

Case No COMP/M.6613 - WATSON / ACTAVIS

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004
MERCER PROCEDURE**

Article 6(1)(b) NON-OPPOSITION

Date: 05/10/2012

***In electronic form on the EUR-Lex website under document
number 32012M6613***



Brussels, 5.10.2012
C(2012) 7127

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus [...]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE

To the notifying party:

**Subject: Case No COMP/M.6613 – WATSON/ACTAVIS
Commission decision pursuant to Article 6(1)(b) of Council Regulation
No 139/2004¹**

Dear Sir/Madam,

1. On 31 August 2012, the European Commission received the notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which the undertaking Watson Pharmaceuticals, Inc. ("Watson") proposes to acquire sole control within the meaning of Article 3(1)(b) of the Merger Regulation of Actavis Pharma Holding 4 ehf., Actavis S.à r.l. and Actavis Inc. (together "Actavis", which directly or indirectly own the companies comprising the Actavis group) by way of purchase of shares.

I. THE PARTIES

2. Watson is a US-based global pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of generic, brand and biologic pharmaceutical products.
3. Actavis is a Swiss-based pharmaceutical group, specializing in the development, manufacturing and sale of generic pharmaceuticals.

1 OJ L 24, 29.1.2004, p. 1 ("the Merger Regulation"). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ("TFEU") has introduced certain changes, such as the replacement of "Community" by "Union" and "common market" by "internal market". The terminology of the TFEU will be used throughout this decision.

II. THE OPERATION

4. Pursuant to the sale purchase agreement signed on 25 April 2012, Watson will acquire the entire share capital of Actavis. The transaction thus constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

III. EU DIMENSION

5. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million² (Watson: 3 300 million; Actavis: [...] million). Each of them has a EU-wide turnover in excess of EUR 250 million (Watson: [...] million; Actavis: [...] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State. The notified operation therefore has an EU dimension.

IV. HORIZONTAL OVERLAPS – FINISHED DOSE PHARMACEUTICALS

1. EXISTING HORIZONTAL OVERLAPS

1.1. Market definition

1.1.1. General approach to product market definition

6. In previous cases the Commission took as a starting point for market definition purposes the Anatomical Therapeutic Chemical ("ATC") division of medicines by therapeutic use devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS").³ This classification has the advantage of being developed and maintained for commercial use and providing ready access to statistics. It is based on finished dose pharmaceutical products and their approved indications in different countries, which may in some cases vary from one country to another.
7. In accordance with more recent pharmaceutical decisions⁴, the notifying party considered market definitions based on the third (ATC3) and fourth (ATC4) level of the ATC classification. In addition, recent pharmaceutical decisions involving generic companies⁵ also considered systematically a narrower market definition that assumes that the relevant market could consist of only drugs that are based on the same "molecule" or "API" (active pharmaceutical ingredient). The notifying party therefore also identified affected markets based on the molecule.
8. In addition, the notifying party identified any additional affected markets based on two further distinctions at each of the three levels (i.e. ATC3, ATC4 and molecule).

² Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p1).

³ It should be noted, for the avoidance of confusion, that the EphMRA ATC classification, whilst similar to the ATC classification maintained by the World Health Organization (WHO), is not exactly the same as the latter. The WHO classification uses similar categories but is based on active ingredients and serves a scientific, rather than commercial, purpose. Thus, a given active ingredient is classified in only one place in the WHO classification, whereas products based on it may be classified in more than one class of the IMS classification, depending on formulation and approved use in a given country.

⁴ See for example M.5865 Teva/Ratiopharm, decision of 3 August 2010.

⁵ See for example M.5865 Teva/Ratiopharm, decision of 3 August 2010.

9. The first of these is the distinction based on the main forms in which a drug based on the same main active ingredient may be available, which was considered in more recent decisions⁶. Medicines are differentiated not only by their active ingredient(s), but also, in particular, as recognized by the European regulatory framework for medicines for human use, by their dosage, pharmaceutical form and route of administration and this may limit their substitutability. For the purposes of this decision, and in accordance with previous decisions, the Commission considered potential distinctions to this effect with reference to the first letter of the typology of form codes (the so-called "New Form Code" or NFC) used by IMS/EphMRA⁷. In general, the first letter differentiates between forms for systemic and topical effect, site of application, and also between long-acting and ordinary forms. Such forms will hereafter be referred to as "NFC-1 forms".
10. The second distinction is between prescription only ("Rx") and over-the-counter ("OTC") drugs, which is a distinction that has traditionally been made in pharmaceutical decisions⁸⁹.
11. It should be noted that in the present case it is typically on the basis of relatively narrow market definitions (molecule or even one particular NFC-1 form of a molecule) that the parties achieve relatively higher market shares. The notifying party considers the markets to be wider in all these cases.
12. The Commission did not previously define separate markets for generic and originator pharmaceuticals. In fact, it was acknowledged that generics are typically the closest substitute to originators and are specifically designed to compete with those medicines¹⁰. This distinction was nevertheless taken into account when assessing the closeness of competition in the markets investigated.
13. In the present case the market definitions can be left open considering all the aspects outlined above as competition concerns do not arise in any affected potential market irrespective of the market definition.

1.1.2. Product market definition in specific markets

14. In some previous cases the Commission identified plausible markets which do not correspond exactly to the regular set of criteria as described above (for example, a market that may include certain products from different ATC3 categories and/or a market that includes only a sub-set of molecules in a given ATC3 category that does not correspond to any given ATC4 category, etc.). The notifying party in the present case identified overlaps in some of these irregular markets. These markets are described in this section.

⁶ See for example M.5865 Teva/Ratiopharm, decision of 3 August 2010.

⁷ www.ephmra.org/pdf/NFCVersion2010Guidelines.

⁸ See for example M.5865 Teva/Ratiopharm, decision of 3 August 2010; M.5778 Novartis/Alcon, decision of 9 August 2010; and M.5661 Abbott/Solvay Pharmaceuticals, decision of 11 February 2010.

⁹ If the distinction by NFC-1 forms and/or the Rx/OTC distinction is not mentioned in the respective assessments of individual markets under Sections 1.2.1 to 1.2.3, it does not make any material difference to the market structure in those markets.

¹⁰ M.5865 Teva/Ratiopharm, decision of 3 August 2010.

15. In addition, the Commission in the present case investigated in detail whether the correct market definition may be the molecule or wider in a few instances where such a distinction made a significant difference in the market structure. These markets are also described below.
16. In all other instances of overlaps the Commission follows for the purposes of the present case the "regular" criteria to market definition as outlined in recitals 6-10. As these criteria are precisely described above, these markets are not described in further detail here.

1.1.2.1. C2A and G4C – antihypertensives and benign prostatic hypertrophy products

17. The ATC3 class C2A includes a group of substances used primarily for the treatment of hypertension, and is split in three ATC4 classes. The ATC3 class G4C includes BPH (benign prostatic hypertrophy) products, which treat the growth of individual prostatic stromal and epithelial cells and is split in seven ATC4 classes, two of which are out of use.
18. The parties' activities overlap regarding doxazosin, classified in ATC4 class C2A2 (plain anti-hypertensives), and tamsulosin, classified in ATC3 class G4C2, in Denmark. Actavis has a further product, finasteride, in ATC4 class G4C3. All three products have an indication for the treatment of benign prostatic hypertrophy (or hyperplasia), despite belonging to different ATC3 classes.
19. In a previous decision¹¹, the Commission considered that the relevant market was not the ATC3 class C2A, but left open whether the relevant market should be defined at ATC4 level, C2A2, or would comprise several molecules within the ATC4 class C2A2, as doxazosin, prazosin and terazosin. Since several molecules previously classified in the classes C2A2 are now grouped into ATC4 classes G4C2 and G4C3¹², the market definition of the precedent that the market should be defined at ATC4 level (C2A2) is no longer meaningful. The parties argue for a wider market comprising several molecules of the ATC4 classes C2A2 and G4C2 due to the common indication for prostatic hypertrophy. The market investigation was not conclusive on the substitutability of doxazosin with terazosin and other molecules in ATC4 classes G4C2 and G4C3; about half of the respondents (both competitors and customers) indicated a wider than molecule market for doxazosin. Regarding tamsulosin, the market investigation indicated that the market could be wider than the molecule and that tamsulosin could be substitutable with other molecules of the ATC4 class G4C2, such as alfuzosin and terazosin.
20. However, for both doxazosin and tamsulosin, the market definition can be left open as the transaction does not raise serious doubts even on the basis of a market definition on the molecule level.

¹¹ See M.5865 Teva/Ratiopharm, decision of 3 August 2010, recital 130.

¹² Following an ATC reclassification in 2012 alfuzosin, tamsulosin and terazosin, which used to be in the ATC4 category C2A2, are now classified in ATC4 class G4C2. In addition, the ATC4 class G4C1 was eliminated and the different molecules in that class are now re-classified in different ATC4 categories.

1.1.2.2. C8A – Calcium-antagonists, plain

21. For the ATC3 category C8A which is not sub-divided into ATC4 categories, the Commission considered a distinction between dihydropyridine (DHP) and non-DHP drugs¹³ in addition to the standard criteria. However, in the present case the market definition can be left open as the transaction does not raise serious doubts on any market definition based on standard criteria or on this irregular market definition.

1.1.2.3. C9A - ACE inhibitors

22. The parties overlap on a molecule called lisinopril, which belongs to a group of anti-hypertensive drugs which have a specific mode of action as compared to other anti-hypertensive drugs. These are called "ACE inhibitors" and are grouped under the ATC3 category C9A. These ACE inhibitors can also be combined with other molecules in the same drug. Such combination drugs are classified in the ATC3 category C9B.
23. Earlier Commission decisions assessing ACE inhibitors specifically defined the market as including all plain ACE inhibitors (the C9A ATC3 category) or wider (also including combination ACE inhibitors in the C9B category)¹⁴. The notifying party concurs with a wider market definition. Whilst a recent Commission decision¹⁵ also looked at market shares at the narrower molecule level, this is not due to the specificities of this particular market that became apparent in later cases but due to a general methodology applied in the assessment of overlaps (in all pharmaceutical products) after the decision in Teva/Barr¹⁶.
24. However, in the present case the market definition can be left open as the transaction does not raise serious doubts on any market definition regarding ACE inhibitors.

1.1.2.4. L4X – other immunosuppressants

25. The L4X category includes other immunosuppressant agents which are substances used to prevent the production of antibodies and are used at different stages of therapy against organ transplant rejection but also for a number of other indications such as other autoimmune diseases such as rheumatoid arthritis. Watson sells azathioprine and mycophenolate mofetil in ATC3 category L4X, while Actavis sells azathioprine and cyclosporin.
26. The Commission previously considered the market for immunosuppressants for the treatment of rejection in organ transplants which were at that time grouped into the ATC3 class L4A together with products of other indications¹⁷. In particular, the Commission considered to subdivide treatments of organ transplant rejection into four categories, but ultimately left the market definition open. The notifying party submits that market definition is most likely the molecule level as immunosuppressants can generally not be substituted, but nevertheless submitted market share data for the other

¹³ The two types of drugs differ in their basic chemical structure and selectivity.

¹⁴ See cases M.1403 Astra/Zeneca, decision of 26 February 1999; M.1878 Pfizer/Warner-Lambert, decision of 22 May 2000; M.2517 Bristol Myers Squibb/Du Pont, decision of 9 August 2001; M.3354 Sanofi-Synthe-Labo/Aventis, decision of 26 April 2004.

¹⁵ M.5661 Abbott/Solvay Pharmaceuticals, decision of 2 November 2010.

¹⁶ M.5295 Teva/Barr, decision of 18 December 2008.

¹⁷ M.4049 Novartis/Chiron, decision of 6 February 2006, recital 20; M.5999 Sanofi-Aventis/Genzyme, decision of 12 January 2011, recitals 65-69.

previously considered market definitions. However, the market definition can be left open as the transaction does not raise serious doubts even on the basis of the narrowest market definition, i.e. the molecule level.

1.1.2.5. M5B – bone calcium regulators

27. Both parties produce and sell bone calcium regulators classified under the ATC3 category M5B. Calcium regulators are predominantly used to treat osteoporosis, which is a disease of bone that leads to an increased risk of fracture, but can also be used for other indications such as oncology. Pharmaceuticals in this ATC3 class are further subdivided at ATC4 level into M5B3, which includes bisphosphonates used in the treatment of osteoporosis, M5B4, which covers bisphosphonates used in oncology for the treatment of tumour-related calcium disorders, and M5B9, which consists of other bone calcium regulators. Besides the standard market definition criteria, the Commission also previously considered the possibility of a relevant market containing all bisphosphonates, i.e. the ATC4 classes M5B3 and M4B4¹⁸.
28. The market definition in the present case, however, can be left open as the transaction would not give rise to serious doubts based either on the standard criteria (including ATC3, ATC4 or molecule basis) or if all bisphosphonates (M4B3 and M5B4 combined) were grouped together.

1.1.2.6. N6A – antidepressants and mood stabilizers

29. The N6A class includes drugs used in the treatment of depression and mood stabilisation. It is further subdivided in the EphMRA classification based on mechanism of action into selective serotonin re-uptake inhibitor (SSRI) antidepressants (N6A4), serotonin–norepinephrine reuptake inhibitors (SNRI) antidepressants (N6A5) and other antidepressants (N6A9). Further two ATC4 categories include herbal antidepressants (N6A2) and mood stabilizers (N6A3). Anti-depressants can also be grouped based on their chemical structure, e.g. into tricyclic (TCAs), tetracyclic (TeCAs), or monoamine oxidase inhibitors (MAOIs). Mirtazapine¹⁹ and mianserin molecules, which are concerned by the proposed transaction, are TeCAs and belong to the N6A9 ATC4 class. All drugs in the ATC4 class N6A9 are prescription products.
30. In Teva/Barr²⁰, the Commission left open whether the market ought to be defined on the basis of the ATC3 class, the ATC3 class excluding the ATC4 classes N6A2 (herbal) and N6A3 (indication for bipolar disorders) or the ATC4 class N6A9, but also noted that there were no indications that the market should be defined at the molecule level. However, in Teva/Ratiopharm²¹ the Commission analysed several molecules on potentially narrower markets, while leaving the market definition ultimately open. In relation to mirtazapine in the Netherlands, the Commission considered in Teva/Ratiopharm that mirtazapine has largely replaced its predecessor mianserin, and that customers would switch to mirtazapine should prices for mianserin increase, but ultimately left the market definition open.

¹⁸ See M.5555 Novartis/Ebewe, decision of 22 September 2009.

¹⁹ Mirtazapine (N6A9) is a pre-synaptic alpha-2-inhibitor, used to treat major depressive disorders, and a predecessor molecule to mianserin. It operates through selective blockade of specific serotonin receptors.

²⁰ See M.5295 Teva/Barr, decision of 18 December 2008, recitals 159-166.

²¹ See M.5865 Teva/Ratiopharm, decision of 3 August 2010, recitals 302-333.

31. In the view of the notifying party, the market should not be defined on the narrow molecule level, in particular because various molecules represent differences in chemical structure and mode of action, but not in therapeutic indication, in particular when considering molecules included in the same ATC4 class.
32. The majority of respondents to the market investigation did not support the view that the relevant product market would be limited to the individual mirtazapine molecule, or alternatively only to mirtazapine and mianserin molecules. A majority of respondents also specified that certain molecules from other ATC4 categories (mostly SSRIs, SNRIs) and certain molecules of a different chemical structure (such as TCAs) could be regarded as interchangeable with mirtazapine based anti-depressants in view of their product characteristics, prices and intended uses. However, it was also emphasized that individual decisions whether to switch a patient to a different molecule remains with treating physicians based on individual patient needs (i.e. "age" , severity of depression, adverse drug reactions, other contra-indications).
33. In any event, in the absence of competition concerns under any plausible market definition, it can be left open whether mirtazapine (or alternatively, mirtazapine and mianserin) molecules constitute a separate market or belong to a broader relevant market category, be it a combination of individual interchangeable molecules, the N6A9 class or the overall N6A ATC3 category. It can also be left open whether the relevant market should be segmented by galenic form, given that the parties and all of their major competitors sell mirtazapine based products in oral solid ordinary form. Therefore, any plausible distinction based on galenic form would have no material impact on the competitive assessment.

1.1.3. Geographic market definition

34. In previous decisions²², the Commission found that the relevant geographic market for finished pharmaceutical products was national. The notifying party does not dispute this market definition and presented the relevant market information on a national basis.

1.2. Competitive assessment

35. Given the large number of affected markets, and in accordance with case practice²³, the notifying party grouped all affected pharmaceuticals markets in three categories. These groupings are:
Group 1: The parties' joint market share exceeds 35% and the increment exceeds 1%.
Group 2: The parties' joint market share exceeds 35% but the increment is up to 1%.
Group 3: The parties' joint market share is between 15% and 35%.
36. The Commission focused its investigation on affected markets falling into category 1 ("Group 1" markets). The three geographic markets where Group 1 markets arise are Denmark, Sweden and the UK. Sections 1.2.1 to 1.2.3 of this decision provide the assessment of the Group 1 markets in these countries.

²² See for example M.5865 Teva/Ratiopharm, decision of 3 August 2010; M.5778 Novartis/Alcon, decision of 9 August 2010; and M.5661 Abbott/Solvay Pharmaceuticals, decision of 11 February 2010.

²³ See for example M.5865 Teva/Ratiopharm, decision of 3 August 2010; M.5778 Novartis/Alcon, decision of 9 August 2010; and M.5661 Abbott/Solvay Pharmaceuticals, decision of 11 February 2010.

37. For all other markets where the parties' activities overlap and their joint market shares do not exceed 35% under any plausible market definition and/or where the increment is below 1%, competition concerns may be excluded. According to the market data provided by the parties, there are no competition concerns. Also the market investigation did not indicate that competition in any of these markets would be significantly impeded. It may therefore be concluded that for none of these markets the transaction raises serious doubts as to its compatibility with the internal market and the EEA-agreement in the sense of Article 6(1)(b) of the Merger Regulation (hereafter referred to as "serious doubts")²⁴.
38. In accordance with case practice the Commission requested value data for all markets as a basis for calculating market shares. For all markets wider than the molecule Group 1 markets are identified based on sales value. In addition, and in accordance with more recent generic cases, the Commission systematically requested data based on weight of active ingredient for molecule markets and for markets based on one specific NFC-1 form of a molecule, as well as on standard units. In Group 1 markets the difference between the market structures using weight compared to standard units is not significant. Volume figures in this decision will therefore be given based on the weight of the active ingredient. It should be further noted that the indication of molecule level market shares by volume may not be representative if a molecule is sold in different NFC forms (unless it is predominantly sold in one and the same NFC form). This is because the same active ingredient in significantly different forms (e.g. liquid vs solid) may require different weights to achieve the same therapeutic result.
39. The Commission cites market shares according to IMS data for 2011 unless otherwise stated; however, it has considered data for the three years from 2009-2011 in its analysis and, in certain cases, also more recent data. Where this leads to a modification to the assessment it is mentioned in the relevant sections below.

1.2.1. Denmark

1.2.1.1. General competitive conditions

40. According to the data published by the European Generics Medicines Association, Denmark has one of the highest levels of generic penetration by volume in Europe. This, as also confirmed by the market investigation, is to a significant extent due to a special regulatory incentive system in place as described below. A study by Danmarks Apotekerforening (Danish Pharmaceutical Association) found that prices are 35% higher in Sweden and 50% in Norway, compared to Denmark²⁵.
41. According to the parties the main generic pharmaceuticals companies active in Denmark include Teva, Sandoz (Novartis), Krka, Astellas Pharma, Aspen Pharma, Desitin, Stada, Orion, Bluefish, and Fresenius. Actavis is, according to the parties, in the top five of generic companies based on IMS. Watson on the other hand does not appear to be a significant player, achieving a total turnover of only EUR [...] million in 2011 (against Actavis' EUR [...] million). The Danish Health and Medicines Agency ("DKMA") confirmed that Watson's corporate brand is not well known in Denmark,

²⁴ The Commission previously used the same methodology for focussing its investigation, e.g. M.5865 Teva/Ratiopharm, decision of 3 August 2010.

²⁵ According to the parties, this is quoted in an article published on 19 September 2012 in the Danish Newspaper Politiken available at <http://politiken.dk/tjek/sundhedogmotion/ECE1757908/danskere-sparrer-enmilliard-kroner-paa-kopimedicin/>

whilst the corporate brand of Actavis is not particularly strong and is comparable to many other generics. Furthermore, neither party appears to have any unique assets or capabilities which at least several competitors would find difficult to emulate.

42. Pharmaceutical companies must report their pharmacy purchasing prices for all pharmaceuticals on the market to DKMA. The DKMA then calculates the pharmacy retail price using a fixed mark-up. The price list is distributed by the DKMA to all pharmacies. The prices can be altered by the company every two weeks when a new official price list is drawn up by the DKMA. This ensures that within the two week period between the price quotes, prices are the same for the same product across Denmark.
43. Reimbursement levels for prescription products are set based on the cheapest available product in the substitution group. This substitution group does not comprise products that are based on different molecules or even different galenic forms of the same molecule. The reimbursement system would therefore have the most impact on markets which are molecule or even narrower (galenic form of the molecule). Pharmacists in Denmark must always dispense the cheapest product they have available in any given substitution group unless specifically prohibited by the doctor or in the event that the patient opposes the substitution (even if s/he has to pay a higher co-payment). In order to facilitate this, products in any given substitution group are allocated an "A", "B" or "C" classification. "A" is the lowest price product and indicates that this pack is a first choice, "B" indicates that the price of the pack is within the acceptable price limits making dispensing optional but not mandatory, and "C" indicates a pack which as a rule should not be dispensed according to the prescription. Pharmacists are required to inform the patient of the existence of an "A" rated product even if they do not have it on stock.
44. The parties consider that the process of bi-weekly price notifications together with the fact that the reimbursement price is set at the lowest price within the substitution group, results in significant competitive pressure and low barriers to entry and re-entry. This was broadly confirmed by the market investigation.
45. In particular, the DKMA confirmed that the bi-weekly price notification system introduces an element of price sensitivity in demand. A significant switch of demand to cheaper alternatives based on the same molecule is therefore expected in case of a durable 5-10% price increase for a prescription drug. If a company already has a marketing authorisation for a product based on the same API, it is expected that it would be able to increase its market share in this scenario.
46. Furthermore, the DKMA estimates that it should take less than 6 months for a company to enter from a neighbouring country with a product if it already has a sales and distribution system in place in Denmark. In general, the DKMA considers the supply of prescription pharmaceuticals in Denmark to be very competitive. Denmark generally seems to get generic alternatives fairly quickly and attracts a number of suppliers that is higher or at least comparable to other EEA countries.
47. Based on the above, there do not appear to be significant barriers to expansion and entry for generic drugs in Denmark that would prevent a competitive supplier of a product to compete effectively with established suppliers of the same product.

1.2.1.2. C2A and G4C – antihypertensives and benign prostatic hypertrophy products

48. The parties' activities overlap regarding doxazosin, classified in ATC4 class C2A2 (plain anti-hypertensives), and tamsulosin, classified in ATC3 class G4C2, in Denmark. Actavis has a further product, finasteride, in ATC4 class G4C3. All three products have an indication for the treatment of benign prostatic hypertrophy (or hyperplasia), despite belonging to different ATC3 classes.
49. The combined market share on the molecule level for doxazosin is [50-60%] with an increment contributed by Watson of [10-20%] (based on value data) and 63% with an increment of [10-20%] (based on volume). There is a significant degree of generic penetration in the market for doxazosin since its basic patent expiry in 1998. Competitors include Orifarm, which is a large, established generics supplier in Denmark, with a market share of [30-40%] by value and [30-40%] by volume, Stada ([5-10%] by value and [0-5%] by volume) and Pfizer ([5-10%] by value and [0-5%] by volume)²⁶. In the market investigation competitors confirmed that they would be able to expand supplies for doxazosin in Denmark in the short term and without significant investments in case of an attempted price increase by the parties post transaction. Accordingly, it can be assumed that the competitors will continue to constrain the merged entity post transaction.
50. Regarding tamsulosin (ATC4 category G4C2), the combined market share on the molecule level is [50-60%] with an increment contributed by Watson of [10-20%] based on value data and [50-60%] with an increment of [20-30%] based on volume. Competitors include Novartis ([20-30%] by value and [20-30%] by volume), Stada ([5-10%] by value and [10-20%] by volume), Teva ([0-5%] by value and [0-5%] by volume) and Astellas Pharma ([10-20%] by value and [0-5%] by volume). In the market investigation competitors confirmed that they would be able to expand supplies for tamsulosin in Denmark in the short term and without significant investments in case of an attempted price increase by the parties post transaction. Accordingly, it is likely that the competitors will continue to constrain the merged entity post transaction.
51. Based on the above, and taking into account the general competitive conditions for the supply of generic pharmaceuticals in Denmark, the transaction does not raise serious doubts regarding the supply of doxazosin and tamsulosin in Denmark, under any plausible market definition.

1.2.1.3. C8A calcium antagonists, plain

52. The parties' products only overlap in the hypothetical market of DHPs. The only molecule supplied by both parties within this segment is "amlodipine". The transaction results in a Group 1 market only at the molecule level (as "amlodipine" is only sold in oral solid ordinary form, the NFC-1 distinction is not relevant). The parties achieve a combined share of [40-50%] (by volume) with an increment of only [0-5%] by Watson. Watson is clearly not the main competitive constraint on Actavis. Novartis has a market share of [30-40%] and other established generic suppliers such as Orifarm and Bluefish have a market share around [10-20%] each. Furthermore, other credible competitors such as Teva, Stada, Pfizer, Orion and Krka are present in the market. In view of the small increment by Watson and the presence of substantially stronger competitors, and taking

²⁶ Competitors are Orifarm with [30-40%], Pfizer with [5-10%] and Stada with [5-10%] based on value data (and [30-40%], [0-5%] and [0-5%] respectively based on volume).

into account the general competitive conditions for the supply of generic pharmaceuticals in Denmark, the transaction does not raise serious doubts in amlopidine, in DHPs or in any other plausible market definition for plain calcium antagonists.

1.2.1.4. C9A – ACE Inhibitors

Lisinopril

53. The transaction only leads to Group 1 markets on a narrowly defined molecule level. The two molecules concerned are lisinopril and trandolapril. These molecules are only sold in one NFC-1 form (Category A – oral solid ordinary), hence market shares are the same based on galenic form.
54. The patent for lisinopril expired 10 years ago and it is therefore already widely genericised. The originator of lisinopril (AstraZeneca) no longer plays a role in the Danish market. The parties together account for [60-70%] of the market (Actavis [40-50%], Watson [20-30%]). The remainder of the market in 2011 was taken by two large multinational generic companies, Stada ([20-30%]) and Mylan ([5-10%]). The value of the market is about EUR [...]. Given that the market is already genericised, the market structure is not materially different considering sales values.
55. Whilst Mylan achieved a [5-10%] market share in 2011, based on the public price notification information and IMS data, it does not appear to have made any sales since mid-2011. According to the notifying party, this is not an indication that Mylan has made a decision to "exit" the lisinopril market in Denmark, or that it will face any barriers should it wish to "re-enter" the market if prices were to increase post-merger. In particular, based on the review of the public price notification data in Denmark in the past 5 years, the notifying party points out that Mylan has also in previous periods, prior to 2011, not tendered a price for lisinopril for certain bi-weekly periods (as long as 7 months in duration), following which it again successfully tendered for lisinopril. The notifying party further submits that, to its knowledge, Mylan updated its Danish marketing authorisation for the supply of lisinopril in October 2011 and continues to be active in the market for the supply of lisinopril in the EEA, including in nearby countries Germany, Sweden and Finland (although, based on the market data provided by the parties, it does not capture a significant part of the market in these countries). The parties therefore consider that Mylan should be regarded as a competitive constraint.
56. In general the parties argue that there remain in any event a sufficient number of actual and potential competitors (besides Mylan) to constrain the merged entity. These include the existing competitor Stada, and a number of companies which have an established presence in Denmark and have a valid marketing authorisation for lisinopril specifically and/or which at least supply lisinopril in other countries (especially those in proximity to Denmark).
57. Based on IMS data, the largest lisinopril suppliers in the nearby countries (and in the EEA in general) are, besides Actavis, Teva, Novartis and Stada. Watson is not a significant supplier in the EEA, it achieves meaningful market shares outside of Denmark only in France and Sweden ([0-5%] and [5-10%] respectively). According to the DMKA all of the larger suppliers have valid marketing authorisations for lisinopril in Denmark.

58. Historical data confirms that the lisinopril market in Denmark is contestable. Actavis lost around [20-30]% of market share between 2010 and 2011, which was picked up by Watson and Stada (more or less evenly). In addition, monthly data for 2011 and 2012 show that market shares are highly fluctuating, frequently falling or increasing by 30%-points or more from one month to the next. This is due to the Danish system of bi-weekly price quotes by the companies on the basis of which the reimbursement levels are fixed and the lowest pricing company taking the vast majority of the market over the next two weeks. The market investigation confirmed that this system significantly facilitates for competitive suppliers of ACE inhibitors (and, in particular, lisinopril) to enter and/or expand their sales significantly in Denmark.
59. Competitors' replies also specifically confirmed that entry and expansion was possible in the lisinopril market in Denmark. In particular, it was confirmed that it was feasible (without significant investments and typically within 1 year) for a supplier of lisinopril in the EEA (and in particular in neighbouring countries) to increase significantly its sales of lisinopril products in Denmark, if it already has an established sales and distribution network in Denmark and, in particular, a portfolio of cardiovascular drugs. All major suppliers of lisinopril in the EEA as listed above meet this criteria. In addition they also have a valid marketing authorisation.
60. Finally, the market investigation did not point to any particular advantages of the parties either in terms of their lisinopril products or general capabilities (sales, distribution, manufacturing) that would in general allow them to compete more effectively in the Danish market²⁷ than their main actual or potential competitors. Again, this supports the conclusion that their market position is contestable by competitors.
61. Based on the above, the lisinopril market in Denmark appears to be a commodity market without any significant barriers to entry and expansion. There are at least three credible actual or potential competitors remaining which are at least comparable to the parties in terms of their product and their product generation and sales and distribution capabilities. In view of this and despite the concentrated market structure, the transaction does not raise serious doubts regarding the supply of lisinopril in Denmark, under any plausible market definition.

Trandolapril

62. In the supply of *trandolapril* the parties achieved a combined market share of [40-50%] with a [[5-10%] increment by Watson. The value of the market is just over EUR [...] million. According to IMS 2011 data there are two generic competitors remaining: Orifarm with [20-30%] and Orion with [20-30%]. Both companies are established regional suppliers of generic pharmaceuticals (and parallel imports) in the Nordic countries and have been confirmed by the market investigation to be credible competitors that could constrain the merged entity. The transaction thus does not raise serious doubts regarding the supply of *trandolapril* in Denmark, under any plausible market definition.

²⁷ Whilst one respondent pointed out as an advantage the parties' access to their own APIs, the parties confirmed that they do not have any supply relationships with any of their competitors. In any event, there are no indications that API sourcing would be a problem due to the merger - the parties did not indicate lisinopril as a vertically affected market, meaning that they do not achieve more than 5% upstream.

1.2.1.5. J1G – Fluoroquinolones - ciprofloxacin

63. In Denmark, according to the data provided by the notifying party, Group 1 markets in anti-epileptics arise only in relation to the ciprofloxacin molecule (ATC4 class J1G1) and based on oral solid galenic form of ciprofloxacin.
64. If ciprofloxacin was considered the relevant market, in 2011 the parties achieved a combined market share of [50-60%] with an increment of [10-20%] (Watson) by volume, while based on value the combined share would be well below [10-20%]. For the oral solid galenic form of ciprofloxacin, the parties achieved a combined market share of [50-60%] with an increment of [10-20%] (Watson) by volume, while based on value the combined share would be [50-60%] with an increment of [10-20%].
65. There is already a significant degree of generic penetration in the market for ciprofloxacin, since the patent expiry in 2003. The molecule was first launched by Bayer in 1983 under the brand "Ciproxin". Watson launched ciprofloxacin in Denmark in 2008, while Actavis is present since 2009. Based on 2011 IMS data, the parties are facing a number of generic competitors with significant shares in oral solid form of ciprofloxacin: Novartis ([10-20%] by value, [10-20%] by volume), Krka ([10-20%] by value, [5-10%] by volume), Teva (<[0-5%] by value, [0-5%] by volume), Stada (<[0-5%] by value, [0-5%] by volume), Medivir²⁸ ([10-20%] by value, [10-20%] by volume). The competitor market shares based on volume in the market for ciprofloxacin comprising all galenic forms remain closely comparable, except for the additional presence of Fresenius with a market share of [5-10%]. The market investigation confirmed the parties' view that a sufficient number of competitors active with ciprofloxacin products remain post-transaction (in particular, Krka, Teva, Novartis/Sandoz/Hexal, Stada were mentioned) and would be able to capture the demand and constrain the merged entity in Denmark.
66. On the basis of the above and the general competitive conditions for generic pharmaceuticals in Denmark, it can therefore be concluded that serious doubts do not arise on the Danish market for ciprofloxacin under any plausible market definition.

1.2.1.6. L4X – other immunosuppressants

67. On the basis of a market definition on the molecule level the parties would together account for [30-40%] of the market based on value (Actavis [20-30%], Watson [10-20%]) and [40-50%] based on volume (Actavis [30-40%], Watson [10-20%]). On the basis of the market definition considered in the precedent²⁹, i.e. the market for accompanying immunosuppressants for general organ transplant therapy, the market shares are not significantly different (combined [20-30%] by value with an increment of [5-10%] and [40-50%] by volume with an increment of [10-20%]). According to the notifying party, the first generic supplier entered the market in 2004 and azathioprine is already widely genericised. Competitors include generic suppliers such as Orifarm (market share of [20-30%] by value and [30-40%] by volume), Teva ([10-20%] by value, [10-20%] by volume) and Orion/Aspen³⁰ ([20-30%] by value and [10-20%] by

²⁸ Medivir has recently exited the market.

²⁹ M.4049 Novartis/Chiron, decision of 6 February 2006, recital 20; M.5999 Sanofi-Aventis/Genzyme, decision of 12 January 2011, recitals 65-69.

³⁰ Orion distributes for Aspen Europe GmbH in Denmark.

volume). These competitors will continue to constrain the merged entity post transaction.

68. On the basis of the above and the general competitive conditions for generic pharmaceuticals in Denmark, serious doubts do not arise with respect to azathioprine in Denmark.

1.2.1.7. N3A - anti-epileptics

69. In Denmark, according to the data provided by the notifying party, Group 1 markets in anti-epileptics arise only in relation to the lamotrigine molecule (ATC3 class N3A).
70. If lamotrigine was considered the relevant market, in 2011 the parties achieved a combined market share of [40-50%] with a minor increment of [0-5%] (Watson) by volume. Based on value, there would be no Group 1 market and combined market shares would not exceed 20%.
71. There is already a significant degree of generic penetration in the market for mirtazapine, since the patent expiry in 2005. The molecule was first launched by GSK under the brand "Lamictal". Watson launched lamotrigine rather recently in 2010, while Actavis is present since 2005. Based on 2011 IMS data, the parties are facing a number of competitors with significant market shares, including the originator GSK and generic players: GSK ([40-50%] by value, [5-10%] by volume), Teva ([20-30%] by value, [20-30%] by volume), Orifarm ([10-20%] by value, [10-20%] by volume), Stada ([10-20%] by value, [5-10%] by volume), Novartis (<[0-5%] by value and by volume), Medivir ([0-5%] by value, [0-5%] by volume). A sufficient number of competitors active with lamotrigine products would be able to capture the demand from a merged entity in Denmark in case of an attempted price increase.
72. On the basis of the above and the general competitive conditions for generic pharmaceuticals in Denmark, it can therefore be concluded that serious doubts do not arise on the Danish market for anti-epileptics (including all plausible narrower product markets, such as lamotrigine).

1.2.2. Sweden

1.2.2.1. General competitive conditions

73. In Sweden, according to IMS data, the top five generic companies are Novartis (Sandoz), Teva, Actavis, Meda and Johnson & Johnson. Other generic companies include Krka, Bluefish, Ranbaxy, Stada, Intas (Accord), Orifarm Generics, Medivir and Sopharma. Although Actavis ranks amongst the first five generic suppliers, Watson is not considered, neither in terms of sales, product range or branding, as a significant market player³¹. All respondents in the market investigation (the Swedish Medical Products Agency "Lakemedelsverket" ("SMPA"), the Swedish Association for generic pharmaceuticals and the Dental and Pharmaceutical Benefits Agency, Tandvards- och Lakemedelsformansverket ("TLV")) confirmed that Watson's corporate brand is not well known in Sweden and that the corporate brand of Actavis is not particularly strong and

³¹ As can be seen from the Parties' revenues in Sweden, Actavis, with its approximately €[...] million of sales, has a more significant presence than Watson, whose Swedish revenues are much smaller (approximately €[...] million).

is comparable to many other generics. Furthermore, neither party appears to have any unique assets or capabilities which at least several competitors would find difficult to emulate.

74. Pricing and reimbursement decisions on prescription pharmaceuticals used in out-patient care are made by TLV, which "sets" both the pharmacy purchase price and the pharmacy margin, thereby effectively determining a fixed national pharmacy retail price. Pharmaceutical companies can quote once per month their price for a particular product. The TLV singles out the generic supplier that has the lowest price on the market. Because generic substitution is mandatory for pharmaceuticals containing the same substance, in the same formulation and deemed comparable by the SMPA, the company which can offer the lowest price will get the vast majority of sales during the following month. The process of monthly price changes enables easy market entry and re-entry. The respondents confirmed that the demand for prescription drugs is to some extent price sensitive and expect a significant switch of demand to cheaper alternatives based on the same molecule in case of a durable 5-10% price increase.
75. Furthermore, the SMPA and the Swedish Association for generic pharmaceuticals estimate that it should take 6-12 months for a company to enter from a neighbouring country with a product if it already has a sales and distribution system in place in Sweden while the TVL estimates an even shorter time period of less than 6 months. The replying authorities and associations consider the supply of prescription pharmaceuticals in Sweden to be very or fairly competitive. Sweden generally seems to get generic alternatives fairly quickly and attracts a number of suppliers that is higher or at least comparable to other EEA countries.
76. Based on the above, there do not appear to be significant barriers to expansion and entry for generic drugs in Sweden that would prevent a competitive supplier of a product to compete effectively with established suppliers of the same product.

1.2.2.2. C9A – ACE inhibitors, plain

77. The transaction will result in a Group 1 overlap only based on a market defined at the level of the molecule, ramipril, and only based on volume.
78. The parties' combined share of ramipril is just [30-40%] with an increment of [10-20%] by Watson. As ramipril is sold in the same galenic form (NFC-1 category "A"- Oral Solid Ordinary), this distinction does not change the assessment. Given that the patent for this molecule expired in December 2004, there is already significant generic competition on the market. In particular, there are several competitors active in the supply of ramipril in Sweden, including Novartis ([30-40%]), Orifarm ([10-20%]), Teva ([10-20%]), the originator Sanofi ([5-10%]) and Stada ([0-5%]).
79. In view of the moderate combined market shares of the parties, which is just above the Group 1 threshold, the competitive pressure stemming from remaining competitors and general competitive conditions for generic pharmaceuticals in Sweden, serious doubts do not arise with respect to the supply of ramipril under any plausible market definition in Sweden.

1.2.2.3. M5B – bone calcium regulators

80. The transaction would result in a Group 1 market only if the market is defined on the basis of the molecule level or narrower (galenic form of a molecule) and only if the

market is calculated on the basis of sales value. The molecule concerned is alendronic acid. The parties' combined share would be [50-60%] (by value) with an increment of just [0-5%] by Actavis. By contrast, combined market shares would be only around [20-30%] based on volume. All suppliers sell alendronic acid in the same NFC-1 form, hence there is no difference in market shares calculated on this basis. The patent for alendronic acid expired in 2008. Whilst the originator, Merck, has [20-30%] on a value basis, its [0-5%] market share by volume shows that the vast majority of demand is met by generics.

81. Actavis submits that it ceased marketing alendronic acid due to [...] (Actavis previously in-licensed the product, whilst Watson's supplies are in-house). Irrespective of whether Actavis is considered as a constraint, there are several generic competitors remaining that can easily replicate the competitive pressure stemming from Actavis on Watson and can effectively constrain the merged entity, as also confirmed by competitors in the market investigation. In particular, these remaining competitors include Teva ([10-20%] by volume, [0-5%] by value), Mylan ([10-20%] by volume, [0-5%] by value), Intas ([10-20%] by volume, [0-5%] by value); Novartis ([5-10%] volume, [0-5%] value), Bluefish ([5-10%] by volume, [0-5%] by value). In addition, IMS and competitors in the market investigation indicate a number of other suppliers (including Stada and Orifarm).
82. In view of the competitive pressure stemming from the remaining competitors and general competitive conditions for generic pharmaceuticals in Sweden, serious doubts do not arise for the supply of alendronic acid in Sweden and for any other wider alternative markets in bone calcium regulators.

1.2.2.4. N6A – antidepressants and mood stabilizers

83. In Sweden, according to the data provided by the notifying party, Group 1 markets in anti-depressants and mood stabilisers arise only in relation to the mirtazapine molecule and on a hypothetical market comprising mirtazapine and mianserin molecules (ATC 4 class N6A9).
84. If mirtazapine was considered the relevant market, in 2011 the parties achieved a combined market share of [40-50%] with an increment of [5-10%] (Watson) by value, whereas by volume the combined firm share would be slightly lower, i.e. [30-40%] with an increment of [10-20%] (Watson).
85. There is already a significant degree of generic penetration in the market for mirtazapine, since the patent expiry in 2001. The molecule was first launched by Organon (now Merck) under the brand "Remeron". Watson launched mirtazapine in 2004, while Actavis entered in 2008. Based on 2011 IMS data, the parties are facing seven competitors in Sweden, including several generic players with significant shares: Krka ([30-40%] by value, [20-30%] by volume), Novartis ([5-10%] by value, [10-20%] by volume), Teva ([5-10%] by value, [10-20%] by volume), the originator Merck ([5-10%] by value, [0-5%] by volume), Bluefish ([5-10%] by value, [5-10%] by volume), Orion and Stada, each with less than 1% by value and volume.³² A sufficient number of competitors active with mirtazapine products would be able to capture the demand from a merged entity in Sweden in case of an attempted price increase.

³² In addition, there are several other companies that have a dormant marketing authorisation for the supply of mirtazapine in Sweden (e.g. Nycomed, Aurobindo) and could launch their respective products.

86. Group 1 markets also arise under a plausible alternative market comprising mianserin and mirtazapine in Sweden (based on value) and for oral solid ordinary galenic form of mirtazapine. However, since neither of the parties markets mianserin, the assessment under such alternative market definitions would not change materially. The same holds true for an alternative market comprising only oral solid ordinary mirtazapine products, since nearly all competitors (except for the originator Merck) sell mirtazapine in the same galenic form (A-oral solid ordinary).
87. On the basis of the above and the general competitive conditions for generic pharmaceuticals in Sweden, it can therefore be concluded that serious doubts do not arise on the Swedish market for anti-depressants and mood stabilisers (including all plausible narrower product markets, such as mirtazapine or mirtazapine/mianserin combinations).

1.2.3. UK

1.2.3.1. General competitive conditions and market share data

88. Based on a report of Espicom³³ provided by the notifying party, the UK pharmaceutical market has a high level of generic penetration compared to other European countries, with overall generic prescription rates of over 80% in 2010 (which increased by 10% since 2005). The main generic suppliers are major players such as Mylan, Teva, Sandoz (Novartis) and Zentiva. Other companies include, e.g. Krka, Stada, Ranbaxy, Wockhardt or Consilient. Based on the market investigation, the corporate brand of Actavis is perceived as very strong and comparable to key generic players (like Teva, Mylan and Novartis/Sandoz) active in the UK, while Watson's corporate brand is perceived as average or less known than Actavis' brand.
89. According to the notifying party the pharmaceutical markets in the UK are among the most competitive in the EU, in part due to its favourable reimbursement regime for generic pharmaceuticals. The UK Department of Health ("DoH"), through the Medicines and Healthcare Products Regulatory Agency, decides whether to grant a marketing authorisation for a new product. Reimbursement prices must be agreed with the DoH before launch, but there is freedom of pricing for new chemical entries. The DoH sets reimbursement prices for prescription pharmaceuticals at prevailing market levels, plus a margin that is counted towards pharmacy remuneration. The notifying party correctly notes that Commission's findings in Teva/Barr³⁴ have previously confirmed that the reimbursement scheme in the UK successfully encourages generic competition given that prices for the vast majority of generic drugs are set by the DoH and are based on a calculation that incorporates the volume-weighted average prices charged by the generics manufacturers in the UK. This process maintains the incentives for individual pharmacies to procure generic drugs efficiently, as reimbursement is based on average prices and pharmacies can negotiate with suppliers to secure better than average prices.
90. The market investigation in the present case confirmed the view that the UK market shows a high level of generic penetration, low barriers to entry, expansion and repositioning for generic suppliers. In general, the UK authorities were of the view that supply of prescription pharmaceuticals in the UK is very competitive with generic

³³ Espicom World Pharmaceutical Market report for UK – Q1 2012.

³⁴ See M.5295 Teva/Barr, decision of 19 December 2008, recitals 181-184.

suppliers largely competing on price as a result of the incentive inherent in the reimbursement arrangements for generic medicines. Typically, the physicians prescribe by generic name and pharmacies are free to dispense any version of that medicine. According to the DoH, the UK reimbursement policy encourages pharmacies to seek for the lowest price possible while maintain supply.

91. Apart from the usual necessity to have a marketing authorisation and comply with labelling and packaging requirements, there seem to be no significant country-specific barriers to entry or disincentives (regulatory or commercial) in the UK for prescription drug suppliers³⁵. In particular, there are no requirements for price or reimbursement approval, substitution approval or similar conditions before a product can be marketed in the UK. This allows manufacturers to enter the UK market with lower cost products.
92. According to respondents to the market investigation the UK market generally seems to get generic alternatives fairly quickly and attracts a number of suppliers that is comparable or higher than in other EEA countries. In general, the vast majority of authorities considered that in a product market where several generic alternatives are available the demand for prescription drugs is price sensitive. Therefore, a significant shift in demand towards cheaper alternatives based on the same active ingredient would be expected in case of a 5-10% price increase³⁶. Furthermore, the health authorities estimated that it should take a maximum of 6-12 months for a company to enter from a neighbouring country with a product if it is already present in the UK.
93. Based on the above, there do not appear to be significant barriers to expansion and entry for generic drugs in the UK that would prevent a competitive supplier of a product to compete effectively with established suppliers of the same product.

Market data for the UK

94. In relation to the market data it has to be noted that, unlike for Sweden and Denmark, IMS data for the UK lists generic players under a joint category "Lab Unknown/Unbranded" and therefore does not permit the identification of individual company market shares for each of the affected markets. However, IMS data show the overall market volume data. In view of this, the notifying party determined their individual and joint market shares by using IMS market data as the measure of the total market size in volume. In addition, the notifying party calculated approximate value based market shares using IMS gross sales data and the parties' own available sales numbers.

³⁵ One respondent, the Pharmaceutical Services Negotiating Committee (PSNC), pointed to the possibility that changing of packaging/leaflets post-merger would require a licence variation. PSNC observed in the past that licence variation might take some time and lead to shortages in supply if alternative suppliers would not able to bring products to the market on a very short notice. However, as regards the Group 1 markets concerned by the proposed transaction, the market investigation largely confirmed that alternative generic players would be able to capture the demand from a merged entity within 1-2 years and without significant investment and they do not seem to face capacity constraints.

³⁶ Only one respondent out of four expressed a general view that some dispensing doctors or pharmacies might sometimes show an element of brand loyalty, but was not aware of any specific instance of strong brand loyalty to any given generic company.

1.2.3.2. A2B – anti-ulcerants

95. Using the standard criteria for market definition, the transaction only results in a Group 1 market at the molecule level, for the supply of lansoprazole. As lansoprazole is supplied mainly in the same NFC-1 form, this distinction does not change the competitive assessment. Lansoprazole was launched by Pfizer under the brand name “Zoton”. Watson’s lansoprazole capsule was introduced in the UK in December 2005. Watson in-licenses the product from [...]. Actavis’ lansoprazole was launched in the UK in 2005 and it is contract manufactured for Actavis by [...] on a non-exclusive basis. The transaction only results in a Group 1 market based on volume: the parties’ combined share would be [40-50%] with an increment of [10-20%] by Watson. According to the parties, based on "British Generic Manufacturers Association ("BGMA")", the main generic competitors include Teva, Zentiva (Sanofi), Ranbaxy and Sandoz (Novartis). The parties also indicate additional suppliers³⁷. The notifying party submits that according to BGMA and the parties' own best information, the parties' main generic competitors in 2011 can be ranked as follows: (1) Teva, (2) Zentiva (Sanofi), (3) Consilient and (4) Ranbaxy. The parties believe Teva, Zentiva and Consilient to each have a share of sales in the UK in excess of 10%.
96. The market investigation clearly confirmed that a sufficient number of credible competitors would remain for the supply of lansoprazole which would effectively constrain the merged entity. The market investigation indicated a significant number (>5) credible competitors including the main competitors indicated by the parties. The Commission therefore concludes, in view of the competitive pressure stemming from the remaining competitors and the general competitive conditions for the supply of generic pharmaceuticals in the UK, that serious doubts do not arise with respect to the supply of lansoprazole or in any other plausible market for the supply of anti-ulcerants in the UK.

1.2.3.3. C9A – ACE inhibitors, plain

97. The transaction only results in a Group 1 market at the molecule level and only based on volume. The molecule concerned is trandolapril. As it is sold only in one NFC-category ("A" – oral solid ordinary), this distinction does not change the competitive assessment. Trandolapril was first launched by Abbott under the brand name “Odril”. Watson launched its trandolapril product in the UK in April 2008, and manufactures the pharmaceutical in-house. Actavis launched its trandolapril product in September 2008, and in-licenses the pharmaceutical from [...].
98. The parties’ combined share of trandolapril would be [30-40%] by volume with an increment of [10-20%] by Watson. The notifying party estimates that, based on BGMA, the main generic competitors in 2011 were Teva, Mylan and Lupin. Each of these generic competitors is believed to have a share of sales in the UK in excess of 10%. Pharmathen, who licenses the product to Actavis, also holds a marketing authorisation for supply of the product in the UK.
99. In view of the moderate combined market share of the parties, which is just above the Group 1 threshold, the presence of large, internationally active credible competitors and the general competitive conditions for the supply of generic pharmaceuticals in the UK,

³⁷ AAH Pharma (wholesaler), Almus Pharma, Consilient Health, Mylan, Niche Generics, Relonchem and Sovereign Medical which all supply lansoprazole.

serious doubts do not arise with respect to the supply of trandolapril or in any other plausible market for the supply of ACE inhibitors in the UK.

1.2.3.4. N6A – antidepressants and mood stabilizers

100. In the UK, according to the data provided by the notifying party, Group 1 markets in anti-depressants and mood stabilisers arise only in relation to the mirtazapine molecule and on a hypothetical market comprising mirtazapine and mianserin molecules (ATC4 class N6A9).
101. If mirtazapine was considered as the relevant market, in 2011 the parties achieved a combined market share of [40-50%] with an increment of [10-20%] (Watson) by value, and a combined share of [70-80%] with an increment of 18% (Watson) by volume³⁸.
102. According to the notifying party, there is already a significant degree of generic penetration in the market for mirtazapine since its basic patent expiry in 1996. The molecule was first launched by Organon (now Merck) under the brand "Zispin". Watson launched mirtazapine in 2004, while Actavis entered in 2009. Despite fairly high market shares based on volume, the parties are facing several generic competitors in the UK, including Teva, Sandoz (Novartis), Wockhardt, Ranbaxy and others³⁹. Although the parties do not have data to estimate the market shares of these competitors, they estimate that at least major generic players (such Teva, Novartis/Sandoz, Wockhardt) would have material sales in the UK.
103. The notifying party's arguments have been supported by the market investigation, which confirmed the presence of a sufficient number of actual or potential competitors for mirtazapine that would be able and have incentives to increase their supply of mirtazapine based products without significant investment in order to capture demand from a merged entity in the UK (e.g. Teva, Stada, Novartis, Genus Pharmaceuticals, recent entrant Pfizer and a few other competitors).
104. Group 1 markets also arise under a plausible alternative market comprising mianserin and mirtazapine in the UK and for oral solid ordinary galenic form of mirtazapine. However, since neither party markets mianserin in the UK and the sales of mianserin are negligible compared to sales of mirtazapine, the assessment under such alternative market definitions would not change significantly. The same holds true for an alternative market comprising only oral solid ordinary mirtazapine products, since nearly all competitors (except for the originator Merck) sell mirtazapine in the same galenic form (A-oral solid ordinary).
105. On the basis of the above and the general competitive conditions for generic pharmaceuticals in the UK, serious doubts do not arise with respect to the market for mirtazapine or any other plausible market definition in the UK.

³⁸ If market shares were identified by galenic form they would not change materially since most players sell mirtazapine based products in oral solid galenic form.

³⁹ In addition, there are (excluding licensees of the parties) more than 12 other companies that have a marketing authorisation or a license for the supply of mirtazapine in the UK, including significant generic players such as Mylan, Stada and Sanofi.

1.3. Conclusion on existing horizontal overlaps

106. Based on the elements outlined above, the Commission concludes that the notified transaction does not lead to serious doubts as to the compatibility with the internal market due to actual horizontal effects.

2. POTENTIAL COMPETITION

107. As both companies have mainly generic activities the transaction only leads to future overlaps between generic products. Such future overlaps may be due to overlaps between an existing product of one party and a pipeline product of another party or overlaps in pipeline products of both parties. A pipeline product is defined for the purpose of the present decision as a product which is based on a molecule or an NFC-1 form of a particular molecule which is not yet supplied in a given geography and which meets the conditions described in recital 110 below.

2.1. Market definition

108. The market definition for potential competition follows the market definition used to assess horizontal overlaps.

2.2. Competitive assessment

109. According to the Horizontal Merger Guidelines⁴⁰, for a merger with a potential competitor to have significant anti-competitive effects, two basic conditions must be fulfilled. First, it must already exert a significant constraining influence or there must be a significant likelihood that it would grow into an effective competitive force. Second, there must not be a sufficient number of other potential competitors which could maintain a sufficient competitive pressure after the merger.

110. In a previous decision involving generic products the Commission⁴¹ considered that entry was feasible within a short period of time, typically within a year, if the competitor already had significant operations in the target country in a related therapeutic area and no disincentives to launch the product. The Commission in the present case considered, on a slightly more conservative basis, products that the parties already sell in one Member State and plan to launch before the end of 2014 in another Member State to be relevant for the consideration of potential competition issues due to new geographic entry. In the case of entirely new product launches in the EEA the Commission took a slightly longer timeline of two years to be the relevant period for considering a pipeline product to be in a sufficiently advanced stage to make entry likely. The longer timeline as compared to new geographic entry is based on the assumption that the launch of a new generic product in the EEA may take longer (i.e. there would not be a marketing authorisation already in place at least in one Member State as in the case of existing products).

⁴⁰ Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, OJ C 31 of 5.2.2004, p. 3.

⁴¹ M.5865 Teva/Ratiopharm, decision of 3 August 2010.

111. There are in the present case only two instances⁴² where one party has a market share of over 35% in any market (based on any market definition) which the other party plans to enter. (In both cases Actavis is already active on the national market in question.) This filter, as also used in previous Commission decisions involving generic markets, is based on the assumption that potential competition in homogeneous products, like generics, would in particular raise issues if the party already present on the market had market power, i.e. if it had not already been subject to a significant competitive pressure from existing competitors. In both instances in the present case there are other actual competitors and/or potential competitors with marketing authorisations besides Watson. Based on the market investigation neither Watson's product nor its general capabilities to sell these products seem to be superior to those of other competitors. Serious doubts do therefore not arise with respect to these markets.
112. In addition to the overlap between existing and pipeline products the notifying party indicated that the two parties plan to launch [...] in the EEA in the next two years which neither of them currently sells. The parties could already identify several other generic competitors which either already supply and/or have a marketing authorisation for most of these products. The market investigation did not provide any indication that the competitive pressure stemming from either party would be more significant than other existing or potential competitors. In particular, the market investigation confirmed that there would remain a sufficient number of generic competitors in the EEA that have comparable or better capabilities to bring new generic products to the market than the parties, including R&D, manufacturing and distribution. These companies include Teva, Novartis, Stada and Mylan, among others.
113. In addition, the three countries where the parties currently achieve the highest market shares and where their product launches can therefore be expected to make the most impact all appear to have competitive generic markets. In particular, the market investigation confirmed that Denmark, Sweden and the UK all get generic alternatives fairly quickly and attract a number of suppliers that is comparable to or higher than other EEA countries.

2.3. Conclusion on potential competition

114. Based on the above, the Commission concludes that the notified transaction does not lead to serious doubts as to the compatibility with the internal market due to pipeline products.

⁴² The market for [product] in [country] and the [product] in [country]. Actavis has a [...] % market share by value ([...] % by volume) of [product] in [country]. The competitors include [...] ([...] % by value and [...] % by volume) and another generic competitor, [...] ([...] % by value, [...] % by volume). According to the information from the parties several companies have already been granted a marketing authorisation, including [names of the companies]. Watson applied, but has not yet received a marketing authorisation. As for [product] in [country], Actavis has a market share of [...] %, which translates to [...] % by volume. There are a number of other significant generic competitors already on market including [...] ([...] % by value, [...] % by volume), [...] ([...] %) and [...] ([...] %). The parties indicate several others with approved marketing authorisations (including Watson).

V. VERTICAL EFFECTS

115. The transaction leads to actual or potential vertical relationships due to the parties' activities in the supply of active pharmaceutical ingredients, outlicensing of pharmaceutical products and contract manufacturing.
116. In particular, it should be noted that based on the filters used in vertically related markets (as described below) it can be excluded that the parties have any significant position for outlicensing or APIs in any market upstream to Group 1 markets and would therefore be in a position to foreclose their competitors in Group 1 markets to an extent that would significantly impede effective competition downstream. In particular, the parties are not active in outlicensing in any of the Group 1 markets. Regarding APIs, the parties did not indicate any Group 1 market as also vertically affected – it follows that, should the parties supply any API on the merchant market that would be relevant for any Group 1 market, their position would in any event be less than 5% in the EEA.

1. MARKET DEFINITION

1.1. APIs

117. In previous decisions⁴³, the Commission considered that APIs form separate markets which are upstream of the markets of the finished pharmaceutical products and that API markets are at least EEA wide⁴⁴. The Commission looked at each individual API as potentially constituting a relevant market by itself, whilst noting that it cannot be excluded that certain APIs may be substitutable with each other for all or for a range of applications. The exact market definition can be left open in this case, as serious competition doubts do not arise even at the narrowest possible market definition, i.e. on the basis of considering the supply of an individual API in the EEA as the relevant market.

1.2. Outlicensing

118. The parties are active in vertically related markets for the outlicensing of pharmaceuticals when one party outlicenses a pharmaceutical product to third parties which then commercialise that product under their own name, while the other party is active in the downstream market for the marketing of the same pharmaceutical in the same Member State under its own name. Usually the licensor licenses to the licensee rights to use a dossier to obtain a marketing authorisation in one or more countries for a product. At the beginning of the licensing arrangement, the licensor will either transfer an existing marketing authorisation to the licensee (which involves registering a name change in relation to the existing license) or manage the registration process in the name of the licensee. Alternatively the licensee can request the dossier from the licensor and manage the registration process himself.
119. Under the parties' outlicensing arrangements, the manufacturing intellectual property rights ("IPR") usually remains with the licensor for at least the first five years of the relationship, and during this time the terms of supply/licensing are essentially fixed.

⁴³ See M.5865 Teva/Ratiopharm, decision of 3 August 2010, recitals 393-394; and M.6258 Teva/Cephalon, decision of 13 October 2011, recital 133.

⁴⁴ See M.5865 Teva/Ratiopharm, decision of 3 August 2010, recital 396; M.5295 Teva/Barr, decision of 18 December 2008, recital 190; and M.6278 Takeda/Nycomed, decision of 29 July 2011, recital 19.

During this time, the licensee will generally buy the finished product (or bulk) from the licensor on an exclusive basis and commercialise the product under its own name, using the marketing authorisation which was licensed to it by the licensor. Neither of the parties manufactures the API for any of its products which they outlicense. The parties have organised their outlicensing activities in separate business units, these are Specifar for Watson and Medis for Actavis.

120. In previous decisions⁴⁵ the Commission considered outlicensing as separate markets which are upstream of the markets of the finished pharmaceutical products and that, from geographic perspective, are at least EEA wide⁴⁶. The Commission looked at the outlicensing of the relevant IPRs for each individual API as potentially constituting a relevant market.
121. The parties equally submit that there is a distinct market for outlicensing of IPRs for a particular API and that the geographic upstream market of outlicensing can be considered EEA-wide, given that licensors typically offer to transfer the marketing authorisations in a number of countries, and that a single licence agreement may cover multiple jurisdictions.
122. The market investigation confirmed that outlicensing constitutes a separate market from the downstream market of finished dose pharmaceuticals, and that it is a distinct market from the supply of active pharmaceutical ingredients and contract manufacturing, although in practice the outlicensing agreements sometimes cover at the same time contract manufacturing for the outlicensed products. Regarding the geographic market definition the market investigation indicated that the markets are at least EEA-wide markets, although a few respondents considered that the market for outlicensing is not wider than the downstream markets for finished dose pharmaceuticals. In any event the market definition can be left open as the transaction does not raise serious doubts irrespective of the market definition.

1.3. Contract manufacturing

123. Contract manufacturing of finished dose pharmaceuticals consists of the manufacturing under contract of finished dose pharmaceutical products, which may or may not include final packaging on behalf of third party pharmaceutical companies. This third party then goes on to market the finished products under its own label or brand(s)⁴⁷. This definition excludes the manufacturing of active pharmaceutical ingredients, since such ingredients are not typically manufactured on a contract basis and typically may be procured from a wide variety of sources. A number of contract manufacturing markets may be defined, corresponding in each case to the pharmaceutical form which is manufactured and also in some cases the conditions of manufacture (types of API involved in the process, toxicity, sterile environment, etc.). As in previous decisions⁴⁸, however, the precise market definition can be left open since, regardless of the market

⁴⁵ See M.5865 Teva/Ratiopharm, decision of 3 August 2010, recital 408; and M.6258 Teva/Cephalon, decision of 13 October 2011, recital 146.

⁴⁶ See M.5865 Teva/Ratiopharm, decision of 3 August 2010, recital 396; M.5295 Teva/Barr, decision of 18 December 2008, recital 190; and M.6278 Takeda/Nycomed, decision of 29 July 2011, recital 19.

⁴⁷ See M.6278 Takeda/Nycomed, decision of 29 July 2011, recitals 20ff; M.5865 Teva/Ratiopharm, decision of 3 August 2010, recital 408.

⁴⁸ M.5253 Sanofi/Zentiva, decision of 4 February 2009; M.5555 Novartis/EBEWE, decision of 22 September 2009; M.5778 Novartis/Alcon, decision of 9 August 2010; M.5953 Reckitt Benckiser/SSL, decision of 25 October 2010.

definition considered, the transaction does not lead to serious doubts on any downstream market for finished dose pharmaceutical products.

124. The Commission previously considered that markets for the provision of contract manufacturing are worldwide or at least EEA-wide, notwithstanding the need for EU certification of manufacturing processes⁴⁹. Again, the precise market definition can be left open since the transaction does not lead to serious doubts on any downstream market for finished dose pharmaceutical products.

2. COMPETITIVE ASSESSMENT

2.1. APIs

125. In previous decisions, the Commission focused its assessment on the vertically related markets for the supply of API where (i) either party has a market share of more than 30% in the upstream API market and the other party has a market share of more than 5% in an ATC3/ATC4 or molecule class containing that particular API (this relationship is referred to as "downstream vertically affected market"), or (ii) either party has a market share of more than 25% in a downstream ATC3/ATC4 or molecule class and the other party has a market share of more than 5% of a corresponding API market (this relationship is referred to as "upstream vertically affected market")⁵⁰.
126. As regards downstream vertically affected markets, the notifying party identified two markets where Watson is active in the upstream API market and Actavis in a corresponding downstream market, namely nabumetone (ATC3 class M1A, ATC 4 class M1A1) in the UK and in the Netherlands, the only two countries where Actavis has marketing authorisations in the EEA.
127. The notifying party estimates that its supplies would account for [...] of total supplies of nabumetone API worldwide, and for [...] of the nabumetone API sold in the EEA. According to the notifying party, [...] Actavis' API purchases of nabumetone for its operations in the UK and the Netherlands in 2011 were from Watson, while it could not clearly exclude that one or more downstream competitors of Actavis might also rely on Watson as a source of supply for their operations in the UK and the Netherlands.⁵¹
128. As regards downstream affected markets in the UK and the Netherlands, the Commission considers that the merged entity would lack the ability to engage in input foreclosure. In particular, based on the results of the market investigation, the merged entity would be facing at least four alternative upstream suppliers for nabumetone, which hold European Pharmacopoeia Certificates of Suitability ("CEP")⁵². All these companies were considered as credible alternative sources of supply for operations in the EEA, especially given that nabumetone suppliers that hold a valid CEP were

⁴⁹ See M.6278 Takeda/Nycomed, decision of 29 July 2011, recitals 20 and 21.

⁵⁰ See M.6258 Teva/Cephalon, decision of 13 October 2011, recital 136, M.5865 Teva/Ratiopharm, decision of 3 August 2010, recitals 393-407; and M.5259 Sanofi-Aventis/Zentiva, decision of 4 February 2009, recitals 179-186.

⁵¹ In case of [...], Watson confirmed that it supplies [...] for its operation in Germany, but could not exclude that [...] also uses the nabumetone purchased from Watson for its operations in the UK and the Netherlands. Watson also could not exclude that some other competitors downstream could rely on Watson as a source of supply indirectly, i.e. by buying resold quantities of nabumetone from Watson's end-customers.

⁵² See <http://www.edqm.eu/en/certification-background-77.html>

preferred from a regulatory and lead-time perspective. Even if the merged firm would stop supplying its customers (or supply them on less favourable terms), the downstream competitors, would be able to switch the source of supply within on average 1-2 years or less, depending on a variety of factors, such as the time required for finding a new supplier (or, alternatively, the ability to produce in-house), to carry out verification and testing on the new API source, etc. The costs associated with a change of supplier having a CEP would mostly relate to regulatory approval costs⁵³.

129. In view of the above, the Commission considers that the notifying party would not have an ability to engage in input foreclosure to its competitors in a downstream market for finished dose nabumetone products in the UK and the Netherlands, and concludes that the notified transaction does not lead to serious doubts as regards input foreclosure.
130. As regards upstream vertically affected markets, the parties identified one with Actavis active in the downstream market and Watson in a corresponding upstream API market, namely nabumetone (M1A) in the UK. Only in the UK Actavis' share of sales exceeds 30%, i.e. [30-40%] by value, [30-40%] by volume⁵⁴.
131. However, based on notifying party's estimates the proportion of Actavis' sales of finished pharmaceutical products based on nabumetone all over Europe and the world (taken as an approximation of Actavis' EEA-wide or worldwide API demand) is very small, i.e. less than 1% in the EEA and *de minimis* on a worldwide market. Consequently, Watson will not be able to foreclose a significant level of demand. There would still be a sufficient API customer basis of finished pharmaceutical product suppliers active on other national downstream markets in the EEA or worldwide for the upstream rivals of the new entity⁵⁵.
132. In view of the above, the Commission concludes that notified transaction does not lead to serious doubts as regards customer foreclosure.

2.2. Outlicensing

133. In accordance with the methodology in a previous case⁵⁶ the Commission focussed its assessment on the vertically related outlicensing markets where the market share of the parties is 35% in the downstream market of finished dose pharmaceuticals including the share of the competitor(s) for which one of the parties is the source of the product and the increment contributed by the other party is more than 1%. This allows to focus the investigation on the markets which could be potentially problematic in a worst-case scenario, i.e. when the competitors downstream were not be considered autonomous players, but would effectively depend on the parties. The methodology was also chosen because the parties were unable to provide reliable market share data on the upstream outlicensing market.

⁵³ Furthermore, as concerns [...], Watson's direct customer and Actavis' downstream competitor in the UK and the Netherlands, Watson is prevented by a contractual arrangement to terminate supply prior to the first expiry date of supply agreement in [...] [...].

⁵⁴ By galenic form A, Actavis' estimated market share is [30-40%] in value, and [30-40%] when based on the weight of the active ingredient.

⁵⁵ See the Commission's "Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings", OJ C 265, 18.10.2008, p. 6.

⁵⁶ See M.5865 Teva/Ratiopharm, decision of 3 August 2010, recital 414.

134. On the basis of this methodology the notifying party identified 14 downstream vertically affected "Group 1" markets. On the basis of Watson's outlicensing arrangements (i.e. Watson outlicenses to third parties, while Actavis is marketing finished dose pharmaceutical) these are the following seven national downstream markets: Nebivolol (C7A) in Poland, Bulgaria, Netherlands; Donepezil (N7D) in Romania; Famciclovir (J5B) in Netherlands; Risperidone (N5A) in Czech Republic; and Clopidogrel (B1C) in Sweden.
135. On the basis of Actavis' outlicensing arrangements the transaction would result in six affected downstream markets: five molecules in France (Venlafaxine (N6A), Sertraline (N6A), Enalapril (C9A), Ramipril and Ciprofloxacin (J1G)) and one molecule in Poland (Terbinafine (J2A))⁵⁷.
136. In addition to the vertical relationship, the parties identified three markets with a horizontal overlap⁵⁸ due to their outlicensing activities, where the combined market share of their licensees would be 35% or above with an increment of at least 1% in the downstream markets of finished dose pharmaceuticals. These are nebivolol (C7A) in Hungary, risperidone (N5A) in Portugal and glimepiride (A10H) in France.
137. In nearly all of these national markets the market structure is such that the transaction does not raise serious doubts even if the licensees were not considered to act independently on the market, as a sufficient number of competitors without licensing arrangements with the parties remain present post transaction. Even if Watson/Actavis tried to terminate its outlicensing agreements, there are strong competitors remaining in the market which would effectively constrain its abilities to increase its profit, which means that there are no incentives to stop current outlicensing agreements.
138. In the remaining markets, i.e. where the market structure is more concentrated, the market investigation confirmed that alternative licensors for the molecules in question are available. The market investigation confirmed that specialized outlicensing companies operate on these markets which focus exclusively on the development and licensing of pharmaceuticals to others and which are not active themselves in selling the product concerned to wholesalers or pharmacies in the downstream market. These outlicensing companies develop products on their own for outlicensing, fund third party development, and/or act as an agent or broker for other companies. The market investigation also confirmed that the specialized outlicensing companies actively compete with (generic) pharmaceutical companies, who license some of their molecules, that licensees consider them as a valid alternative and that it is in general possible to switch the outlicensor within 1-2 years.
139. Regarding nebivolol in Poland, Watson's licensees account together for [60-70%] (both by value and weight of the active ingredient) and Actavis' market share is [10-20%] by value and [20-30%] by volume. While Watson's licensees are not protected by long-term contracts, but have annually renewable contracts, alternative outlicensors of nebivolol are available, such as AET, Generic Licensing (acting as a broker for five pharmaceutical companies offering dossiers for nebivolol) and a further pharmaceutical

⁵⁷ In addition to these markets, Actavis used to have an outlicensing agreement for aziathioprine with [...] in Denmark which was terminated by [...] in [...] 2011. [...] now licenses aziathioprine directly from [...] [...]. Given the termination of the licensing agreement in [...] 2011, the market for aziathioprine in Denmark is no longer considered a vertically affected market.

⁵⁸ This means where both parties license a certain dossier for a certain molecule to competitors which are active downstream in the market for finished dose pharmaceuticals.

company. In addition, further competitors, such as Menarini ([10-20%] by value and [10-20%] by volume) and a number of smaller competitors with 1-2% are present in the market and will continue to exert competitive pressure downstream, which would constrain Watson's ability to increase its profit by terminating the licensing agreements.

140. In the Netherlands, Watson licenses nebivolol to [...] (with a market share [40-50%] by value and [20-30%] by volume) while Actavis has a market share of [10-20%] by value and [40-50%] by weight of the active ingredient. Given the alternative outlicensors for nebivolol, [...] should be able to find a new outlicensor in case its licensing agreement, which expires in [...], would not be prolonged. In addition, [...] 's subsidiary [...] also has a marketing authorisation for nebivolol and accordingly [...] does not depend on the outlicensing agreement with Watson in order to be able to market nebivolol, but would only need to find a new supplier/contract manufacturer for the product.
141. Regarding nebivolol in Bulgaria, the parties' and their licensees' combined market share is [30-40%] by volume (Watson's licensee [...]: [5-10%]; Actavis: [30-40%]). A sufficient number of competitors will remain present post transaction, such as Menarini with [30-40%] market share and generic companies [Competitor 1] with [10-20%], [Competitor 2] with [0-5%], [Competitor 3] with [0-5%] and [Competitor 4] with [0-5%] (market shares all by weight of the active ingredient), which will continue to exert competitive pressure downstream and constrain Watson's ability to increase its profit by terminating the licensing agreements.
142. Regarding famciclovir in the Netherlands, the parties' and their licensees' combined market share is [50-60%] by value and weight of the active ingredient (Watson's licensee [...]: [20-30%], Actavis: [20-30%]). [...] licensing agreement runs until [...] under the current, fixed terms. The market investigation confirmed that alternative outlicensors are available, so that [...] should be able to switch in case the license agreement would not be prolonged. The other competitor present in the market is [Competitor 5] with a market share of [50-60%], which will continue to constrain the new entity's ability to increase its profit by terminating the licensing agreements.
143. Regarding donepezil in Romania, the parties' and their licensees' combined market share is [30-40%] by value and [40-50%] by weight of the active ingredient (Watson's licensees together [20-30%] and [30-40%] respectively; Actavis: [5-10%] and [10-20%] respectively). A sufficient number of competitors such as the originator of donepezil, Pfizer (with a share of [10-20%] by value, [5-10%] by weight of the active ingredient) and generic companies Ranbaxy ([20-30%] by value, and [20-30%] by weight of the active ingredient), Servier ([5-10%] by both value and weight of the active ingredient), Glenmark Pharm ([5-10%] by value and [5-10%] by weight of the active ingredient), Krka ([5-10%] by value, [5-10%] by weight of the active ingredient), Teva ([5-10%] by value, [0-5%] by weight of the active ingredient), Novartis ([0-5%] by both value and by weight of the active ingredient) will remain present and will continue to constrain the new entity's ability to increase its profit, which means there are no incentives to terminate the licensing agreements.
144. Regarding clopidogrel in Sweden the parties' and their licensees' combined market share is [30-40%] by value (Actavis: [30-40%]; Watson's licensee [...] [0-5%]). It is no Group 1 market by weight of the active ingredient. A large number of competitors⁵⁹,

⁵⁹ Such as Sanofi the originator of clopidogrel (with [30-40%] by value and [60-70%] by weight of the active ingredient) and generic companies including [Competitor 1] ([5-10%] by value and [30-40%] by weight of the active ingredient), [Competitor 2] ([5-10%] by value, [10-20%] by weight of the active

most of which are much larger than the increment contributed by Watson's licensee, will remain present and will continue to constrain the new entity's ability to increase its profit, which means there are no incentives to terminate the licensing agreements.

145. Regarding risperidone in the Czech Republic the parties' and their licensees' combined market share is [40-50%] by weight of the active ingredient (Watson's [...] licensees [30-40%]; Actavis is [0-5%]). It is not a Group 1 market on the basis of value figures⁶⁰. Competitors include the originator of the molecule Johnson & Johnson ([60-70%] by value, [20-30%] by volume); generic companies including Krka ([0-5%] by value, [5-10%] by volume), Sanofi ([5-10%] by value, [5-10%] by volume), Servier ([0-5%] by value, [5-10%] by volume), Teva, Mylan and Novartis with market shares between [0-5%] by volume. The competitors will continue to constrain the new entity's ability to increase its profit, which means there are no incentives to terminate the licensing agreements.
146. Regarding venlafaxine (galenic form A) in France, Actavis' licensee [...] has a market share of [40-50%] (both by value and volume) while Watson's market share is [5-10%], resulting in a combined market share of [50-60%]⁶¹. Several other competitors would remain present in the market; [Competitor 6] ([10-20%]), [Competitor 7] ([20-30%]), [Competitor 8] ([0-5%]) and three further minor competitors ([Competitor 9], [Competitor 10], [Competitor 11]) will constrain the new entity's ability to increase its profit, which means there are no incentives to terminate the licensing agreements.
147. Regarding sertraline in France, the parties' and their licensees' combined market share is [40-50%] by weight of the active ingredient (Actavis' [...] licensees [40-50%]; Watson [5-10%]). The market shares are slightly lower on the basis of value figures. Competitors include the originator of sertraline, Pfizer, with a share of [20-30%] by volume and generic companies Servier ([10-20%] by volume), Novartis ([5-10%] by volume), Stada ([0-5%] by volume) and others. These competitors will constrain the new entity's ability to increase its profit, which means there are no incentives to terminate the licensing agreements.
148. Regarding ciprofloxacin in France, the parties' and their licensees' combined market share is [30-40%] by weight of the active ingredient (Actavis' [...] licensees [20-30%]; Watson [5-10%])⁶². The market shares are slightly lower on the basis of value figures. Competitors include the originator of ciprofloxacin, Bayer, with a share of [10-20%] by volume and generic companies such as Mylan ([20-30%] Pan Medica ([0-5%]), Teva ([10-20%]), Novartis ([0-5%]), Stada ([0-5%]) and others. These competitors will constrain the new entity's ability to increase its profit, which means there are no incentives to terminate the licensing agreements.
149. Regarding enalapril in France, the parties' and their licensees' combined market share is [40-50%] by weight of the active ingredient (Actavis' [...] licensees [40-50%]; Watson

ingredient), [Competitor 3] ([0-5%] by value, and [5-10%] by weight of the active ingredient), [Competitor 4] ([5-10%] by value and [5-10%] by weight of the active ingredient), [Competitor 5] ([0-5%] by value and [5-10%] by weight of the active ingredient), etc.

⁶⁰ The market shares for Risperdone – galenic form A are slightly higher but the same reasoning applies.

⁶¹ If only venlafaxine as molecule (and not the narrower category of galenic form) is considered the combined market share is around [20-30%] and it is not a Group 1 market.

⁶² The market shares for ciprofloxacin – galenic form A are slightly higher (combined [30-40%]) but the same reasoning applies.

[0-5%]). Competitors include the originator of enalapril, Merck, with a share of 17% by volume and generic companies such as Servier ([20-30%]), Stada ([5-10%]), and Sanofi ([0-5%]). Irrespective of whether the licensees can be considered independent competitors due to long-term contracts, these competitors will constrain the new entity's ability to increase its profit, which means there are no incentives to terminate the licensing agreements.

150. Regarding ramipril in France, [...]. Actavis licensees' combined market share is [30-40%] by weight of the active ingredient (Actavis' other licensees: [30-40%]; [...]: [0-5%]). The market shares are slightly lower on the basis of value figures. Competitors include Sanofi, the originator of ramipril, with a share of [20-30%] and Novartis with [5-10%]. It is difficult to see that Actavis would terminate its outlicensing agreements with its licensees (such as [...], [...] and [...]) in the hope that [...] would be able to attract these sales previously done by established generics suppliers in France.
151. Regarding terbinafine in Poland, the parties' and their licensees' combined market share is [40-50%] by weight of the active ingredient (Actavis' licensee [...] [20-30%]; Watson [10-20%])⁶³. Competitors include the originator of terbinafine, Novartis, with a share of [5-10%] by volume and generic suppliers such as [Competitor 12] ([20-30%]), [Competitor 13] ([10-20%]), [Competitor 14] ([5-10%]), and [Competitor 15] ([0-5%]). Irrespective of whether [...] can be considered independent, these competitors will constrain the new entity's ability to increase its profit, which means there are no incentives to terminate the licensing agreements.
152. Regarding the three markets where a horizontal overlap occurs due to outlicensing arrangements of both parties, i.e. where the parties license their products to third parties which compete downstream, but are themselves not active downstream (nebivolol in Hungary, glimepiride in France and risperidone in Portugal) the combined market shares of the parties' licensees are [30-40%], [50-60%] and [50-60%] respectively. The market investigation confirmed alternative licensors in each case. Moreover, since the parties are not active downstream, the transaction does not alter their incentives to supply the licensees, which also means that there is no incentive to terminate the license agreements.
153. Based on the above, the notified transaction does not lead to serious doubts as regards input or customer foreclosure in relation to outlicensing.

2.3. Contract manufacturing

154. Actavis does not have contract manufacturing activities. Watson through its subsidiary Specifar had limited contract manufacturing activities in the EEA in 2011 in relation to three molecules in standard immediate release tablet form, consisting of core, non-specialised technologies: atorvastatin, carvedilol and simvastatin, for total revenues of less than EUR [...] million⁶⁴. Actavis supplies these molecules in the EEA.

⁶³ Market shares on the level of terbinafine - galenic form A are slightly higher with combined [40-50%] but the same reasoning applies.

⁶⁴ In addition, Watson supplied a minimal amount of isosorbide mononitrate, lansoprazole, trimetazidine, Vitamin C and butamirate under contract manufacturing in [...], for total revenues of approximately EUR [...]. Given the limited amount of Watson's sales under these contract manufacturing arrangements, Watson believes that these services do not affect its EEA-wide share of contract manufacturing services

155. In accordance with previous precedents⁶⁵, the Commission requested the notifying party to identify any markets where Watson supplies a competitor and the parties' individual or combined market shares and the customer's market share together account for 25% or more. The notifying party did not identify any such market in the Form CO.
156. Watson estimates its share of contract manufacturing services in the EEA, even taking into account only tablet forms (which accounts for the vast majority of contract manufacturing), to be less than 5%. Conversely, Actavis' market share at the molecule and galenic form level by value and by volume is below 25% in the downstream market in all EEA Member States not only for the above three molecules, but also the level of the ATC3 and ATC4 categories to which these molecules belong.
157. Based on the above, the notified transaction does not lead to serious doubts as regards input or customer foreclosure in relation to contract manufacturing services.

3. CONCLUSION ON VERTICAL EFFECTS

158. Based on the elements outlined above, the Commission concludes that the notified transaction does not lead to serious doubts due to vertical effects.

VI. CONCLUSION

159. For the above reasons, the European Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation.

For the Commission

(signed)
Joaquín Almunia
Vice-President

estimated to be below 5%. Watson also has an agreement with [...] for the packaging of fluvastatin. However, Watson does not manufacture fluvastatin for [...] or other third parties.

⁶⁵ See for example M.5259 Sanofi-Aventis/Zentiva, decision of 4 February 2009.