EN

Case No COMP/M.6258 - TEVA/ CEPHALON

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) in conjunction with Art 6(2)
Date: 13/10/2011

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Brussels, 13.10.2011

C(2011) 7435 final

PUBLIC VERSION

MERGER PROCEDURE

To the notifying party:

Dear Sir/Madam,

Subject: **Case No COMP/M.6258 - TEVA/ CEPHALON**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1]

1. On 25 August 2011, the Commission received the notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004, hereafter the "Merger Regulation", by which the undertaking Teva Pharmaceutical Industries Limited ("Teva", Israel) acquires, within the meaning of Article 3(1)(b) of the Merger Regulation, indirect sole control over the whole of Cephalon Inc. ("Cephalon", US) by way of purchase of shares.

I. THE PARTIES

2. Teva (Israel) is the world's largest generic pharmaceutical company, with limited originator activities. Cephalon is a US-based company supplying both originator and generic pharmaceuticals. Cephalon only recently entered the generic pharmaceuticals business through the 2010 acquisition of the Swiss-based generic pharmaceutical company "Mepha".[2]

II. THE OPERATION

3. Following the entry into a definitive Agreement and Plan of Merger between Teva and Cephalon's board, Teva has obtained on 14 July 2011 the required support from Cephalon's shareholders to acquire 100% of Cephalon's outstanding shares.

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.

2 Teva and Cephalon will in the following be referred to as "the parties".

III. CONCENTRATION

4. The proposed transaction constitutes a concentration within the meaning of Article 3(1)(b) of Regulation 139/2004.

IV. EU DIMENSION

5. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion[3] (Teva EUR 12,160 million, Cephalon EUR 2,120 million). Each of them has an EU-wide turnover in excess of EUR 250 million (Teva: EUR […] million; Cephalon: EUR […] 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 within the meaning of Article 1(2) of the Merger Regulation.

V. COMPETITIVE ASSESSMENT

1. HORIZONTAL EFFECTS

1.1. Introductory comments on the approach on market definition and assessment of horizontal overlaps

1.1.1. Product markets – finished dose pharmaceuticals - general approach

6. In previous cases the Commission has taken 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").[4] 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 decisions[5], 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 companies[6] also considered systematically an even narrower market definition that assumes that the relevant market could consist of only drugs that are based on the exact same "molecule" or "API" (active pharmaceutical ingredient). The Parties therefore also provided affected markets based on the molecule.

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3 Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C 95, 16.4.2008, p. 1).

4 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.

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

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

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).

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 decisions[7]. 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 has 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/EphMRA[8]. 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". In the present case, a further distinction according to the second and third letter of the NFC classification does not make a difference in the competitive assessment. In some markets, due to one form being the predominant form in which drugs are sold (e.g. anti-ulcerants in Portugal and Estonia; or anti-spasmodics in France), market shares would not materially change based on the further distinction of NFC-1 categories. Where market shares materially differ based on this distinction (e.g macrolides and non-steroidal antirheumatics), market shares are provided based on a further division according to NFC-1 categories. Even in these markets, however, the relevance of the NFC-1 categorisation for market definition does not have to be decided as the transaction would not raise competition concerns in either the markets including all forms of the drugs concerned or on the narrower markets including specific NFC-1 forms only.

10. The second distinction is between prescription only (hereinafter "Rx") and over-the-counter (hereinafter "OTC") drugs, which is a distinction that has traditionally been made in pharmaceutical decisions[9]. In the present case, competition concerns can be excluded irrespective of this distinction.

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 has not previously defined 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 medicines[10]. Given that both companies have both generic and originator activities with a different focus[11], this distinction has nevertheless been taken into account when assessing the closeness of competition in the markets investigated.

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

8 www.ephmra.org/pdf/NFCVersion2010Guidelines.

9 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.

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

11 Teva primarily generic, Cephalon primarily originator.

13. In the present case the market definitions can be left open considering all the aspects outlined above (ATC classification, molecule, NFC-1 form and OTC/Rx distinction) as competition concerns do not arise in any affected market irrespective of the market definition.

1.1.2. Geographic market

14. In previous decisions[12], 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.

1.1.3. General approach to the competitive assessment of horizontal overlaps

15. Given the large number of affected markets, and in accordance with case practice[13], the notifying party was required to group 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 less than 1%.
    Group 3: The parties' joint market share is between 15% and 35%.

16. The Commission has focused its investigation in particular on affected markets falling into category 1 ("Group 1 markets"). Section 1.2 of this decision summarises the outcome of the market investigation in all Group 1 markets. [14]

17. 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 none of these markets 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").[15]

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12 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.

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

14 For ease of review, Group 1 markets are presented hierarchically, according to the relevant ATC3 category.

15 The Commission has previously used the same methodology for focussing its investigation, e.g. case COMP/M.5865 – Teva/ratiopharm, , decision of 3 August 2010.

1.2. Assessment of Group 1 markets

1.2.1. A2B – Anti-ulcerants – Portugal, Estonia

18. There are four main groups of anti-ulcerant products, each belonging to a different ATC4 category. According to the notifying party two of these groups, in particular H2-inhibitors (classified in A2B1) and Proton pump inhibitors or PPIs (classified in A2B2) directly compete with each other. As the sales of other types of anti-ulcerant products are negligible, the combination of these two categories largely corresponds to an ATC3 market definition.

19. In the Commission's antitrust and merger practice the market has not up till now been defined at a narrower level than PPIs[16], i.e. the ATC4 level. In the present case potential competition concerns are only apparent if the market is defined at a narrower level than PPIs, i.e. at the level of molecule and/or at the level of PPIs available as OTC.

20. There are two countries where the transaction gives rise to Group 1 markets in anti-ulcerants. These are Portugal (for products based on *rabeprazole* only) and Estonia (for all PPIs and for products based on *omeprazole*).

21. A significant majority of respondents to the market investigation (both competitors and users) confirmed that neither rabeprazole, nor omeprazole has any special characteristics/indications that are not replicated by other PPIs, and which would significantly limit their substitutability with other PPIs for patients who are prescribed rabeprazole or omeprazole. In other words, both rabeprazole and omeprazole seem to be effectively substitutable with all or at least some other PPIs. Furthermore, there are some indications that the prices of alternative PPIs exert constraint on the sales of rabeprazole. This notwithstanding, the market definition can be left open in the present case as the transaction does not raise competition concerns irrespective of the market definition.

22. In Portugal both of the parties started to supply generic rabeprazole[17] in the past three years and have been accumulating market shares rapidly (combined market share of [30-40]% in value, [40-50]% in volume) to the expense of the originator (Johnson & Johnson). The total value of the market is EUR 7 million. Whilst until recently the parties were the only generic suppliers of rabeprazole, this market is dynamic and several competitors have recently entered the market. The new entrants include for example two significant generic players (Novartis and Krka), which together acquired within the short period of the first quarter of 2011 together a market share of [5-10]%. Other entrants include Generis Pharma, Stada and Well Pharma. Based on the results of the market investigation, it can be concluded that the merged entity would not have any significant assets/capabilities which would allow them to compete more effectively for the supply of rabeprazole than other generic suppliers. The market investigation confirmed that there would remain a sufficient number of credible

16 In the AstraZeneca antitrust case (Case COMP/A. 37.507/F3. AstraZeneca) PPIs were considered as the relevant market definition. A previous merger decision, M.4418 Nycomed/Altana Pharma, decision of 13 December 2006, also found arguments in favour of a PPI only market definition, although the market definition was left open.

17 In Portugal, all rabeprazole products are sold as Rx.

alternative suppliers (including several new entrants) that would constrain the merged entity.

23. The market for omeprazole[18]-based products in Estonia is completely genericised. Despite high combined market shares (Cephalon [40-50]%, Teva [10-20]%) the parties would continue to face constraints from two well-established competitors that are stronger than Teva: Novartis ([30-40]%) and Krka ([10-20]%). The market investigation confirmed two other smaller competitors, Chemo and ProMed (with market shares below 1%) and a recent entrant, Stada. The market structure would be similar if only Rx omeprazole products were considered and if market shares were expressed in volume[19]. Based on the results of the market investigation, it can be concluded that the merged entity would not have any significant assets/capabilities which would allow them to compete more effectively for the supply of omeprazole than their main competitors. The market investigation also confirmed the absence of significant barriers to expansion for competitors. Finally, the market investigation confirmed a number of competitors to be credible alternative suppliers of omeprazole that would constrain the merged entity.

24. Whilst the transaction also leads to a Group 1 market for prescription PPIs in Estonia, the overlap of the parties' activities is mainly due to omeprazole-based products. The parties' combined market share is not high ([30-40]% including an [5-10]% increment by Teva). Competitors include the supplier of the new generation originator esomeprazole product, AstraZeneca ([20-30]%), Novartis ([20-30]%), Krka ([10-20]%) and Nycomed Pharma ([0-5]%). Cephalon only sells omeprazole, whilst Teva has also relatively minor sales of pantoprazole products (amounting to [0-5]% of the market). Such sales do not significantly strengthen the parties' position especially as there are other suppliers with higher sales of pantoprazole (Nycomed, Krka and Actavis). Whilst […], the transaction is unlikely to lead to concerns […]. This is because Cephalon is already constrained by existing competitors and new entrants offering the same product (omeprazole).

25. Based on the above, the transaction does not lead to serious doubts as to the compatibility with the internal market in either Portugal or Estonia in the market for the supply of PPIs and, in particular, of rabeprazole and omeprazole respectively. This conclusion holds irrespective of any further distinction according to NFC-1 categories or of Rx-OTC status.

1.2.2. A3A - Plain antispasmodics and anticholinergics – France

26. Antispasmodics and anticholinergics belong to the ATC3 class A3A. These products are used to relieve cramps or spasms in particular of the digestive system. This class consists of products sold both OTC and on prescription. The ATC3 category A3A is not subdivided further into ATC4 classes. Teva submits that the ATC3 category is the most relevant approach to market definition without considering the Rx/OTC

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18 Omeprazole products are available both as Rx and OTC in Estonia. However, the parties overlap only in products available as Rx. It is only therefore the Rx and the overall segment (including both Rx and OTC) that is considered.

19 The parties have lower market shares based on volume, amounting to 50% with a 10% increment by Teva.

distinction. Previous Commission decisions[20] followed the ATC3 approach but subject to a possible distinction between OTC and Rx products.

27. In the present case it is only in France that the transaction leads to Group 1 markets. In France, Cephalon sells originator products under the brand name "Spasfon". Spasfon is a combination product based on *phloroglucinol trimethoxy benzene*. These products are available OTC but are reimbursed when prescribed. The parties estimate that 80% of Spasfon products are sold on prescription. Teva has a plain phloroglucinol based product in its portfolio that is also available OTC. In addition, Teva has products based on two other molecules in its portfolio, which are only available as Rx.

28. The majority of respondents to the market investigation confirmed that plain phloroglucionol products can frequently and effectively substitute Cephalon's Spasfon products. However, for the purposes of the present case it does not have to be decided whether these products belong to the same market as no competition concerns arise either way.

29. In the overall ATC3 category, the parties would have a combined market share of [60-70]% with an increment of [0-5]% by Teva. There are four competitors with higher market shares than Teva (Mylan [5-10]%, Servier [5-10]%, Abbott and Renaudin [5-10]% each). In addition there are four other competitors with [0-5]% (Novartis, Stada, Cooper France and Watson). If only drugs available OTC are considered, the parties would have a higher combined market share of [80-90]% but with a smaller increment by Teva ([0-5]%) due to its sales of Rx products. There are four competitors who have more sales than Teva (Aguettant [0-5]%, Mylan [0-5]%, Servier and Novartis [0-5]% each) and numerous other competitors with a market share of 1% or less. At the molecule level (all OTC) including both plain and combination phloroglucinol products the parties would have a combined market share of [80-90]% with an increment of [0-5]% by Teva. Other competitors include Mylan and Servier ([0-5]% each), Novartis ([0-5]%) and at least 7-8 other competitors with [0-5]% or less. If only plain phloroglucinol products were considered, the parties would have lower combined market shares ([70-80]%) with a [0-5]% increment by Teva. The remaining competitors would be the same, with Mylan, Servier and Novartis having more sales than Teva.

30. According to the parties there would be no material difference in their market shares if the market was considered to comprise all drugs sold on prescription (i.e. Rx drugs and OTC drugs sold on prescription). Furthermore, given that oral solid ordinary is the predominant NFC-1 form in this market and that this is the only NFC-1 form where the parties overlap, there is no material difference in market shares based on NFC-1 form.

31. Whilst the transaction would lead to high combined market shares due to the strong competitive position of Cephalon, the market investigation overwhelmingly confirmed that the competitive constraint of Cephalon's Spasfon range would not significantly decrease following the merger. This is because Teva does not appear to exercise a significant competitive constraint on Cephalon (which is also evidenced by its low

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20 M.3493 Yamanouchi/Fujisawa, decision of 18 August 2004; M.4367 APW/APSA/Nordic Capital/Capio, decision of 16 March 2007; M.5253 Sanofi-Aventis/Zentiva, decision of 4 February 2009.

market shares). In particular, respondents did not consider Teva to be among the three closest competitors to Cephalon. Furthermore, a significant majority of respondents confirmed that Cephalon would not acquire through the transaction any special assets and capabilities in France that would allow it to compete significantly more effectively in this market than it already does. It appears that in case of an attempted price increase by Spasfon, it would more likely be companies with stronger market shares and brands that would benefit from any loss of sales as a result.

32. Based on the above, the transaction does not lead to serious doubts as to the compatibility with the internal market in the A3A ATC3 category under any market definition.

1.2.3. C9A – ACE[21] inhibitors – Portugal

33. Both parties manufacture captopril-, enalapril-, lisinopril-, and ramipril-based products which belong to the ATC3 class C9A including plain ACE inhibitors that are mainly used to treat cardiac arrhythmias and hypertension. ACE inhibitors sold in combination (e.g. with diuretics or antihypertensives) are classified in the C9B class. The C9A class is not subdivided into ATC4 classes.

34. Lisinopril is mainly indicated for the treatment of hypertension (as well as symptomatic heart failure and acute myocardial infarction). Lisinopril is also approved for the treatment of renal disease in hypertensive patients with Type 2 diabetes mellitus and incipient nephropathy.

35. As in previous decisions of the Commission[22] the market definition can also be left open in the case at hand, as under any definition there would be no affected market.

36. At the ATC3 level, the combined market share of the Parties would remain below 15%. The same would remain true for a potential market comprised of both C9A and C9B products.

37. Only if looked at a molecule level, there would be a group 1 market, being for lisinopril-based products sold in Portugal for which the combined market share of the Parties would be just above [30-40]%, with an increment above [0-5]% (combined market share of [30-40]% with an increment of [0-5]%).

38. The Parties would continue to face competition from the three originators in the market, which still hold a market share of [30-40]% (AstraZeneca [10-20]%, Merck KGAA [10-20]% and Merck & Co [5-10]%) and which are considered as strong players in the pharmaceutical market. Besides them, there are eleven other competitors selling lisinopril-based products in Portugal with market shares between 1% and 5%, among them Novartis, Fresenius, Generis Farma, Esteve and Stada. These companies also exercise a significant competitive constraint on the parties as they would be able to increase their output without delay. As there are no technological entry barriers for generics, other additional competitors could enter the market.

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21 Angiotensin Converting Enzyme.

22 M.5253 Sanofi-Aventis/Zentiva, decision of 4 February 2009, para. 176; M.3354 Sanofi-Synthelabo/Aventis, decision of 26 April 2004, para. 79-82; M.2517 Bristol Myers Squibb/Du Pont, decision of 9 August 2001, para. 14.

39. As a result, serious doubts as to the compatibility with the internal market can be excluded even for a narrow hypothetical market for lisinopril-based, ACE inhibitors in Portugal.

1.2.4. J1F – Azithromycin – ordinary solid form – Estonia, Latvia, Lithuania and Poland

40. The activities of the parties overlap in regard of systemic macrolides belonging to the J1F class at ATC3 level. Antibiotic macrolides are used to treat various infections of tract or soft tissue and include such antibiotics as, for example, azithromycin, clarithromycin, erythromycin or clindamycin. Azithromycin is derived from erythromycin and is one of the world's best-selling antibiotics. Azithromycin is used to treat or prevent certain bacterial infections, most often those causing middle ear infections, tonsillitis, throat infections, laryngitis, bronchitis, pneumonia, typhoid, and sinusitis. The parties' azithromycin products are Sumamed (Teva) and Azimepha (Cephalon). Regarding their NFC-1 form, they overlap only in oral solid ordinary.

41. In past decisions[23,] the Commission considered that the relevant product market consists of all systemic antibiotics belonging to the J1F class. However, at the same time, in the Teva/Ratiopharm decision, it was noted that "*a certain number of arguments were raised in the market investigation in favour of the molecule (in combination with NFC-1 form) as a relevant market definition, although this cannot be concluded with certainty as a degree of substitution with other macrolides […] would appear to exist*"[24]. The market investigation in the case at hand indicated that there is a high degree of substitutability between various J1F class antibiotics within the geographical markets in question and no indications were raised to the contrary. Some participants to the market investigation also confirmed that there is some degree of substitutability with other systemic antibiotics such as betalactam antibiotics, namely penicillins and cephalosporins. Therefore, it is likely that the relevant product market is broader than the azithromycin molecule and that the azithromycin molecule face competitive constraints from other types of macrolide antibiotics. However, in the present case the exact market definitions can be left open in regard of macrolide antibiotics as no serious doubts arise under any plausible market definition.

42. In the present case, the transaction leads to Group 1 markets in Estonia, Latvia, Lithuania and Poland only at the molecule level for drugs based on azithromycin.[25]

43. In Estonia, the parties' combined market share for azithromycin is [60-70]% in value ([70-80]% in the case of oral solid ordinary form) and [60-70]% in volume. The remaining competitors in this narrower market are Sanofi-Aventis ([10-20]%), Novartis ([5-10]%) and Pfizer ([5-10]%). Novartis and Sanofi-Aventis sell their azithromycin products in the NFC-1 oral solid ordinary form.

44. Regarding Latvia, the parties combined market share for azithromycin is [50-60% in value ([20-30]% in the case of oral solid ordinary form, segment where Novartis is

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23 M.5253 Sanofi-Aventis/Zentiva, decision of 4 February 2009, para. 176; M.5295 Teva/Barr, decision of 19 December 2008, para. 140-143; M.5865 Teva/Ratiopharm, decision of 3 August 2010, para. 186.

24 M.5865 Teva/Ratiopharm, decision of 3 August 2010, para. 180.

25 The parties' combined market shares at ATC3 level in Estonia, Latvia, Lithuania and Poland remain moderate (21.38%, 16.65%, 19.64% and 20.56% respectively). A large number of credible competitors exist in those markets at ATC3 level.

currently market leader and provides its product at the lowest price) and [50-60]% in volume. According to the information provided by the parties, other competitors are Novartis ([30-40]%) and Pfizer ([0-5]%). Only Novartis offers oral solid ordinary azithromycin products in Latvia, however, as explained below, the market investigation has showed that potential competitors would also be able to enter the Member States where they are not currently active and constrain the merged entity with oral solid ordinary products.

45. As for Lithuania, the parties combined market share for azithromycin is [50-60]% in value ([50-60]% in the case of oral solid ordinary form) and [40-50]% in volume. According to the parties, the remaining competitors are Sanofi-Aventis ([30-40]%), Pfizer ([5-10]%), who is a recent entrant, and Novartis ([5-10]%). Novartis and Sanofi-Aventis sell their azithromycin products in the NFC-1 oral solid ordinary form.

46. Finally, in regard of Poland, the parties combined market share for azithromycin is [40-50]% in value ([30-40]% in the case of oral solid ordinary form) and [40-50]% in volume. There are a large number of undertakings which provide azithromycin to the Polish market, including Tarchomin ZF PLF ([10-20]%), Zentiva ([10-20]%), Novartis ([10-20]%), Lek-am ([5-10]%) and other players holding less than 2% of the market. Ten of the competitors offer azithromycin in the NFC-1 oral solid ordinary form.

47. For all four countries, the market shares of competitors would be higher if market share data were calculated based on volume, as Teva offers the originator product "Sumamed" which is higher priced than those of the generic competitors.

48. The market investigation largely confirmed that in any of the four countries there are credible actual and potential competitors who could offer azithromycin-based antibiotics. For every of these countries, the present competitors stated that there would be a sufficient number of credible competitors remaining to constrain the merged entity in the field of azithromycin based antibiotics. In addition, the results of the market investigation showed that existing competitors and potential entrants have the ability to constrain the merged entity through output increase or entry into the Member States where they are not active. The majority of all actual competitors in the four countries would be ready to expand their sales. Finally, the majority of the actual and potential competitors did not indicate any barriers to entry which could prevent them from expanding their sales or third parties from successfully entering the market.[26]

49. As a result, serious doubts as to the compatibility with the internal market can be excluded even for a narrow hypothetical market for azithromycin in Estonia, Latvia, Lithuania and Poland.

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[26] One competitor considered the already strong position of Teva in the market as well as the limited price elasticity in the market potential barriers to entry. Another one submitted that the setting of the reference price by the originator may constitute a general barrier to sales expansion/entry. It follows from these submissions that only if the merged entity sets competitive, low prices, there might be difficulties for potential competitors to enter the market as they would not expect gain sufficient market shares at a given price level. If prices were to rise on a non-temporary basis, market entrance would be feasible which constrains the parties' behaviour.

1.2.5. M1A – Antirheumatics, non-steroidal - Latvia, Lithuania, Poland

50. The ATC3 category M1A consists of non-steroidal anti-rheumatics and includes all non-hormonal anti-inflammatory products for systemic treatment of muscosceletal inflammation. It is subdivided into three ATC4 categories. In previous decisions, the Commission has considered that assessing all products classified under M1A class together was appropriate for market definition purposes, although the exact market definition was left open.[27]

51. The notifying party submits that the relevant product market should be defined by reference to the ATC 3 class, because all non-steroidal anti-rheumatics compete with each other in the countries concerned.

52. According to the market investigation results, the substitutability among various M1A products in Latvia, Lithuania and Poland is limited, in particular with regard to products based on diclofenac (where the parties' activities overlap to the largest extent and would result in high market shares) and its various NFC-1 forms. The exact product market definition can be left open in this case, as concerns can be excluded under any alternative market definition.

53. Both parties sell diclofenac-based product in oral solid ordinary, oral solid long acting, parenteral, and rectal systemic NFC-1 forms, and oral solid ordinary ibuprofen-based products. Teva also markets metoxicam, indometacin and ketofen-based drugs in M1A ATC3 class.

54. The transaction leads to Group 1 markets only on a molecule level (i.e. diclofenac based products) and based on various NFC-1 forms in three countries, i.e. Latvia, Lithuania and Poland whilst there would be no affected markets based on the ATC3 or ATC4 level.

55. In Latvia, the parties achieve in diclofenac based parenteral ordinary products combined market shares of [50-60]% (Teva [20-30]%, Cephalon [30-40]%). The generic competitors are Menarini ([10-20]%), Cilpa ([5-10]%), Medochemie ([5-10]%) and Krka ([5-10]%). The originator Novartis holds [5-10]% of the market.

56. In Lithuania, the parties achieve in the diclofenac based parenteral ordinary products combined market shares of [40-50]% (Teva [10-20]%, Cephalon [20-30]%). The generic competitors are Menarini ([10-20]%) and Krka ([10-20]%). The originator Novartis holds [20-30]% of the market.[28] The parties' combined shares would also lead to a Group 1 market for diclofenac-based rectal systemic products with a market share of [60-70]% (Teva [60-70]%, Cephalon [5-10]%), facing other companies with rectal systemic diclofenac products, i.e. Menarini [20-30]% and GL Pharma [0-5]%, Krka [0-5]%, Novartis [0-5]%.

57. In Poland, for all diclofenac based products the parties would achieve a combined market share of [40-50]% (Teva [5-10]%, Cephalon [30-40]%), facing Menarini ([30-40]%, with rectal systemic and oral solid long-acting productc), Novartis ([5-10]%,

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27 M.1835 Monsanto/Pharmacia & Upjohn, decision of 30 March 2000, para. 26; M.5253 Sanofi-Aventis/Zentiva, decision of 4 February 2009, para. 135-137.

28 All M1A rectal systemic products or M1A1 diclofenac rectal systemic products in Lithuania: Teva 64-65%, Cephalon 4-5%, Menarini 23-27% and GL Pharma 2.5%, Krka 1.3%, Novartis.

with oral solid ordinary, oral solid long-acting products), Krka ([5-10]%, with oral solid ordinary and oral solid long-acting products) and a number of smaller players with products of various NFC-1 forms. In diclofenac based parenteral ordinary products the parties would achieve combined market shares of [60-70]% (Teva [10-20]%, Cephalon [40-50]%). The generic competitors are Krka ([10-20]%), Sandoz/Novartis ([10-20]%) and Wasserman ([0-5]%). The originator Novartis holds [0-5]% of the market.[29] In diclofenac based oral solid ordinary products, the parties' market shares are somewhat lower (Teva [5-10]%, Cephalon [30-40]%) whilst Menarini ([30-40]%) is the strongest competitor next to Novartis ([5-10]%), Krka ([5-10]%) and Polfarma ([0-5]%).

58. The market investigation confirmed the parties' view that sufficient competition from existing and potential players would remain following the proposed transaction. Based on the market investigation, there are no obvious indications that any of the major competing players (including generic diclofenac alternatives) that are active in all of the above segments and across the overall M1A category would face capacity constraints in case of a price increase of the parties' products. In addition, a number of companies that are not currently active in these segments would consider entry into Lithuania, Latvia and Poland with their diclofenac based products.

59. In view of the above, serious doubts as to the compatibility with the internal market do not arise for M1A markets under any plausible market definition in Lithuania, Latvia and Poland.

1.2.6. M3B – Muscle Relaxants, Central – United Kingdom

60. The ATC3 group M3B is part of a broader category of muscle relaxants (M3) and is comprised of centrally acting muscle relaxants primarily used to treat spasticity.

61. In Novartis/Hexal[30], the Commission considered whether M3B constituted a relevant product market or whether this ATC3 class should be further subdivided into baclofen products indicated to spasticity of cerebral origin and other M3B products indicated for treatment of other diseases, but left the exact market definition open. In the case Sanofi/Synthelabo[31] the Commission analysed the market at ATC3 level.

62. Teva submits that the relevant product market should be defined by reference to the ATC3 class since all M3B products perform similar functions. In any event the market definition can be left open in the present case as the transaction does not raise serious doubts irrespective of the market definition.

63. At the ATC3 level, the combined share of the Parties is below 15%. The combined market share of the Parties would be [10-20]% if baclofen-based products are excluded from the ATC3 market.

64. Based on the molecule tizanidine, the concentration would give rise to a Group 1 market only in the United Kingdom.

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29 All diclofenac based products (within ATC3 groups M1A and S1R): Teva 13%, Cephalon 26%, Menarini 19%, Sandoz/Novartis 12%, rest: smaller players.

30 M.3751 Novartis/Hexal, decision of 27 May 2005.

31 M.1397 Sanofi/Synthelabo, decision of 17 May 1999.

65. At the molecule level (tizanidine), the parties' combined market share is [40-50]% ([10-20]% in volume) with a small increment (Teva [0-5]%). All tizanidine-based products sold in the UK are used to treat spasms, cramping and tightness of muscles caused by various medical problems. They are sold under prescription and come in the oral solid ordinary NFC-1 form. Cephalon's product is the originator and is licensed from Sandoz.

66. The sales in volume of Cephalon's Zanaflex decreased from 2009 to 2010 (from […] KSUs[32] to […] KSUs) with a significant erosion of Cephalon's market share in volume ([30-40]% to [10-20]% - versus [50-60]% to [40-50]% in value). According to Teva, the following competitors have a license for tizanidine in the United Kingdom: Generics UK (Mylan), Dr Reddy's Laboratories, Ranbaxy (owned by Daiichi Sankyo), Niche Generics and Actavis.

67. The market investigation confirmed that the generics account for circa 55% and that at least Mylan, Actavis and Ranbaxy are active in the UK market with tizanidine-based products[33]. The market investigation also did not point at any technological entry barrier or any other barrier to expansion for existing players.

68. In view of the above, the transaction does not raise serious doubts as to the compatibility with the internal market in the M3B ATC3 category in the United Kingdom under any market definition.

1.2.7. N4A – anti-parkinson preparations – Germany

69. The ATC3 class N4A comprises anti-parkinson drugs that aim at restoring the balance between dopamine and acetylcholine in the brain. The N4A class is not further sub-divided into ATC4 classes.

70. In Glaxo Wellcome/Smithkline Beecham[34], the Commission carried out its competitive analysis at the ATC3 level.

71. Teva proposes to analyse the market at the ATC3 level, given that the treatment of Parkinson is complicated and involves multiple drugs. According to Teva, all drugs in this class, including selegiline, can be used as a monotherapy or in combination with other drugs and are as such interchangeable.

72. In any event, the exact market definition can be left open, as no serious doubts arise at the ATC3, ATC4, or molecule level with respect to the N4A class.

73. For this product category the concentration would give rise to only one Group 1 market in Germany. At the ATC3 level, the combined share of the parties is below

32 Kilogram Standard Units.

33 Teva submits that as far as the United Kingdom is concerned, it is not always possible to identify precisely each competitor and its market share. This is due to the fact that, in this country, IMS only reports individual sales of originator companies, and not of generic companies, which are indistinctively reported as "lab unknown". Even though Teva combined IMS data with BGMA (British Generics Manufacturers association) data to obtain a more complete structure of the UK markets, this does not always allow having a full picture of the market shares of all companies, because many generic companies do not subscribe to BGMA.

34 M.1846 Glaxo Wellcome/Smithkline Beecham, decision of 8 May 2000.

15% in Germany. At the molecule level, namely seligiline, the parties' combined market share is [30-40]% (Teva [20-30]% and Cephalon [10-20]%). In volume the combined market share is [20-30]% with a limited increment of [0-5]%[35].

74. The Parties would continue to face competition from established players such as Stada ([20-30]%), Novartis ([10-20]%), Neuraxpharma ([10-20]%) and Orion ([5-10]%), plus a number of smaller competitors, such as Meda, Watson, DR Reddy Lab and Mylan.

75. The market investigation did not point at any technological entry barrier for generics, whereas Teva is only one among several generic competitors and the patent expired in 2003.

76. In view of the above, the transaction does not raise serious doubts as to the compatibility with the internal market in the N4A ATC3 category in Germany under any market definition.

1.3. Conclusion - horizontal effects

77. 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

2.1. Introductory remarks

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

79. A potential overlap may arise due to the i) launch of an existing product in a new member state (i.e. one that is already sold in another member state); and ii) launch of a completely new product that has not previously been sold in the EEA. The Commission looked at both of these scenarios in the assessment of potential competition.

80. In a previous decision[36] involving generic products the Commission considered that in the first scenario (i.e. if the product is already sold in at least one member state), 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 has 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 December 2012 in another member state to be relevant for the consideration of potential competition issues due to new geographic entry.

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35 Teva notes that the combined share of the Parties would amount to 29.0% in units and 27.5% in kilograms. Cephalon, the originator, would have a share in volume of 0.6% in kilograms and 2.96% in Standard Units instead of 12.1% in value.

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

81. The Commission considered, for the purposes of the present case, generic pipeline products to be launched in the EEA before August 2013 (i.e. within two years) to be relevant for the assessment of potential competition stemming from entirely new generic launches (except for modafinil, see below) in the EEA (i.e. the launching of products that are not yet sold in the EEA). 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). For originator pipelines, the Commission considered, in accordance with case practice[37], pipeline products which reached the Phase III (clinical trials) stage of development to be sufficiently advanced to qualify the pipeline product as a concrete potential constraint.

2.2. Generic launches

2.2.1. Originator/generic potential overlaps – modafinil

82. The Parties identified one instance where one party (Teva) is planning to launch in the EEA the generic equivalent of the other party's (Cephalon) originator drug. This concerns the launch of the generic version of *modafinil* sold under the brand name "Provigil".

2.2.1.1. Market definition

83. Modafinil-containing medicines are used for patients who suffer from excessive daytime sleepiness (EDS), which can be caused by narcolepsy, a disorder that may cause the person to fall asleep during the day, or it can be due to disturbed night-time sleeping patterns leading to daytime sleepiness. This can be seen in people who work a shift-pattern or in those who suffer from obstructive sleep apnoea (a condition in which pauses in breathing occur repeatedly during the night, disturbing sleep). Excessive sleepiness can also happen with no known causes (idiopathic hypersomnia).[38] Modafinil is a central nervous system stimulant alleviating EDS and reducing cases of sleep attacks.

84. On 27 January 2011, following the review of the safety and effectiveness of modafinil by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) under Article 31 of Directive 2001/83/EC, which was initiated because of safety concerns about modafinil, the European Commission adopted a formal decision resulting in removal of the following indications for modafinil: obstructive sleep apnoea, shift work sleep disorder and idiopathic hypersomnia. Accordingly, modafinil is licensed only for the treatment of excessive sleepiness associated with narcolepsy (with or without cataplexy). Modafinil is not approved for pediatric use.

85. Modafinil-based medicines are grouped in the ATC 3 class N6B, which also includes other psychostimulants, e.g. methylphenidate, fenetylline, dexamphetamine, pemoline and amphetamines. In Novartis/Hexal[39] the Commission assessed the market at N6B

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[37] See for example Case COMP M.5476 Pfizer/Wyeth, decision of 17 July 2009.

[38] *Source*: http://www.ema.europa.eu.

[39] M.3751 Novartis/Hexal, decision of 27 May 2005.

level. However, the assessment was limited to the Netherlands, where the N6B class included exclusively methylphenidate based medicines, which are used to treat Attention Deficit Hyperactivity Disorder (ADHD). This conclusion therefore does not mean that modafinil is in the same relevant market as methylfenidate and other drugs in the N6B ATC3 class.

86. The notifying party submits that the whole of the N6B class should be considered as the appropriate market definition and that, in the event that N6B was not regarded as the relevant market, several products should be considered as directly competing with modafinil, i.e. methylphenidate-based products (e.g. Concerta of Johnson and Johnson, Ritalin of Novartis), dexamphetamine-based products of the N6B class, and central nervous system depressants based on sodium oxybate (e.g. Xyrem by USB), classified in the N7X class (Other central nervous system drugs).

87. For the purposes of the present case, it does not have to be decided whether fenetylline, dexamphetamine and pemoline molecules belong to the same market as modafinil[40]. These products would not affect the competitive assessment, due to the very low value of sales (<1%) of these medicines in any potentially affected market based on any broader market definition proposed by the parties. The market investigation has therefore focussed on the potential competitive constraints on modafinil stemming from methylphenidate (N6B) and sodium oxybate (N7X) based products.

88. During the market investigation both competitors and specialists in narcolepsy (key opinion leaders) were contacted for their views. The market investigation results did not confirm the parties' proposed market definition for a wider market. In particular, the market investigation indicates only a limited substitution between methylphenidate and sodium oxybate on the one hand, and modafinil on the other. In particular, methylphenidate, sodium oxybate and modafinil based products are only sometimes or rarely substitutable for the same therapeutic uses (including both licensed and off-label uses).

89. As explained in the Novartis/Hexal[41] decision, methylphenidate products are preferred as a first choice treatment for attention deficit hyperactivity disorder (ADHD).[42] Although some methylphenidates are also licensed for narcolepsy (e.g. Ritalin of Novartis)[43], according to key opinion leaders methylphenidates and modafinil are not used as valid alternatives for this indication in practice. In particular, according to key opinion leaders methylphenidates can be proposed to treat narcolepsy, idiopathic

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40 Specifically for Estonia, the parties have also included a *caffeine* based product as a competing alternative to modafinil. The market investigation results, however, have shown that caffeine based products cannot be effectively used in substitution to modafinil. Caffeine can therefore be excluded from the relevant product market definition in the present case.

41 M.3751 Novartis/Hexal, decision of 27 May 2005.

42 E.g. Concerta of Johnson & Johnson or Ritalin of Novartis. According to respondents, modafinil is not indicated for ADHD, although it may be used as a second line (off-label) treatment for ADHD, where patients are irresponsive to methylphenidate (NICE clinical guidelines 72).

43 According to the information available to the Commission, other best selling methylphenidates, e.g. Concerta of Johnson and Johnson or Equasym of Shire, are not indicated for narcolepsy.

hypersomnia or rare causes of hypersomnias, in cases of absence of a sufficient response to modafinil. Methylphenidates are less tolerated by patients suffering from these conditions than modafinil. Key opinion leaders in the market investigation considered modafinil to be safer and hence the primary treatment for narcolepsy. According to some key opinion leaders, sometimes methylphenidates are prescribed (off-label) for children, as modafinil is not licensed for paediatric uses. The market investigation did not identify any other approved or off-label indication which accounted for a significant part of the use of both drugs.

90. Sodium oxybate-based products are sedatives, used for the treatment of cataplexy in combination with narcolepsy, an indication where modafinil is also used. Cataplexy involves sudden muscle weakness often in response to an emotional reaction. It is often associated with narcolepsy. Sodium oxybate is taken during the night in order to induce night time sleep, whilst reducing the periods of daytime sleep. According to key opinion leaders sodium oxybate and modafinil cannot be regarded as closely substitutable medicines. Sodium oxybates are generally more complex to administer than modafinil and are more expensive. Sodium oxybates are therefore most often prescribed for patients with severe cataplexy symptoms during daytime or in cases where there is a failure to respond to modafinil or where troublesome side effects of the use of modafinil are present.

91. Based on the above, it appears that the use of modafinil is diverse (due to off-label use) and that there are significant limitations on the substitutability of modafinil with methylfenidate or sodium oxybate. By contrast, a generic modafinil product could substitute the originator for all the uses of the latter. The competitive constraints stemming from the generic version of modafinil would therefore be significantly stronger than any current competitive pressure from other molecules under any market definition. In view of this, it can be concluded that, based on the information available to the Commission and assuming the presence of generic modafinil, the most likely product market definition in the present case is that for modafinil-based products.

92. In any event, due to the significant differences in the degree of therapeutic substitutability of Provigil with generic modafinil on the one hand and with methylphenidate/sodium oxybate on the other, the transaction would result in the elimination of a product that would have been the closest competitor to Cephalon's product. Products based on other molecules, as described above, would be significantly more distant competitors. Therefore, competition concerns due to an elimination of generic constraints on modafinil cannot be excluded irrespective of the exact market definition.

2.2.1.2. Assessment

93. Cephalon has marketing authorisations for the originator modafinil product under various brand names (e.g. Provigil) in 21 countries in the EEA[44] and had sales in 2010 in 19 countries[45]. Cephalon's EEA sales amount to EUR 46 million. Cephalon has

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44 Austria, Belgium, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, UK.

45 Austria, Belgium, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Netherlands, Poland, Portugal, Slovakia, Spain, Sweden, UK.

registered patents in the EEA. In terms of generic entry the most relevant patent appears to be a "particle size" patent which expires on October 6 2015. The validity of this patent has been questioned by a number of generic companies, including Teva, who tried to launch a generic version in the UK as early as 2005.

94. At the molecule level, Cephalon had in 2010 a monopoly in nearly all of the EEA countries where modafinil is sold. This notwithstanding, in 2010 two generic companies had sales of modafinil: Generis Farma in Portugal and Orifarm in Denmark and Sweden. The respective market shares of these generic companies were [30-40]% in Denmark, [20-30]% in Sweden and [30-40]% in Portugal. Both companies subsequently faced patent infringement lawsuits brought by Cephalon. Generis Farma already had to suspend the sales of modafinil as a result, whilst Orifarm had to suspend sales in Sweden. It still continues to sell modafinil in Denmark after Cephalon's application for an interim injunction was rejected. This however does not preclude that Orifarm might have to withdraw its modafinil product at the end of the court procedure should Cephalon win the case.

95. Teva has completed the development of the main dosage form of modafinil and was the first generic to start selling it in the EEA. In particular, Teva received a marketing authorisation ("MA") in the UK for its modafinil product in June 2005, which it subsequently started selling. In response, Cephalon filed a patent infringement lawsuit against Teva and applied for an interim injunction. As a result of a patent settlement agreement reached in 2005 with Cephalon, Teva has agreed to postpone entry until 6 October 2012 (or three years before patent expiry). As of this date, however, Teva is free to launch modafinil in the EEA, without facing litigation by Cephalon. An earlier entry by Teva could apparently occur under the agreement in case of entry of another generic version of Provigil under certain conditions. In addition, Teva was appointed as the exclusive distributor of Cephalon's modafinil products in the UK until October 2011. Other competitors can only launch modafinil at risk before October 2015. In the UK, generics can at present sell their modafinil products, but it is uncertain if this situation will endure beyond the next year or so (see below).

96. Since 2005, Teva had applied to and/or acquired MAs in […] Member States[46] out of the 20 Member States where Cephalon currently sells modafinil directly or through distributors. By the end of 2010, Teva appears to have had valid MAs for modafinil in at least 9 Member States[47].

97. Based on the information provided in the Form CO, other generics made attempts to come to the market with modafinil in eight Member States[48]. In all these instances Cephalon brought legal action against them on the grounds of patent infringement. It is only in the UK that patents were declared invalid by a court judgment on 24 June 2011 so generics are currently free to sell modafinil. However, Cephalon has sought permission to appeal the decision invalidating its patent and which enabled Mylan to come onto the market with its modafinil product. It is unclear at this stage if the appeal will be allowed. If this is the case, a decision on the merits of the appeal will be

46 […].

47 Austria, Denmark, France, Ireland, Netherlands, Slovakia, Spain, Sweden, UK.

48 Denmark, France, Netherlands, Germany, Portugal, Spain, Sweden, UK.

expected around […], according to the parties.[49] (Mylan has recently launched modafinil in the UK, in France and in the Netherlands. As is the case with Orifarm in Denmark, it is uncertain whether it can sell modafinil on a lasting basis as this depends on actions by Cephalon and of the courts. In Germany, Sweden and Portugal, Cephalon has successfully blocked attempts by other generics to sell modafinil[50]. In the Netherlands, France and Denmark generic modafinil is on the market but there is ongoing litigation. According to the parties, decisions may be expected in these cases in […] (Netherlands, first instance), […] (France first instance) and […] (Denmark, end of main proceedings) respectively and generics are expected to be able to sell their products at least until these dates.[51]

98. Based on the above, it cannot be established at this point of time that it is more likely than not that other generics would be able to enter on a lasting basis markets with their modafinil products before October 2015 in any EEA Member State. For the purposes of the present decision, the Commission therefore has to assume, on a conservative basis, that other generic companies could not have entered sustainably the EEA before October 2015 in the absence of the merger. In other words, given that patent litigation is ongoing in a number of countries, it is not clear if between October 2012 and October 2015 generic companies other than Teva would be able to exert a significant competitive pressure on Cephalon's modafinil product. Thus, the transaction would result in the removal of the most likely competitive constraint on Cephalon at least in the period from October 2012 to October 2015. Whilst the timeline may be longer than what might be considered in other cases for generic launches in the context of an assessment of potential competition, the specificities of the case justify the consideration of this timeline. In particular, the case at hand is specific insofar as the settlement agreement between Cephalon and Teva has a significant influence on the parameters of competition, including the temporal aspect.[52]

99. Whilst it is uncertain if other generics could have sustainably constrained Cephalon in the absence of the merger before October 2015, Teva submits that it would not have constrained Cephalon either. This is because despite having developed and obtained marketing authorisations for its product and having the guaranteed right to launch the product from October 2012, Teva submits that it decided in […] to abandon plans to launch modafinil. This occurred, according to the parties and the chronological timeline included in the proxy statement of Cephalon, before the first merger contacts between the parties ([…]). Teva therefore argues that the relevant counter-factual is that in the absence of the merger Teva would not have entered the EEA with its modafinil product.

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49 Submission of 5 October 2011 (as this information was submitted late in the procedure, it was not possible to verify it).

50 In Sweden Cephalon obtained an injunction. In Germany, the litigation was settled with the defendant, who gave a declaration not to launch. In Portugal, the MA of the generic company has been suspended by court order.

51 Again, as this information was submitted late in the procedure it was not possible to verify it.

52 That said, the analysis made herein for the purposes of the application of the EU Merger Regulation does not prejudge any other analysis that may be made of the agreement under antitrust rules.

100. Teva claims that its decision to abandon plans to market modafinil in the EEA in [date] was due to [description of event that, according to Teva, justified its decision to abandon modafinil].

101. According to Teva, in view of [event that, according to Teva, justified its decision to abandon modafinil], it had concluded in [date of Teva's decision to abandon modafinil]that [effect of event that, according to Teva, justified its decision to abandon modafinil] and decided to abandon launch plans in the EEA. In particular, Teva considered that [description of business impact of event that, according to Teva, justified its decision to abandon modafinil]

102. According to Teva, the employees who took the decision to stop modafinil were not aware of any plans by Teva to acquire Cephalon, although […]

103. Teva submits that the decision to stop modafinil [description of the way decision was taken][…] Teva submits that [this process of taking decisions is customary in Teva]and provides, in support of its claim, two examples of […] on the cancellation of other projects.

104. It transpires from the email exchange submitted that the decision to stop the launch of […] modafinil […] was justified *"if we [Teva] have to [reason related to the event that, according to Teva, justified its decision to abandon modafinil]*. The email exchange in addition contains a reference to [another reason]. In later submissions,[53] Teva emphasised the importance of this [other reason] in coming to its decision. Teva submits that [detailed description of the other reason] […] It appears from this that Teva did […] However, it is not clear from the market investigation, including the evidence provided by the parties that this would have played a decisive role in Teva's entry plans. In particular, these [issues related to the other reason] appear to have emerged in […], and this time period does not correspond to the time period […], when the decision to stop the launch of modafinil was allegedly taken.

105. Teva submits that despite [reference to the way the decision was taken], the decisions to stop the launch of a product have a lasting effect. To support this argument, Teva submits that following the decision not to launch modafinil, [Teva took a certain action][54] to withdraw the MAs. Between […] January and […] March 2011, […] out of […] valid MAs were withdrawn according to the information provided by Teva.

106. The MA in the UK has a different status because Teva chose the UK as the Reference Member State (RMS) for the purpose of obtaining MAs in the other Member States. This means that once the MA is granted in the UK (which happened back in 2005) it can be used as a reference for the grant of MAs in other Member States. In the UK, Teva did not use its MA to put its modafinil product on the market following the patent settlement agreement and by June 2010, the MA was about to expire. Teva did apply for renewal (October 2009), although this renewal application was subsequently cancelled in January 2011. However, it appears from […] that for a complete withdrawal of the MA in the UK, Teva has to wait until all the other MAs are effectively cancelled and then has to cancel the UK Reference Member State Status as

53 […].

54 […].

a final step.[55] Teva did not submit any evidence that this has occurred by the date of this Decision. Teva has only provided documentary evidence of the acknowledgement by the relevant UK authority of Teva's request to cancel the renewal and not of the official withdrawal of the MA.

107. According to the parties the first merger contacts occurred on This is supported by the chronological list of events outlined in […]. By this date, MAs had not been officially withdrawn in several Member States (and Teva had not even applied for cancellation in others)[56][…] Teva maintains, however, that as of 20 January 2011 all MAs had been effectively invalidated. This is because due to Teva's cancellation of the renewal request, the UK MA became invalid retroactively, and, as a consequence all other MAs would have been invalid as well.

108. According to the original estimates provided in the Form CO, re-activating these MAs would take [more than a year]. In a later submission, Teva explained the various steps involved in the procedure in more detail and concluded that in an *"optimistic"* scenario, the reactivation of MAs may take altogether [more than a year].

109. The market investigation did not confirm all of Teva's statements, and, most importantly, the statement on the status of its UK MA. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) confirmed that as late as of 11 October 2011, Teva had a "live" MA in the UK for the 100 mg dosage form of modafinil and that the UK's status as Reference Member State for the purpose of obtaining MAs for modafinil in other Member States was still valid. Whilst the MHRA confirmed that Teva withdrew their renewal submission and applied for a Drug Master File update variation, the MHRA had not by 11 October 2011 received a final notification requesting withdrawal.

110. It was also not confirmed by the market investigation that Teva could not keep MAs in other member states if the UK MA was withdrawn or cancelled. In particular, the market investigation pointed to the possibility of changing the Reference Member State through a specific procedure.

111. Furthermore, according to the MHRA the re-activation of the MA would be expected to take less than 6 months if it was based on the original file. Other authorities from other Member States, with some exceptions, also indicated that re-activation of a cancelled MA is likely to take shorter (less than 6-12 months) than the granting of an original MA. Based on the market investigation the existence of a MA that has the status of Reference Member State for purposes of the grant of the authorization appears to significantly expedite the granting of MAs in other member states.

112. However, the exact timeline for re-activating MAs does not have to be calculated for the assessment of Teva's potential competitive constraint, because the definitive

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55 In a meeting on 3 October 2011, Teva claimed that, contrary to the statement in the email, the cancellation of all other MAs is not necessary for completing the cancellation in the UK.

56 Teva had not before this date submitted a cancellation request in […] (request submitted on 20 September 2011), […] (request submitted on 20 September 2011); […](request submitted on 30 March 2011). Whilst a request for withdrawal was submitted before 30 March 2011 in […] and […], a confirmation of withdrawal has not been provided.

withdrawal of MAs, and in particular the UK MA, cannot be taken as the relevant counter-factual. This is because, based on the market investigation, it appears that Teva's MAs in several member states, including the UK, had not been cancelled definitively by the time the merger talks started, according to the parties (or even by the date of notification).

113. Teva stated in a submission of 5 October 2011 that *"A reconsideration of the decision to stop the development of the product is extremely unlikely. […]* Again, for the above reasons, whether Teva reconsiders decisions to terminate the development of other products when the relevant MAs have been cancelled is not relevant for the present assessment as the cancellation of what appears to be the majority[57] of the MAs that were valid in November 2010 cannot be established to have taken place by the time merger talks started. In particular, there is no confirmed withdrawal for several key markets with relatively high sales (France, UK, Spain[58]).

114. By […] Teva had developed and obtained MAs for the main dosage form of modafinil. Its entry of October 2012 was secured thanks to the patent settlement agreement with Cephalon. These factors made Teva's entry with modafinil very likely at the time. The cancellation of such entry plans is therefore not dissimilar to the discontinuation of an existing product. In previous pharmaceutical cases[59] the Commission has accepted the discontinuation of products as a relevant counter-factual under strict conditions. The potential reversibility of a decision to exit a market has been cited as the key argument against accepting this counter-factual. In *Novartis/Alcon[60]* the potential reversibility in itself was considered as the decisive factor not to accept the discontinuation counterfactual despite evidence of the decision having been taken: "*[…] the discontinuation appears to be mainly a business decision which is potentially reversible, in particular as long as the market authorization is still valid. Therefore, on a conservative basis, the horizontal overlap associated with the pruned products […] will be taken into account for the purposes of the competitive assessment […]*" As explained above, despite taking concrete steps to cancel MAs, Teva did have valid MAs in several Member States at the time when the merger talks started and even on the date of notification of the concentration.

115. Whilst in *Teva/Ratiopharm[61]* the discontinuation scenario was accepted in some cases despite reversibility, this was subject to fulfilling strict conditions. In *Teva/Ratiopharm* the Commission considered that "*[i]nsofar as the decision to exit those product markets can be said to be reversible, […], the Commission has asked the Parties to provide documentary evidence of the decision to exit and to explain the business grounds on which it was taken.* In particular, whilst these included documentary evidence in support of the decision to exit, the explanation of the

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58 Together accounting for around EUR […] million of Cephalon's EEA sales.

59 M.5865 Teva/Ratiopharm, decision of 3 August 2010; and M.5778 Novartis/Alcon, decision of 9 August 2010.

60 M.5778 Novartis/Alcon, decision of 9 August 2010.

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

business grounds on which the decision to exit was taken was considered to be the decisive element. In particular, in *Teva/Ratiopharm* the Commission considered that *"[i]n the event that such business grounds appeared uncertain or open to change in the relevant counterfactual, that is absent the merger, on a conservative basis the Commission has taken the view that sales of the product might have continued or been resumed.*" This is further reiterated by the emphasis on the *"solid justification of the decision to exit the relevant market based for example, on the lack of profitability"* that is required for the Commission to accept the discontinuation of products as the relevant counter-factual.

116. Whilst the existence of valid MAs was considered in these precedents as a significant argument in favour of concluding that the decision to exit the market is reversible, this does not mean that the withdrawal/absence of MAs would, *a contrario*, confirm the market exit as the relevant counter-factual in the present case. This is because in the present case, it is potential competition, and, in particular, competition between October 2012 and October 2015 that is the focus of the investigation. For existing products the withdrawal of an MA is likely to have an immediate and probably lasting impact on the competitiveness of the product. In other words, even if a company decided to reverse their decision to exit and then re-apply for an MA, the time of absence from the market would provide other competitors with the opportunity to secure the demand previously supplied by the company. The withdrawal of the MA for an existing product would therefore significantly raise the barriers to (re-)entry for that product. In the present case, this is not evident. Assuming that Cephalon succeeds in maintaining patent protection for its products until October 2015 (as per para. 98 above), the decisive barrier for competitors would be the right to enter the market. In particular, even if Teva's argument is accepted, i.e. that its MAs had been cancelled by the time merger talks started and it would take significant time to re-activate them (a scenario that has not been confirmed by the market investigation), Teva can re-obtain MAs in approximately […] (and, given that the MA for the Reference Member State still seems to be valid, probably in less time). Competitors, on the other hand, would be blocked from entry until October 2015.

117. Whilst Teva submits, by way of documentary evidence, a copy of an email exchange in support of their view which concludes in the discontinuation of the product being the course of action at the time, Teva has not, despite requests from the Commission to this effect[62], provided any detailed […] that would confirm the business grounds to abandon modafinil in the long run. In particular, Teva could not demonstrate that the business grounds for the decision were not *"open to change"*.

118. [Description of evidence submitted by Teva in support of alleged business reason to abandon modafinil] [63]Teva could not provide, in response to the Commission's request to this effect, any internal document that would have contained a more elaborate assessment of [evidence for alleged business reason]. Whilst a reference to this [evidence for alleged business reason] is contained in an internal email sent before [date of decision to stop modafinil] the fact still remains that the [alleged business reason] was not presented as a reason in itself to stop the launch of the product.[…]

62 […].

63 […].

Also, notwithstanding that there are important company-specific factors that influence […], the attempts by competitors to launch generic modafinil, even in the face of litigation, seem to point to a significant market opportunity even following the […].

119. [recall of main reason] that appears to have tipped the balance in favour of the alleged decision to stop the launch at the time. Despite requests by the Commission, Teva did not provide any contemporary documentary evidence that contains a concrete reference to [evidence supporting the main reason to stop modafinil[64]].

120. In addition, Teva clarified in response to a question from the Commission that it […] In this case, Teva would not [have been faced with a situation which was the main reason to abandon modafinil]. Based on information from Cephalon, however, […]. It is also not clear that Teva […]. In particular, there are some indications from the market investigation that it can be reasonably assumed that […]. This appears to show that there was some doubt as to whether [there was a real risk of a situation which was the main reason to abandon modafinil[65]].

121. Based on the above, it can be concluded, that what is alleged to have been the decisive reason for the decision to halt the launch of modafinil […] may not have been a realistic prospect. Whilst this does not call into question that this assumption did provide the grounds for deciding on a course of action at the time, it cannot be ascertained, in light of this, that the business grounds are not *"open to change"*.

122. In later submissions, Teva also emphasises the importance of additional considerations that support the business case of stopping the launch, in particular [description of additional reason] (as briefly referred to in the email exchanges) and [other reason][66]. […]. It should be noted, however, that there is no solid documentary evidence showing that these considerations […] would have played a decisive role in deciding to stop the launch of modafinil in the absence of the merger.

123. This notwithstanding, Teva submits that even on the assumption that its decision could be reversed […], based on a *"dramatic"* change of circumstances, their entry would be significantly delayed to the point which is beyond the time period the Commission normally considers for potential competition in the case of generic pharmaceuticals. In particular, the most obvious events that could qualify as such dramatic change in Teva's view would not occur until […] or […] Due to the time required because of […] and the need to re-acquire MAs, it would then need around […] to re-enter.

124. The Commission considers that there are significant uncertainties concerning these assumptions. In particular, the market investigation did not confirm that Teva did not have, at the time when merger talks allegedly started, valid MAs in a number of member states, including the Reference Member State. It is not therefore clear that their entry would have been significantly delayed (i.e that they could not have entered

64 […].

65 […].

66 […]. This aspect does not appear in the key email exchange leading up to the decision to halt the launch of modafinil in […]..

well before October 2015[67]). It is not clear either if Teva's assumptions about the necessary timelines are correct. In any event it is not clear why it would not have been profitable for Teva to launch modafinil even if […]. In particular, Teva did not provide any evidence to the Commission that would have shown that competitors launching at risk would have deterred Teva from launching modafinil in the first place. Even the patent settlement agreement itself foresees this possibility (i.e. according to the Form CO under the agreement with Cephalon, Teva is apparently allowed to enter the market before October 2012 in case another generic version of Provigil enters the market).

125. Therefore, the Commission considers in light of the results of the market investigation and the circumstances of the case that the decision by Teva not to launch modafinil cannot be considered irreversible. There are no solid grounds within the context of the market investigation to conclude that Teva's launch of modafinil could not be profitable, in particular if Teva is the only generic competitor on the market for at least most of the period from October 2012 to October 2015.

2.2.1.3. Conclusion - modafinil

126. Based on the above, by the time the parties allegedly started merger talks Teva i) had developed a generic version of Cephalon's originator modafinil product; ii) appears to have had several valid MAs in Europe, including the key RMS MA in the UK; and iii) was the only competitor that had the guaranteed right to enter EEA markets between October 2012 and October 2015. Whilst there are other competitors with authorised generic modafinil products (hence meeting points i) and ii) above) it cannot be established that they would have the right to market these products continuously until October 2015. In the absence of compelling evidence as to the permanent withdrawal of plans to launch modafinil in the EEA between October 2012 and October 2015, it cannot be excluded that the transaction leads to the elimination of the most significant potential competitor to Cephalon for modafinil-based products before patent expiry. In particular, in light of the conservative scenario that Cephalon could maintain patent protection in every country, including in the UK (following its appeal), it cannot be excluded that there would not remain a sufficient number of other potential competitors which would maintain a sufficient competitive pressure after the merger. As the competitive pressure stemming from generic modafinil is significantly stronger than the competitive pressure that may stem from other molecules, competition concerns cannot be excluded even on a wider hypothetical market of N6B or as proposed by the parties.

127. The transaction therefore raises serious doubts as to its compatibility with the internal market in the EEA countries where modafinil is sold[68] (and where Teva alone had the guaranteed right to enter between October 2012 and October 2015).

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67 With respect to the time period considered, as noted in para. 96, the case at hand is specific insofar as the settlement agreement has a significant influence on the parameters of competition, including the temporal aspect.

68 Austria, Belgium, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Netherlands, Poland, Portugal, Slovakia, Spain, Sweden, UK.

2.2.2. Other generic launches

128. There are a number of other instances where one of the parties plans to launch a generic product in a national market where the other party is present with either a generic product and/or an originator product based on a molecule that is different from the API of the product to be launched.

129. Given the large number of such possible cases (Teva alone has hundreds of generic launches in the pipeline, and in accordance with previous precedents[69], the market investigation focussed on instances where one party is planning to enter a market with a new product[70] and the other party (or the parties combined) has a market share of 35% or more on any possible market definition, where the pipeline and existing products overlap. This filter is based on the assumption that potential competition 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.

130. There are only two instances that meet these criteria. The launch of […] is already discussed under the assessment of […]. The other launch concerns […]. The potential overlap occurs at the ATC3 level only, where the combined market share is [40-50]%. Since Cephalon only accounts for well below 1% of the market, the merger would not change either the existing incentives for or the potential impact of the launch of the product.

2.3. Originator launches

131. There are no instances of potential overlaps between originator products of the parties which reached the stage of development which has been considered in previous Commission precedents to be sufficiently advanced to qualify the pipeline product as a concrete potential constraint (i.e. Phase III – clinical trials). Furthermore, the parties confirmed that there are no pipeline originator products to be launched in any market where the other party would have a market share of over 35% (including on-market generic products).[71] The transaction does not therefore raise serious doubts as to the compatibility with the internal market due to originator pipelines.

2.4. Conclusion – pipelines

132. 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 pipelines with the exception of the market for modafinil.

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69 Most recently M.5865 Teva/Ratiopharm, decision of 3 August 2010.

70 A new product is defined as a new product based on any aspects considered relevant for market definition. i.e. a new molecule or a new NFC-1 form of a molecule or a changed Rx/OTC status of a molecule.

71 With the exception of Teva's pipeline product Custirsen which could be classified in the same ATC class as Cephalon's Trisenox. However L1X9 (all other antineoplastics) is a "catch all" ATC4 class gathering products that have very different indications. Therefore, in practice, and notwithstanding the potential same classification, the parties' products cannot be considered substitutable.

3. VERTICAL EFFECTS

3.1. Markets for Finished Dose Pharmaceutical Products and Active Pharmaceutical Ingredients (API)

3.1.1. Affected markets

133. In previous decisions[72] the Commission has found that APIs form separate markets upstream to the markets of finished pharmaceutical products and that API markets are, from a geographic scope, at least EEA wide. As Teva produces many of its API in Israel for customers based in the EEA or America, the market may even be worldwide. However, as in those previous decisions, the exact market definition can be left open also in this case as no competition concerns arise, even on 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.

134. Teva manufactures a wide portfolio of API and sells it externally to third parties, whereas Cephalon does not engage in sales of API. Therefore, the transaction does not give rise to any horizontally affected markets for API.

135. Vertically affected markets arise in two different situations:

- where Teva holds a market share in excess of 25% on an upstream API market and Cephalon manufactures a finished dose pharmaceutical belonging to a downstream market comprising products that could contain Teva's API; and

- where Cephalon holds a market share in excess of 25% on a downstream market comprising finished dose pharmaceuticals that could contain one or more of Teva's API.

136. In line with the Commission's approach in Teva/Barr[73] and in Teva/Ratiopharm[74] the Commission focuses, in order to identify vertically affected markets which may give rise to serious doubts, on actual vertical relationships between the parties, i.e. where Teva manufactures an API that is used by Cephalon in case that either of the following applied:

- Teva holds a market share in excess of 30% on a given upstream API market and Cephalon holds, with that same API, more than 5% on a downstream market (be it defined at the ATC3, ATC4 or molecule level). This relationship is referred to as a "downstream vertically affected market"; or

- Cephalon holds a market share in excess of 25% on a downstream market (be it defined at the ATC3, ATC4 or molecule level) and, at the upstream level, Teva holds more than 5% of a corresponding API market. This relationship is referred to as an "upstream vertically affected market".

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72 See for instance M.3394 Johnson and Johnson/J&J MSD Europe, decision of 29 March 2004; M.3493 Yamanouchi/Fujisawa, decision of 18 August 2004; M.3751 Novartis/Hexal, decision of 27 May 2005; M.3928 Teva/Ivax, decision of 24 November 2005; M.5295 Teva/Barr, decision of 19 December 2008; M.5865 Teva/Ratiopharm, decision of 3 August 2010.

73 M.5295, Teva/Barr, decision of 19 December 2008.

74 M.5865, Teva/Ratiopharm, decision of 3 August 2010; see also M.5295, Teva/Barr, decision of 19 December 2008.

3.1.2. Input foreclosure (downstream vertically affected markets)

137. The parties have identified 10 downstream vertically affected markets where Teva's market share may exceed 30% in the upstream API market and Cephalon has a market share of more than 5% in a corresponding downstream market, namely:

- Diltiazem HCL (C8A) in Ireland;
- Lovastatin (C10A) in Portugal;
- Doxorubicin in France, Germany, Italy, Spain, Belgium, Greece and the Czech Republic;
- Venlafaxine HCL (N6A) in Portugal.

138. For Venlafaxine in Portugal, the new entity will have no ability to implement an input foreclosure strategy post-merger because already pre-merger Teva does not supply any competitors at the downstream level with its APIs.

139. In the other three API markets, there are sufficient competitors upstream which impede the new entity from following an input foreclosure strategy. Regarding Diltiazem, Teva's most important competitor is Sanofi/Tanabe (20-30% market share, other competitors such as Piramal, Zambon, Profarmaco, Divis, Zach System, Mitsubishi Tanabe, Synthelabo, Dr. Reddy's have about [20-30]% market share). Regarding Lovastatin, Teva's most important competitor is Lupin ([30-40]%), other competitors such as Henan, Zhejiang Hisun, Biocon, Krebs Biochemicals, Concord, and KRKA have about [20-30]%.Regarding Doxorubicin, Teva's most important competitor is Pfizer (15-20%), others are RPG [10-20]%), BDR [10-20]%), Zhejiang, Hisun, Boryung, Meiji Seika, Sicor, Adorkem and Transo-Pharm Handels GmbH with about 20-25% of the market together.

140. Therefore, it can be concluded that the notified transaction does not lead to serious doubts as to the compatibility with the internal market as regards input foreclosure in relation to an API.

3.1.3. Customer foreclosure (upstream vertically affected markets)

141. The risk associated with upstream vertically affected markets revolves mainly around customer foreclosure. As explained by the Commission in its Guidelines, *"customer foreclosure may occur when a supplier integrates with an important customer in the downstream market. Because of this downstream presence, the merged entity may foreclose access to a sufficient customer base to its actual or potential rivals in the upstream market (the input market) and reduce their ability or incentive to compete"*.[75]

142. The parties have identified 13 upstream vertically affected markets where Cephalon has a market share of more than 25% in a downstream ATC3 class and Teva may have a market share of more than 5% in a corresponding upstream API market, namely:

- Modafinil (N6B) in France, Germany, Greece, Italy, Ireland, Sweden and the UK;
- Verapamil HCL (C8A) in the UK;

75 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, para. 58.

- Doxorubicin (L1D) in Italy and Spain;
- Diltiazem (C8A) in Ireland;
- Pantoprazole sodium (A2B) in Portugal;
- Clarithromycin (J1F) in France.

143. As explained by the Commission in Teva/Ratiopharm[76], at the upstream level, the API markets are likely to be either EEA wide or worldwide in scope, whereas, at the downstream level, the markets are national in scope. Therefore, even when the new entity holds a meaningful market share on a given national downstream market, it will not be able to foreclose its suppliers' access to a sufficient customer base by switching all its API demand to Teva. The reason is that the market for APIs is at least EEA wide if not worldwide while the new entity's EEA or worldwide demand position is weak[77]. This can be derived from the proportion of Cephalon's sales of finished pharmaceutical products all over Europe or the world serving as an approximation of its EEA-wide or worldwide API demand:

Downstream molecule market	**Cephalon's FD market share as approximation of their API demand**	
	Europe	**Worldwide**[78]
Clarithromycin	[0-5]%	[0-5]%
Doxorubicin	[10-20]%	[5-10]%
Modafinil	[70-80]%	[90-100]%
Pantoprazole	[0-5]%	[0-5]%
Verapamil	[0-5]%	[0-5]%

144. Consequently, Teva will not be able to foreclose a significant level of demand. There will still be a sufficient API customer basis of FD suppliers active on other national downstream markets in the EEA or worldwide for the upstream rivals of the new entity.[79] Therefore, it can be concluded that the notified transaction does not lead to serious doubts as to its compatibility with the internal market as regards customer foreclosure in relation to API.

3.2. Contract Manufacturing/Outlicensing

3.2.1. Affected markets

145. Contract manufacturing of finished dose pharmaceuticals consists in the manufacturing under contract, on behalf of third party pharmaceutical companies, of finished pharmaceutical products, which may or may not include final packaging. This third party (not the contract manufacturer) then markets the pharmaceutical products under its own label or brands. This definition excludes the manufacturing of active

76 M.5865, Teva/Ratiopharm, decision of 3 August 2010, para. 405; see also M.5295, Teva/Barr, decision of 19 December 2008.

77 The exception is modafinil, as this molecule is still patent protected. However, Cephalon produces all API required for its modafinil production in Europe in-house.

78 For countries where IMS sales data are available (all major countries are covered).

79 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.

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 decisions[80], however, the precise market definition can be left open since, regardless of the market definition considered, the transaction does not lead to serious doubts on any downstream market for finished dose pharmaceutical products. For the same reasons, there is no need to decide at which geographical level competition to supply private label sellers takes place as there are at hand are no competition concerns even when assessing at a national level.

146. Unless they own the Intellectual Property rights of a drug, Teva and Cephalon do not typically[81] manufacture finished dose pharmaceutical products for third parties. However, in cases where Teva and Cephalon license to third parties the right to commercialize drugs developed by Teva or Cephalon under third parties' own label or brand through so called outlicensing agreements, they may act as contract manufacturer for their licensees.

147. There are two vertically affected markets where (i) one party is active on a downstream finished dose molecule market, (ii) the other party is active upstream as a licensor and contract manufacturer of a downstream competitor and where (iii) the combined share of the parties and the licensee on the downstream market (at ATC3 or molecule level) are in excess of 25%.

148. These markets are Omeprazole (A2B) in Poland and Mirtazapine (N6A) in Portugal, where Teva has out-licensing agreements with third parties. Here, (i) Cephalon is active downstream as a seller of finished dose pharmaceutical products, (ii) Teva is active upstream as both, the licensor and supplier of one of Cephalon's competitors and (iii) the combined share of Cephalon, Teva and Teva's licensees in the potential market for finished dose pharmaceutical products market is in excess of 25% at the ATC 3 or molecule level.

3.2.2. Competitive Assessment

149. Regarding omeprazole in Poland, Teva has outlicensing agreements with […]. The parties' and their licensees' combined market share is [30-40]% (Teva: [0-5]%; Cephalon: [5-10]%, licensees: [20-30]% all together). There is no reason to believe that the transaction in question would change Teva's incentives to outlicence its omeprazole production and to act as a contract manufacturer for its licensees. First of all, the parties submit that […]. The parties combined market share is less than 10% and even if Teva tried to terminate its outlicensing agreements, there are strong competitors remaining in the market, being Zentiva ([20-30]% market share), Sandoz ([10-20]%) and Biopharm ([10-20]%) which would effectively constrain its abilities to increase its profit, which means that there are no incentives to stop current

80 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.

81 There are some rare instances where Teva produces products for third parties, but these do not give rise to affected markets.

outlicensing agreements. Moreover, licensees normally have several alternatives to source the required input such as in-house production, contract manufacturing or an outlicensing agreement with another manufacturer. Teva's Polish partners […] may chose among other omeprazole API suppliers Chemoiberica (Liconsa), Esteva, Uquifa, Nobel Turquie, and Ilsan Intas. Finally, even if Teva decided to implement a foreclosure strategy, there would be no impact on the market conditions downstream as there are other competitors, among them Zentiva, Sandoz, and Biopharm active in the narrowest possible market of Ompeprazol (finished dose pharmaceutical) in Poland holding about [60-70]% of the market. They will exercise a significant competitive pressure downstream which would effectively constrain Teva's abilities to increase its profit by terminating the licensing agreement.

150. As regards mirtazapine in Portugal, the combined market share of the parties' and their licensee […] is [20-30]% (Teva: [10-20]%; Cephalon: [0-5]%; Atral-Ceipan: [10-20]%). The combined market share is moderate and is not suggestive of any competition concerns. It must be also noted that Cephalon's market share is below [0-5]% and it is therefore unlikely that Teva's incentives to licence mirtazapine and to contract manufacture the product for […] would change post-transaction. First of all, the parties submit that […]. Moreover, the parties submit that its licensee has several alternatives to source the required input such as in-house production, contract manufacturing or an outlicensing agreement with another manufacturer. Finally, even if Teva decided to implement a foreclosure strategy, there would be no impact on the market conditions downstream as there are other competitors, among them Merck and Generis active in the narrowest possible market of Mirtazapine FD in Poland holding about [60-70]% of the market. They will exercise a significant competitive pressure downstream which would effectively constrain Teva's abilities to increase its profit by terminating the licensing agreement.

151. Therefore, the vertical relationships which result from outlicensing agreements and related contract manufacturing agreements in the present case do not lead to serious doubts as to the compatibility of the transaction with the internal market.

3.3. Conclusion – vertical effects

152. 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 vertical effects.

4. CONCLUSION – SERIOUS DOUBTS

153. For the reasons set out above, the Commission concludes that the notified transaction gives rise to serious doubts as regards its compatibility with the internal market and the EEA-agreement in respect of the markets for the provision of modafinil-based finished dose pharmaceuticals in the countries where Cephalon currently sells modafinil directly or indirectly (Austria, Belgium, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Netherlands, Poland, Portugal, Slovakia, Spain, Sweden, UK).

VI. MODIFICATIONS TO THE PROPOSED OPERATION

154. In order to remove the serious doubts resulting from the proposed transaction, Teva formally submitted commitments to the Commission on 22 September 2011.

5. DESCRIPTION OF THE COMMITMENTS

155. The detailed text of these commitments is annexed to this Decision. The main elements of the commitments are summarised below.

156. Teva offered to divest Cephalon's generic modafinil pipeline product and related rights, including Cephalon's marketing authorization for a generic version of modafinil in France and a license on the content of the relevant registration dossier and Cephalon's European Economic Area (hereinafter referred to as "EEA") modafinil patents.

157. The business to be divested (hereinafter referred to as "the Divestment Business") includes a) the full transfer of Cephalon's existing French marketing authorization for a generic version of modafinil and an irrevocable, assignable, sub-licensable, and royalty free license for the EEA on all know how and information contained in the relevant registration dossier; b) all related licenses, permits and authorizations; c) the existing inventory of Cephalon's generic modafinil product; d) a non-exclusive license to Cephalon's modafinil patents and the information and know how that is common to Cephalon's French generic marketing authorization dossier and Cephalon's other modafinil related rights; e) a three year (non-exclusive) supply agreement for Cephalon's generic modafinil product.

158. Teva also covenants that it will not sue the purchaser of the Divestment Business for infringement under any patents owned by the parties related to modafinil for the manufacture or the sale by the purchaser of a generic modafinil product in the EEA as of 6 October 2012.

159. At the option of the purchaser, Teva agrees to provide reasonable assistance and documentation in its possession, including appropriate waivers of exclusivities or evidence of patent licenses as reasonably necessary for the purchaser to obtain, on the basis of the French marketing authorization mentioned above, all the other regulatory approvals and marketing authorizations of its generic modafinil product in any EEA country as soon as possible within the context of the applicable regulatory framework. In addition, Teva will use its best efforts to make the appropriate preparations to facilitate the obtaining of such marketing authorizations as soon a possible.

160. Teva also commits to grant a non-exclusive, assignable, sub-licensable, and royalty free license to use the studies carried out by Cephalon in response to the EMA recommendations of November 2010[82] in connection with the purchaser's sale of a generic modafinil product.

82 Available at http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Modafinil_31/WC500096080.pdf.

6. ASSESSMENT OF THE COMMITMENTS

161. The Commission considers that the Commitments are suitable to remove its serious doubts since they provide a guaranteed opportunity for a company to launch a generic version of modafinil in the countries where Cephalon currently sells modafinil. By this, it is ensured that even if Cephalon successfully enforces its modafinil patents until October 2015, the transaction would not result in the removal of competitive constraints on Cephalon in the period between October 2012 to October 2015 when Teva could have launched its generic modafinil product. In addition, in order not to limit the number of potential entrants that could benefit from the Commitments to those companies who already have a modafinil product, the Commitments include the divestment of a generic pipeline product. Due to the possibility to rely only on the covenant not to sue, i.e. in the absence of an obligation to purchase the whole Divestment Business, the Commitments are also suitable to remove the competition concerns if the prospective buyer already has a generic modafinil product.

162. As regards the geographic scope of the Divestment Business, under para 18 of the Commitments, the purchaser has the right in principle to acquire product rights in less than the 30 member states of the EEA. This notwithstanding, the scope of the Commitments cannot in any event cover fewer member states than those where serious doubts are raised (see paragraph 153, above).

163. The market test has confirmed that the initial set of commitments would fully eliminate the competition concerns identified by the Commission. The market test also confirmed that, assuming that a suitable pharmaceutical company acquires the Divestment Business, the acquisition would give such company the potential to come to market in a timely fashion with a viable generic modafinil product and compete effectively with the merged entity.

164. The market test confirmed that the Divestment Business contains all the assets (including Intellectual Property Rights and know-how) that are necessary for a purchaser to come to market in a timely fashion with a generic modafinil product and compete effectively with the merged entity. In particular, the market test confirmed that the provisions of the Commitments would allow the purchaser to acquire MAs in countries other than France in a timely fashion through the Mutual Recognition Procedure.

165. A previous experience with developing modafinil products was considered as an advantage, but not a basic requirement for a suitable purchaser. The majority of respondents did not identify any additional specific criteria for a suitable purchaser. Some respondents mentioned more general criteria, e.g. experience with the generics business and market knowledge. However, the Commission considers that these criteria are in any event covered by para. 19 points b) and c) of the Commitments.

166. The market test has also revealed that there are a number of potential purchasers for the Divestment Business.

7. CONCLUSION

167. The Commission therefore considers that the Commitments are sufficient to eliminate all serious doubts as to the compatibility of the transaction with the internal market[83].

VII. CONCLUSION

168. The Commission has concluded that the remedies submitted by the notifying party are sufficient to remove the serious doubts raised by the concentration. Accordingly, subject to the full compliance with the conditions set out in Sections B, C and D and Schedules of the Commitments submitted by the notifying party on 22 September 2011 and with the obligations set out in the other Sections of the Commitments, the 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) and Article 6(2) of Council Regulation (EC) No 139/2004.

For the Commission
(signed)
Joaquin Almunia
Member of the Commission

83 The acceptance of the Commitments by the Commission is without prejudice to the Commission's antitrust investigation of the patent settlement between Cephalon and Teva of 2005 concerning modafinil **(**"Case COMP/39.686 – "Cephalon").

By hand and by fax: 00 32 2 296 4301

European Commission – Merger Registry

DG Competition

Rue Joseph II 70 Jozef-II straat

B-1000 BRUSSELS

Case M. 6258 – Teva/Cephalon

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2), of Council Regulation (EC) No. 139/2004 as amended (the "***Merger Regulation***"), Teva Pharmaceutical Industries Limited ("***Teva***") hereby provides the following Commitments (the "***Commitments***") in order to enable the European Commission (the "***Commission***") to declare the acquisition of the Cephalon group ("***Cephalon"***) (collectively the "***Parties"***), compatible with the internal market and the EEA Agreement by its decision pursuant to Article 6(1)(b) of the Merger Regulation (the "***Decision***").

The Commitments shall take effect upon the date of adoption of the Decision. This text shall be interpreted in the light of the Decision to the extent that the Commitments are attached as conditions and obligations, in the general framework of Community law, in particular in the light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004.

SECTION A. DEFINITIONS

For the purpose of the Commitments, the following terms shall have the following meaning:

Affiliated Undertakings: undertakings controlled by the Parties and/or by the ultimate parents of the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in the light of the Commission Notice on the concept of concentration under Council Regulation (EC) No 139/2004.

Cephalon: Cephalon, Inc. is a limited liability company organized under the laws of the United States of America with registered offices at 41 Moores Road, P.O. Box 4011, Frazer, Pennsylvania, USA.

Divestment Business: Cephalon's generic Modafinil pipeline product and related rights, including Cephalon's marketing authorization for a generic version of Modafinil in France and a license on the content of the relevant registration dossier and the Modafinil Patents.

EMA studies: the clinical and safety data obtained by Cephalon from the studies carried out following the EMA Assessment Report for Modafinil, as defined in Schedule 1.

Effective Date: the date of adoption of the Decision.

Entry date: October 6, 2012

Generic Modafinil Product: any Modafinil Product that is not marketed under the trademarks Provigil, Modiodal, Vigil, and Modasomil.

First Divestiture Period: the period of [confidential] from the Effective Date.

Divestiture Trustee: one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by Teva and who has received from Teva the exclusive Trustee Mandate to license the Divestment Business at no minimum price.

Purchaser: the entity approved by the Commission as Purchaser of Generic Modafinil Product in accordance with the criteria set out in Section D.

Modafinil Patents: Cephalon's EEA Patents for Modafinil.

Modafinil Products: all finished pharmaceutical products that contain the compound Modafinil including, without limitation, its salts, esters, enatiomers, isomers and polymorphs.

Monitoring Trustee: one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by Teva, and who has the duty to monitor Teva's compliance with the conditions and obligations attached to the Decision.

Teva: Teva Pharmaceutical Industries Ltd. is a limited liability company, incorporated under the laws of Israel, with its registered office at 5 Basel Street Peach Tikva 49131, Israel and registered with the Israeli Company Register under number 520013954.

Trustee Divestiture Period: the period of [confidential] from the end of the First Divestiture Period.

Trustee(s): the Monitoring Trustee and the Divestiture Trustee.

SECTION B. THE DIVESTMENT BUSINESS

Commitment to divest

1. In order to restore effective competition, Teva commits to divest, or procure the divestiture of the Divestment Business by the end of the Trustee Divestiture Period on terms of sale approved by the Commission in accordance with the procedure described in paragraph 16.

2. To carry out the divestiture, Teva commits to find one or more Purchaser(s) and to enter into a final binding agreement for the transfer of Cephalon's Generic Modafinil pipeline Product and related rights within the First Divestiture Period with a view to allow the Purchaser to sell Modafinil in the EEA as of the Entry Date or as soon as practicable thereafter.

3. If Teva has not been able to enter into such an agreement at the end of the First Divestiture Period, Teva shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 30 in the Trustee Divestiture Period.

4. Teva shall be deemed to have complied with this commitment if, by the end of Trustee Divestiture Period, Teva has entered into a final binding sale and purchase agreement, if the

Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph X, and if the Closing of the transfer of the Divestment Business takes place within a period not exceeding 3 months after the approval of the Purchaser and the terms of sale by the Commission.

5. In order to maintain the structural effect of the Commitments, the Parties shall, for a period of 10 years after the Effective Date, not acquire direct or indirect influence over the whole or part of the Divestment Business, unless the Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the common market.

6. Subject to the Commission's approval in accordance with the procedure described in paragraph 16, and at the option of Teva's counterparty, the agreement may exclude the transfer of the Divestment Business and provide for a Covenant not to sue as described in paragraph 12 below.

Structure and definition of the Divestment Business

7. The Divestment Business is described in more detail in the attached Schedule 2 and includes all tangible and intangible assets (including intellectual property rights), which contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as well as a all licences, permits and authorisations issued by any governmental organization for the benefit of the Divestment Business. This includes:

   (a) the full transfer of Cephalon's existing French marketing authorization for a generic version of Modafinil and an irrevocable, assignable, sub-licensable, and royalty free, license for the EEA on all know how and information contained in the relevant registration dossier of such marketing authorization, which contains the following modules:

      - Module 1: administrative information about the marketing authorizations holder, release site, mock-ups of packaging, etc.

      - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);

      - Module 3: chemical, pharmaceutical and biological documentation;

      - Module 4: Non clinical Study Reports;

      - Module 5: Clinical Study Reports.

   (b) at the Purchaser's option, the existing inventory of Cephalon's Generic Modafinil Product;

   (c) a non exclusive license to the Modafinil Patents and the information and know how that is common to Cephalon's French generic marketing authorization dossier and Cephalon's other Modafinil related rights (for the avoidance of doubt, the Purchaser will be allowed to manufacture its own Generic Modafinil Product, in the 100 mg and 200 mg dosage forms, on the basis of such license).

8. For the avoidance of doubt, Teva will remain free to develop and launch a generic version of Modafinil that would be based on a different marketing authorization than the one that is transferred to the Purchaser.

Supply arrangement

9. At the option of the Purchaser, Teva and the Purchaser shall enter into a supply arrangement for the supply of Cephalon's Generic Modafinil Product, for a period of three years renewable at the option of the Purchaser, and on a reasonable cost plus basis to be agreed with the Purchaser.

10. The supply arrangement referred to in paragraph 9 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Generic Modafinil Product.

11. The Purchaser shall be entitled to terminate the supply arrangement at any moment by providing a [confidential] months written prior notification to Teva. At the option of the Purchaser, Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Generic Modafinil Product to the Purchaser's production facilities and undertakes not to oppose all regulatory changes that would be required as a result of such transfer.

Covenant not to sue and regulatory assistance

12. Teva covenants that it will not sue the Purchaser for infringement under the Modafinil Patents or any patents owned by the Parties related to Modafinil, for the manufacture or the sale by the Purchaser of a Generic Modafinil Product (in the 100 mg and 200 mg dosage forms) in the EEA as of the Entry Date.

13. At the option of the Purchaser, Teva agrees to provide reasonable assistance and documentation in its possession, including appropriate waivers of exclusivities or evidence of patent licenses as reasonably necessary for the Purchaser to obtain, on the basis of the French marketing authorization mentioned above, all the other regulatory approvals and marketing authorizations of its Generic Modafinil Product in any EEA country as soon as possible within the context of the applicable regulatory framework. As of the Effective Date, Teva will use its best efforts to make the appropriate preparation to facilitate the obtaining of such marketing authorizations as soon a possible.

Access to EMA Studies

14. Teva commits to grant a non-exclusive, assignable, sub-licensable, and royalty free license to use the EMA studies in connection with the Purchaser's sale of Generic Modafinil Product.

SECTION C. RELATED COMMITMENTS

Preservation of Viability, Marketability and Competitiveness

15. From the Effective Date until Closing, Teva shall preserve the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimize as far as possible any risk of loss of competitive potential of the Divestment Business. In particular Teva undertakes not to carry out any act upon its own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business and to make available sufficient resources for the development of the Divestment Business.

16. Teva also commits not to engage in any action that would affect the validity and value of the rights that form part of the Divestment Business, and in particular, but without limitation, Cephalon's French marketing authorization.

Due Diligence

17. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, Teva shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process provide to potential purchasers sufficient information as regards the Divestment Business, in particular on the know how and information contained in the registration dossier of Cephalon's existing French marketing authorization for a generic version of Modafinil.

Reporting

18. Teva shall submit written reports in English on potential Purchasers and developments in the negotiations with such potential Purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request).

SECTION D. THE PURCHASER

19. In order to ensure the immediate restoration of effective competition, the Purchaser, in order to be approved by the Commission, must:

    (a) be independent of and unconnected to the Parties;

    (b) have the financial resources, proven expertise and incentive to develop Generic Modafinil Product as a viable and active competitive force in competition with the Parties and other competitors;

    (c) be a company active in the sales and marketing of pharmaceutical products in the EEA, unless otherwise approved by the Commission, and

    (d) neither be likely to create, in the light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed (the before-mentioned criteria for the purchaser(s) hereafter the "***Purchaser Requirements***");

20. The final sale and purchase agreement shall be conditional on the Commission's approval. When Teva has reached an agreement with a potential purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), to the Commission and the Monitoring Trustee. Teva must be able to demonstrate to the Commission that the Purchaser meets the Purchaser Requirements and that the Purchase Agreement is being signed in a manner consistent with the Commitments. For the approval, the Commission shall verify that Purchaser fulfils the Purchaser Requirements and that the Purchase Agreement is being signed in a manner consistent with the Commitments. The Commission may approve the sale of the Divestment Business without one or more assets, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

SECTION E. TRUSTEE

Appointment Procedure

21. Teva shall appoint a Monitoring Trustee to carry out the functions specified in the Commitments for a Monitoring Trustee. If Teva has not entered into a binding agreement one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by Teva at that time or thereafter, Teva shall appoint a Divestiture

Trustee to carry out the functions specified in the Commitments for a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

22. The Monitoring Trustee shall be independent of the Parties, possess the necessary qualifications to carry out its mandate, for example as an investment bank or consultant or auditor, and shall neither have nor become exposed to a conflict of interest. The Trustee shall be remunerated by the Parties in a way that does not impede the independent and effective fulfillment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final fee value of the license, the Trustee's fee shall also be linked to a license within the Trustee Divestiture Period.

Proposal by the Parties

23. No later than one week after the Effective Date, Teva shall submit a list of one or more persons whom Teva proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period, Teva shall submit a list of one or more persons whom Teva proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the proposed Trustee fulfils the requirements set out in paragraph 23 and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Monitoring Trustee to fulfill its duties under these Commitments;

(b) the outline of a work plan which describes how the Monitoring Trustee intends to carry out its assigned tasks.

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or rejection by the Commission

24. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfill its obligations. If only one name is approved, Teva shall appoint or cause to be appointed, the individual or institution concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Teva shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by the Parties

25. If all the proposed Trustees are rejected, Teva shall submit the names of at least two more individuals or institutions within one week of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 22 to 25.

Trustee nominated by the Commission

26. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Teva shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

Functions of the Trustee

27. The Monitoring Trustee shall assume its specified duties in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Monitoring Trustee or Teva, give any orders or instructions to the Monitoring Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

28. The Monitoring Trustee shall:

(i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision;

(ii) oversee the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by Teva with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with paragraphs 16 and 17 of the Commitments;

(iii) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision;

(iv) propose to Teva such measures as the Monitoring Trustee considers necessary to ensure Teva's compliance with the conditions and obligations attached to the Decision in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business;

(v) review and assess potential Purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, potential Purchasers receive sufficient information relating to the Purchase Agreement;

(vi) provide to the Commission, sending Teva a non-confidential copy at the same time, a written report within 15 days after the end of every month so that the Commission can assess the progress of the divestiture process as well as potential Purchasers. In addition to these reports, the Monitoring Trustee shall promptly report in writing to the Commission, sending Teva a non-confidential copy at the same time, if it concludes on reasonable grounds that Teva is failing to comply with these Commitments;

(vii) submit to the Commission a reasoned opinion as to the suitability and independence of the proposed Purchaser and whether the Purchase Agreement is signed in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the divestiture of the Divestment Business without one or more assets affects the viability of the Divestment Business after the sale, taking account of the proposed Purchaser.

Duties and obligations of the Divestiture Trustee

29. Within the Trustee Divestiture Period, the Divestiture Trustee shall transfer the Divestment Business at no minimum fee to a Purchaser, provided that the Commission has approved

both the Purchaser and the final Purchase Agreement in accordance with the procedure laid down in paragraph 21. The Divestiture Trustee shall include in the Purchase agreement such terms and conditions as it considers appropriate for a transfer in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the Purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the transfer. The Divestiture Trustee shall protect the legitimate financial interests of Teva, subject to the Parties' unconditional obligation to transfer the Divestment Business at no minimum fee in the Trustee Divestiture Period.

30. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to the Parties.

Duties and obligations of the Parties

31. Teva shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of the Parties' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Teva shall provide the Trustee upon request with copies of any document. The Parties shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Monitoring Trustee with all information necessary for the performance of its tasks.

32. Teva shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request. Teva shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential Purchasers. Teva shall inform the Monitoring Trustee on possible Purchasers, submit a list of potential Purchasers, and keep the Monitoring Trustee informed of all developments in the divestiture process.

33. Teva shall indemnify the Trustee and its employees and agents (each an "***Indemnified Party***") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Teva for any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the willful default, recklessness, gross negligence or bad faith of the Monitoring Trustee, its employees, agents or advisors.

34. At the expense of Teva, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Teva's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Teva refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Teva. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 33 shall apply mutatis mutandis. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Teva during the First Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient transfer.

Replacement, discharge and reappointment of the Trustee

35. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a conflict of interest:

(a) the Commission may, after hearing the Trustee, require Teva to replace the Trustee; or

(b) Teva, with the prior approval of the Commission, may replace the Trustee.

36. If the Trustee is removed according to paragraph 35, the Monitoring Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 22 to 25.

37. Beside the removal according to paragraph 35, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

SECTION F. THE REVIEW CLAUSE

The Commission may, where appropriate, in response to a request from Teva showing good cause and accompanied by a report from the Monitoring Trustee:

(i) Grant an extension of the time periods foreseen in the Commitments, or

(ii) Waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments.

Where Teva seeks an extension of a time period, it shall submit a request to the Commission no later than one month before the expiry of that period, showing good cause. Only in exceptional circumstances shall Teva be entitled to request an extension within the last month of any period.

……

On behalf of Teva

Name:

Title:

SCHEDULE - 1

EMA STUDIES

Risk	Study	Status and expected approval date Expected reports	Reference to the appropriate sections of the CHMP recommendations and the ensuing EMA decision
Cardiovascular disorders	[confidential]	[confidential]	[confidential]
Off label use	[confidential] [confidential] [confidential]	[confidential] [confidential] [confidential]	[confidential] [confidential] [confidential]
Serious skin reactions	[confidential] [confidential]	[confidential] [confidential]	[confidential] [confidential]
Abuse, misuse and diversion	[confidential]	[confidential]	[confidential]
Pregnancy	[confidential]	[confidential]	[confidential]

SCHEDULE - 2

Cephalon's generic modafinil

1. Divestment Business consists of Cephalon's rights, title and interests in a generic version of Modafinil in the EEA with a view to its sale for any indication whatsoever in the EEA. Modafinil is indicated for the treatment of certain sleep disorders including narcolepsy.

2. Divestment Business includes all tangible and intangible assets (including intellectual property rights), which contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as well as a all licences, permits and authorisations issued by any governmental organization for the benefit of the Divestment Business. This includes the full transfer of Cephalon's generic marketing authorization in France, and an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the EEA; including all know how and information relating to Cephalon's Generic Modafinil Product and in particular the information contained in the registration dossier that form the basis of Cephalon's marketing authorization for Modafinil Cephalon in France, which contains the following modules:

    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports.

3. The Divestment Business will include, at the Purchaser's option, the existing inventory of Cephalon's Generic Modafinil Product.

4. The Divestment Business includes all proprietary information associated with the production process of the Divestment Business and a non exclusive license on the Modafinil Patents (for the avoidance of doubt, the Purchaser will be allowed to manufacture its own Generic Modafinil Product, in the 100 mg and 200 mg dosage forms, on the basis of such license).

5. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the supply of Cephalon's Generic Modafinil Product, for a period of three years and on a reasonable cost plus basis to be agreed with the Purchaser.

6. The transitional supply arrangement referred to in paragraph 5 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Modafinil in for a period of three years.

7. Teva commits to make its best efforts to cooperate with the Purchaser for the transfer, at the Purchaser's option, of the production of Modafinil to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

8. At the option of the Purchaser, Teva commits to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Generic Modafinil Product, including any transitory regulatory, logistics and distribution services, for a period of three years, on a reasonable cost plus basis to be agreed with the Purchaser.

9. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provides technical assistance to the Purchaser expeditiously. Teva shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.