 10 323 000
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18. CONCLUSION

- (1397) In light of the considerations set out in this Decision, the Commission finds that Lundbeck, Merck, Arrow, Alpharma and Ranbaxy have infringed Article 101 of the Treaty and Article 53 of the EEA Agreement by concluding and implementing the agreements covered by this Decision and that fines should be imposed on them pursuant to Article 23(2) of Regulation (EC) No 1/2003.

HAS ADOPTED THIS DECISION:

Article 1

- (1) H. Lundbeck A/S, Generics [UK] Limited and Merck KGaA infringed Article 101 of the Treaty and Article 53 of the EEA Agreement by participating, from 24 January 2002 to 1 November 2003, in two agreements analysed in this Decision, one concerning the United Kingdom and one concerning the EEA excluding the United Kingdom, which together constitute a single and continuous infringement. Lundbeck Limited infringed Article 101 of the Treaty and Article 53 of the EEA Agreement by participating, from 24 January 2002 to 1 November 2003, in the agreement concerning the United Kingdom.
- (2) H. Lundbeck A/S and Arrow Group ApS infringed Article 101 of the Treaty and Article 53 of the EEA Agreement by participating, from 24 January 2002 to 20 October 2003, in two agreements analysed in this Decision, one concerning the United Kingdom and one concerning Denmark, which together constitute a single and continuous infringement. Arrow Generics Limited and Resolution Chemicals Limited infringed Article 101 of the Treaty and Article 53 of the EEA Agreement by participating, from 24 January 2002 to 20 October 2003, in the agreement concerning the United Kingdom.
- (3) H. Lundbeck A/S, Xellia Pharmaceuticals ApS, Zoetis Products LLC and A.L. Industrier AS infringed Article 101 of the Treaty and Article 53 of the EEA Agreement by participating, from 22 February 2002 to 30 June 2003, in an agreement concerning the EEA analysed in this Decision.
- (4) H. Lundbeck A/S, Ranbaxy (U.K.) Limited and Ranbaxy Laboratories Limited infringed Article 101 of the Treaty and Article 53 of the EEA Agreement by participating, from 16 June 2002 to 31 December 2003, in an agreement concerning the EEA analysed in this Decision.

Article 2

- (1) For the infringement referred to in Article 1.1, the following fines are imposed:
H. Lundbeck A/S: EUR 19 893 000
of which jointly and severally with Lundbeck Limited: EUR 5 306 000;
Merck KGaA: EUR 21 411 000
of which jointly and severally with Generics [UK] Limited: EUR 7 766 843.
- (2) For the infringement referred to in Article 1.2, the following fines are imposed:
H. Lundbeck A/S: EUR 12 951 000;
Arrow Group ApS: EUR 9 975 000
of which jointly and severally with Arrow Generics Limited: EUR 9 360 000
of the latter amount of which jointly and severally with Resolution Chemicals Limited: EUR 823 735.
- (3) For the infringement referred to in Article 1.3, the following fines are imposed:
H. Lundbeck A/S: EUR 31 968 000;
Zoetis Products LLC and Xellia Pharmaceuticals ApS jointly and severally:
EUR 10 530 000
of which jointly and severally with A.L. Industrier AS: EUR 43 216.
- (4) For the infringement referred to in Article 1.4, the following fines are imposed:
H. Lundbeck A/S: EUR 28 954 000;
Ranbaxy Laboratories Limited and Ranbaxy (U.K.) Limited, jointly and severally:
EUR 10 323 000.
- (5) The fines shall be paid in euro within three months of the date of the notification of this Decision to the following 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 /COMP / AT.39226

After the expiry of that period, interest shall 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 shall cover the fine by the due date by either providing an acceptable bank guarantee or

making a provisional payment of the fine in accordance with Article 90 of Commission Delegated Regulation (EU) No 1268/2012²²⁸².

Article 3

The undertakings listed in Article 1 shall refrain from repeating any act or conduct described in Article 1, and from any act or conduct having the same or similar object or effect.

Article 4

This Decision is addressed to:

Lundbeck Limited

Lundbeck House
Caldecotte Lake Business Park
Caldecotte
Milton Keynes MK7 8LG
United Kingdom

H. Lundbeck A/S

Ottiliavej 9
2500 Valby
Denmark

Generics [UK] Limited

Albany Gate
Darkes Lane
Potters Bar
Hertfordshire EN6 1AG
United Kingdom

Merck KGaA

Frankfurter Strasse 250
64293 Darmstadt
Germany

²²⁸² OJ L 362, 31.12.2012, p. 1.

Arrow Generics Limited

7 Cavendish Square
London W1G 0PE
United Kingdom

Arrow Group ApS

Sankt Peders Straede 2, 1
4000 Roskilde
Denmark

Resolution Chemicals Limited

Wedgwood Way
Stevenage
Hertfordshire SG1 4QT
United Kingdom

Xellia Pharmaceuticals ApS

Dalslandsgade 11
2300 Copenhagen S
Denmark

Zoetis Products LLC

100 Campus Drive
Florham Park
New Jersey 07932
United States of America

A.L. Industrier AS

Harbitzalléen 3
P.O. Box 158 Skøyen
0212 Oslo
Norway

Ranbaxy (U.K.) Limited

Building 4

Chiswick Park
566 Chiswick High Road
London W4 5YE
United Kingdom

Ranbaxy Laboratories Limited

Plot No. 90
Sector 32
Gurgaon – 122 001
Haryana
India

This Decision shall be enforceable pursuant to Article 299 of the Treaty and Article 110 of the EEA Agreement.

Done at Brussels, 19.6.2013

For the Commission

*Joaquín ALMUNIA
Vice-President*

