EN

Case No COMP/M.5295 - TEVA / BARR

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) in conjunction with Article 6(2) NON-OPPOSITION
Date: 19/12/2008

In electronic form on the EUR-Lex website under document number 32008M5295

Office for Official Publications of the European Communities
L-2985 Luxembourg

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.12.2008
SG-Greffe(2008) D/208501
C(2008) 8908

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION IN CONJUNCTION WITH ARTICLE 6(2)

To the notifying Party:

Dear Sir/Madam,

Subject: **Case No COMP/M.5295 – TEVA / BARR**
Notification of 3 November 2008 pursuant to Article 4 of Council Regulation No 139/2004

1. On 3 November 2008, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ("the Merger Regulation")[1] by which the undertaking Teva Pharmaceutical Industries Limited ("Teva", Israel) acquires, within the meaning of Article 3(1)(b) of the Council Regulation, sole control of the whole of the undertaking Barr Pharmaceuticals, Inc. ("Barr", United States of America).

2. The Commission has concluded that the notified operation falls within the scope of the Merger Regulation. Having finalised its first-phase market investigation, the Commission concluded that the notified operation raised serious doubts. During the course of the proceedings, Teva has submitted commitments in accordance with Article 6(2) of the Merger Regulation, which are designed to eliminate the competition concerns identified by the Commission. In the light of these modifications to the notified operation, the Commission concludes that the notified operation no longer raises serious doubts as to its compatibility with the common market and EEA Agreement.

1 OJ L 24, 29.1.2004 p. 1.

I. THE PARTIES

3. Teva is a global pharmaceutical company specialising in the development, production and marketing of generic pharmaceutical products and proprietary branded pharmaceutical products, as well as active pharmaceutical ingredients ("APIs"). Teva is the largest generic pharmaceutical company in the world.

4. Barr is a global pharmaceutical company primarily engaged in the development, production and marketing of generic pharmaceutical products, proprietary branded pharmaceutical products and APIs.

II. CONCENTRATION

5. On 17 July 2008, Teva, Teva's wholly-owned subsidiary Boron Acquisition Corp. ("Boron I", United States of America) and Barr entered into an agreement providing for the acquisition of Barr by Teva. According to this agreement Boron I will merge with and into Barr, with Barr surviving the merger as a wholly-owned subsidiary of Teva. Immediately following the closing of the merger, Barr will be merged with and into Boron Acquisition LLC ("Boron II", United States of America). After these transactions, Barr will become a wholly-owned subsidiary of Teva, the latter acquiring sole control over Barr.

6. The transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

III. COMMUNITY DIMENSION

7. The combined aggregate world-wide turnover of the undertakings concerned exceeds EUR 5,000 million (Teva 6,860 million, Barr 1,800 million). Both Teva and Barr each have an aggregate Community-wide turnover exceeding EUR 250 million (Teva […], Barr […]). Neither Teva, nor Barr achieve more than two-thirds of their Community-wide turnover within one and the same Member State.

8. The notified operation therefore has a Community dimension pursuant to article 1(2) of the Merger Regulation.

IV. COMPETITIVE ASSESSMENT

A. Overview

9. The notified operation predominantly concerns generic pharmaceuticals, since both Teva and Barr are mainly active in the production and marketing of generic copies of originator drugs ("generics"). Both parties also produce and sell to third parties Active Pharmaceutical Ingredients ("APIs"). By acquiring Barr, Teva will strengthen its position as the world's largest producer of generics.

B. Finished Dose Pharmaceuticals - Horizontally Affected Markets

RELEVANT PRODUCT MARKETS

ATC classification

10. In previous decisions,[2] the Commission noted that pharmaceuticals may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Chemical" classification ("ATC"), devised by European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS"). The ATC is hierarchical and has 16 categories (A, B, C, D etc.) each with different levels. At the third ATC level ("ATC3") pharmaceuticals are grouped in terms of their therapeutic indication, i.e. their intended use. This level is generally used as the starting point for investigating and defining relevant product markets in competition cases.

11. However, it is appropriate to carry out analyses also at other ATC levels, or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level and there are indications that ATC3 class does not lead to a correct market definition.[3] The Commission has previously departed from the ATC3 class in cases where the market investigation indicated that another market definition was more appropriate, for example the ATC4 class or medicines based on the same active pharmaceutical ingredient (molecule level).[4]

Prescription pharmaceuticals and over-the-counter pharmaceuticals

12. In the past, the Commission has considered that drugs available over-the-counter ("OTC") – i.e. without prescription – normally belongs to a different product market than drugs available only on prescription.[5] Medical indications, side effects, legal framework, distribution and marketing tend to differ between these drug categories, even if the active ingredients are sometimes identical. OTC pharmaceuticals may be advertised to the general public, whereas advertising of prescription pharmaceuticals is restricted in most Member States. In most cases, consumers choose OTC pharmaceuticals themselves and purchases are not reimbursed. Prescription pharmaceuticals are prescribed by a doctor and part of the patient's purchase price is reimbursed by the public health-care system. Marketing of prescription pharmaceuticals is therefore targeted at the prescribers and not the patients.

---

2 See for example cases COMP/M.1846 – Glaxo Wellcome/SmithKline Beecham, decision 8 May 2000; COMP/M.1878 – Pfizer/Warner-Lambert, decision 22 May 2000; COMP/M.3751 – Novartis/Hexal, decision 27 May 2005; COMP/M.4402 – UBC/Schwarz Pharma, decision 21 November 2006.

3 Case COMP/M.3751 – Novartis/Hexal.

4 Case COMP/M.3751 – Novartis/Hexal.

5 See for instance cases COMP/M.3544 Bayer Healthcare/Roche, decision 19 November 2004; COMP/M.3394 Johnson & Johnson/Johnson & Johnson MSD Europe, decision 29 March 2004.

13. In the present case, the market investigation has largely confirmed that OTC and prescription pharmaceuticals constitute separate product markets.

Originator pharmaceuticals and generic pharmaceuticals

14. In line with previous decisions, the Commission considers that originator drugs and their generic copies belong to the same relevant product market. It was found in previous decisions that generics can efficiently substitute originator drugs after patent expiry, especially if the regulatory system encourages switching.[6] When assessing the competitive situation in a given product market, the Commission takes into account the fact that the originator drug is exposed to generic competition. Most off-patent drugs are available both in their original version and as generic copies. Once a drug goes off-patent and generic producers enter the market, the originator tends to lose market share, unless he reduces his price.

15. The notified operation is particular in the sense that it concerns a merger between two firms specialised in generics.

16. Innovator drugs are developed, authorised and marketed based on whether they can address effectively and safely a particular medical objective. Innovator drugs aiming to address the same medical objective (i.e. having the same indication) compete with each other on how effectively and safely they can achieve this objective. By contrast, the main criteria for the development, authorisation and marketing of a generic drug is how reliable and effective a copy it is of an innovator drug. The innovator drug and its generic copies are based on the same molecule and by definition drugs based on the same molecule are each other's closest competitors. In generisised markets, price is of much greater importance than in markets where innovator drugs compete with each other and no generic copies have been introduced.

17. The market investigation has indicated that - in particular for drugs purchased by hospitals - competition primarily takes place between drugs based on the same molecule. A majority of hospitals queried by the Commission stated that, in particular for serious illnesses, they would not consider switching from drugs based on one molecule to drugs based on another, even if the price for the molecule would increase significantly. In addition, when hospitals procure pharmaceuticals by means of competitive tenders, they are often limited to drugs based on the same molecule. These hospital replies indicate that generic competition may be based on molecules, in particular as regards drugs for serious illnesses.

18. Due to the greater importance of competition between drugs based on the same molecule in generisised markets - in particular for drugs aimed at serious illnesses and procured by hospitals - the Commission has analysed the markets affected by the notified operation not only at the ATC3 level but also at molecule level.

RELEVANT GEOGRAPHIC MARKETS

6 Case COMP/M.3751 – Novartis/Hexal

19. The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope. The market investigation has confirmed that this is still the case. Competition between pharmaceutical firms still predominantly takes place at a national level and the same approach is appropriate for generic pharmaceuticals.

ASSESSMENT

Introduction – Focus of the Investigation

20. Within the EEA, both parties have sales in 11 countries, namely Bulgaria, the Czech Republic, Estonia, Germany, Hungary, Latvia, Lithuania, Poland, Slovakia, Slovenia and the United Kingdom. Within those countries where overlaps occur, Teva has identified 21 horizontally affected markets, assuming that the ATC3 level constitutes the relevant product market. In two of these cases, prescription L1C products and prescription A11C products, Teva considers the ATC3 class to be inappropriate for defining the relevant product market.

21. In order to better reflect the greater emphasis on molecule-based competition in generisised markets, in particular for drugs for serious illnesses, the Commission requested the parties to provide market data not only for all affected markets based on ATC3 but also for national markets where the parties' activities overlap, where the parties have a joint market share exceeding 35% on molecule level, where the increment exceeds 1% and where competition concerns could not be excluded. The 35% threshold has been used in previous pharmaceuticals cases.[7]

22. Using these criteria to focus the market investigation, 36 markets were investigated, in particular markets in the field of oncology in five Member States in Central and Eastern Europe: the Czech Republic, Hungary, the Slovak Republic, Slovenia and Poland. In addition, a number of markets outside the field of oncology were investigated, in particular in Poland and the UK.

23. For all other markets where the parties' activities overlap and their joint market shares do not exceed 35% either at ATC3 level or molecule level and/or where the increment is below 1%, competition concerns may be excluded. Third parties did not indicate that competition would be significantly impeded on any of these markets.

[7] See for instance cases COMP/M.3354 Sanofi-Synthélabo/Aventis, decision 26 April 2004; COMP.M.3751 – Novartis/Hexal.

24. According to the parties, barriers to market entry are lower for generics than for innovator drugs. For generics, R&D aims at ensuring that a finished product is equivalent to the innovator drug. The development of a generic drug typically takes from eight months up to four and a half years. It should however be noted that generics producers usually start the development work well before the innovator drug's patent expires.

25. Market authorisations for generic products must be obtained from national authorities in the Member state where the products will be marketed. In the European Union, a company that wishes to bring a medicine – innovator or generic – to the market may also submit a single application to the EMEA for a marketing authorisation (licence) that is valid simultaneously in all EU Member States (and the EEA-countries Iceland, Liechtenstein and Norway). This is called the "centralised (or "Community") authorisation procedure", and is mandatory for certain types of medicines and optional for others. The precise scope is set out in the Regulation (EC) No 726/2004.[8]

26. The Commission market investigation indicated that the investment required to get a marketing authorisation, to build up an operation, to register for reimbursement, to get reimbursement approval, to promote and organize the distribution of a generic drug are the main entry barriers. Furthermore, a generic company needs to have credibility in the national market and knowledge of the national market. In addition, there is a certain degree of market saturation in some of the affected countries and therefore prices are low. To enter a national market with a generic drug takes one to two years.

27. The Commissions concludes that there are significant barriers to entry in the affected countries for generic market entrants, irrespective whether they are already present in the national market or not. Compared to innovator drugs, generic entry requires less but still significant investments to obtain market authorisations and, in particular, to build up a marketing and distribution organisation. Reimbursement rules can also constitute barriers to entry. The parties state that the development of a generic drug takes at least ten months. Once the development of the drug has been finalised, a certain time is required for the administrative procedure. Development and administrative procedure adds up to more than one year and it might take several years depending on the product. This means in general that the strategic decision to enter national markets with a certain generic drug must be taken well in advance before entry actually occurs.

8 Regulation (EC) No 726/2004 of The European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136/1, 30.04.2004.

Markets in the field of oncology with serious doubts

Introduction

28. In Sanofi-Synthélabo/Aventis the Commission examined the oncology sector. In that case, the Commission market investigation confirmed the parties' allegation that the ATC3 category was inappropriate for the competitive analysis of oncology products. In that decision, the treatment regime used for a specific type of cancer as well as the role and substitutability of individual molecules in the regime were used as a basis for the competitive analysis. In addition, the Commission found that treatment may vary according to the characteristics and the location of the tumour and the development stage of the disease. In the Sanofi-Synthélabo/Aventis decision, the Commission defined the treatment of a particular cancer type in an advanced stadium as the relevant market. The same decision, however, also addressed the differences of drugs at the molecule level within the treatment of another type of cancer. Even though both parties had products for the treatment of the same type of cancer, the Commission concluded that these were not substitutable and the overlap did therefore not give rise to competition concerns.[9]

29. Based on the delineation of markets according to the main active pharmaceutical ingredient (molecule), the proposed transaction would lead to a number of affected markets in the field of oncology, where the parties would have a combined market share in excess of 35%. These markets are listed as follows:

(1.) Drugs based on paclitaxel in the Czech Republic and Poland,

(2.) Drugs based on calcium folinate in the Czech Republic and Poland,

(3.) Drugs based on carboplatin in the Czech Republic, Hungary and Slovenia,

(4.) Drugs based on cisplatin in the Czech Republic, Hungary, Slovak Republic and Slovenia,

(5.) Drugs based on fluorouracil in the Czech Republic,

(6.) Drugs based on methotrexate in the Czech Republic and Hungary,

(7.) Drugs based on tamoxifen in Slovakia.

9 COMP/M.3354 – Sanofi-Synthélabo/Aventis.

L1C (Vinca alkaloids and other plant products) – Paclitaxel – Czech Republic and Poland

30. The ATC3 class L1C products are part of a broader category of Antineoplastics (L1). This category includes all preparations mainly indicated for the treatment of cancers and all packs specifically produced for the use in anticancer therapy, e.g. special anticancer packs of antibiotics. The ATC3 class L1C includes vinca alkaloids and analogues, podophyllotoxin derivates and colchicine derivates. Paclitaxel, irinotecan and topotecan are classified here. In the ATC3 class L1C the parties overlap only in drugs based on the molecule paclitaxel.

31. The parties have alleged that the ATC3 group L1C may be too wide. Although they are grouped together, the indications and mechanisms of action of L1C drugs may vary. The parties argue that there are two drugs within the ATC3 class that should be grouped together under the category of taxanes: drugs based on paclitaxel and docetaxel respectively. The parties argue that these products have similar indications and similar effects in breast and lung cancer and the same mechanism of action. Furthermore, they are synthesised from similar plants. The parties therefore consider taxanes to be the narrowest possible relevant market.

32. The market investigation has not indicated a high degree of substitutability between drugs based on paclitaxel and docetaxel. Whereas there appears to be some commonality in indications, this does not appear to be sufficient to conclude that these products belong to the same relevant product market. It appears that both drugs have clearly distinct indications. Whereas the Clinical Recommendations of the European Society for Medical Oncology does use the collective term taxanes in their recommendation of treatment regimes for certain types and stages of cancer, for some other types of cancer a clear difference is made and it is specified exactly whether docetaxel or paclitaxel should be used. There seems to be an overlap in the use of docetaxel and paclitaxel for different occurrences of breast cancer and non-small-cell lung cancer but for other types of cancer only one or the other is specified as the appropriate drug for the chemotherapy. The market test also confirmed that there was no overlap at all in the application of these drugs for ovarian cancer and prostate cancer.

33. Based on the replies of most hospitals to the Commission market investigation, it may be concluded that paclitaxel may only rarely be substituted by docetaxel. Hospitals queried by the Commission stated that they would not switch from paclitaxel to docetaxel in case of a 10% price increase. Finally, the market investigation did not support the parties' arguments that there was a high degree of supply-side substitutability between drugs based on these molecules.

34. For the purposes of this decision, the Commission therefore concludes that products based on the molecule paclitaxel should be considered as a separate product market.

35. Of all drugs based on the molecule paclitaxel in the Czech Republic, the combined share of the parties in 2007 would amount to [70-80]% (Teva [40-50]%, Barr [20-30]%). The transaction would merge the largest and the second largest providers in the market and it would substantially strengthen the position

of the current market leader, Teva. Other competitors have much smaller market shares: the originator Bristol Myers Squibb has [10-20]% and there is only one other generic competitor, Ebewe with [10-20]%.

36. The combined share of the parties in 2007 in Poland would amount to [60-70]% (Teva: [10-20]%, Barr: [50-60]%). The merger would significantly strengthen the market leader Barr. The two remaining competitors would have much smaller market shares: Actavis has [20-30]% and Tarchomin ZF Polfa has [10-20]%.

37. In addition to the general barriers to entry in generic markets as described above, there appear to be specific barriers to entry in the case of paclitaxel as well as other oncology drugs with respect to production and supply chain requirements. It was indicated by competitors that oncology drugs are often hazardous (cytostatic) and therefore have special production and handling requirements.

38. In light of the high combined market shares of the parties, the level of concentration in the markets and the barriers to entry in genericised oncology markets in the affected countries, the proposed concentration would raise serious doubts on the markets for drugs based on paclitaxel in the Czech Republic and Poland.

V3D (Detoxifying agents for anti-neoplastic treatment) – Calcium folinate – Czech Republic and Poland

39. The ATC3 class V3D includes amifostine, calcium folinate, calcium levofolinate, dexrazoxane and mesna when indicated for adjuvant therapy in antineoplastic treatment. Products containing calcium folinate and which have multiple indications are classified here. Calcium folinate is used in combination with other drugs in chemotherapy against cancers to prevent or reduce the side effects of the chemotherapy. In the ATC3 class V3D the parties overlap only in drugs based on calcium folinate. This category also includes products based on amifostine and dexrazoxane.

40. The parties consider the ATC3 category V3D to be the relevant basis for the product market definition for the drugs in this category (i.e. calcium folinate, dexrazoxane and amifostine). According to the parties, all these drugs are used in combination with other drugs to treat colon and ovarian cancer.

41. With respect to the ATC3 category V3D, the market investigation clearly indicates that there is a limited degree of substitution between calcium folinate and other drugs in the category. Despite the fact that V3D drugs are used in combination with other products, the market investigation indicated that calcium folinate has markedly different indications than other drugs in this category (dexrazoxane or amifostine). According to the replies of hospitals and competitors to the Commission market investigation, calcium folinate can never be effectively substituted with dexrazoxane or amifostine. Although all the products are used in chemotherapies to prevent and/or reduce side effects of the chemotherapy itself, they each target different side effects and can therefore not be substituted for one another.

42. For the purposes of this decision, the Commission therefore concludes that drugs based on the molecule calcium folinate should be considered as a separate relevant product market.

43. Of all drugs based on the molecule calcium folinate, in the Czech Republic the combined share of the parties in 2007 would amount to [70-80]%. The merger would reduce the number of competitors from three to two leaving only one other competitor, Ebewe with a share of [20-30]%.

44. Of all drugs based on the molecule calcium folinate in Poland, the combined share of the parties in 2007 would amount to [40-50]% (Teva: [0-5]%, Barr: [40-50]%). Ebewe has a [50-60]% market share. Although the increment added by Teva is small, Teva is a recent entrant in a highly concentrated market. Given Teva's extensive oncology portfolio and the company's overall presence in the Polish market, Teva must be regarded as a competitor with substantial growth potential in the Polish market for drugs based on calcium folinate. The merger would therefore not only reduce the number of competitors from two to one but would also remove a recent entrant that may exert significant competitive pressure on the other two competitors in the future.

45. In light of the high combined market shares of the parties, the level of concentration in the markets and the barriers to entry in genericised oncology markets in the affected countries, the proposed concentration would raise serious doubts on the markets for drugs based on calcium folinate in the Czech Republic and Poland.

L1X (All Other Antineoplastics) – Carboplatin and Cisplatin

46. The ATC3 category L1X combines all other antineoplastics. It includes two ATC4 categories. The ATC4 category L1X2 - Platinum compounds includes drugs based on carboplatin and cisplatin.

Carboplatin – Czech Republic, Hungary, Slovenia

47. Carboplatin is a platinum-containing chemotherapy agent. Drugs based on carboplatin are used for all stages of several types of cancer. For the treatment of ovarian cancer of epithelial origin (the most common ovarian cancer), carboplatin is usually used in combination with other drugs (typically paclitaxel) but can be used as a monotherapy as well. For the treatment of small cell lung cancer (the second most common lung cancer), carboplatin is typically combined with cyclophosphamide or etoposide but can also be used as a monotherapy. For the treatment of non small cell lung cancer (the most common lung cancer) carboplatin is usually used in combination with vinorelbine, gemcitabine or a taxane (paclitaxel or docetaxel). Carboplatin may be used both as first and second line therapy, although in the case of non small cell lung disease, it is mainly used as a first line treatment.

48. Carboplatin is a drug bought by and used in hospitals for the treatment of life-threatening diseases. It is a mature and genericised product that has been used for many years for the treatment of cancers in Europe.

49. For the purposes of this decision and due both to the fact that indications for carboplatin and cisplatin are only partially overlapping and to hospitals' buying patterns, drugs based on carboplatin are considered to constitute a separate relevant product market.

50. Of all drugs based on this molecule, the combined share of the parties in 2007 would amount to [70-80]% (Teva: [30-40]%, Barr: [40-50]%) in the Czech Republic. The only other competitor is Ebewe with [20-30]%. The merger would therefore significantly strengthen the market leader Teva and would reduce the number of competitors from three to two.

51. In Hungary, the parties would have a combined market share of [70-80]% (Teva: [50-60]%, Barr: [10-20]%), Ebewe has [10-20]% and the innovator BMS has [10-20]%. The merger would therefore significantly strengthen the market leader Teva with the merged entity's market share being more than three times as large as its nearest competitor.

52. In Slovenia the parties would have a combined market share of [70-80]%, but the increment by Barr is below [0-5]%. The only competitor here is the innovator BMS. Although the increment added by Barr is small, Barr is active in a highly concentrated market. Given Barr's extensive oncology portfolio and the company's overall presence in the Slovenian market, Barr must be regarded as a competitor with substantial growth potential in the Slovenian market for drugs based on carboplatin. The merger would therefore not only reduce the number of competitors from two to one but would also remove a competitor that may exert significant competitive pressure on the other two competitors in the future.

53. In light of the high combined market shares of the parties, the level of concentration in the markets and the barriers to entry in genericised oncology markets in the affected countries, the proposed concentration would raise serious doubts on the markets for drugs based on carboplatin in the Czech Republic, Hungary and Slovenia.

Cisplatin – Czech Republic, Hungary, Slovak Republic, Slovenia

54. Cisplatin is also a platinum-containing chemotherapy agent. Cisplatin is used for treatment of both the early and metastatic stages of lung cancer (both small cell and non small cell types), ovarian cancer, and also cervical, testicular, gastric and bladder cancer. Cisplatin is typically used in combination with etoposide or cyclophosphamide for the treatment of small cell lung cancer; with vinorelbine, gemcitabine or a taxane for the treatment of non small cell lung cancer; with capecetibine for treatment of gastric cancer and with gemcitabine for bladder cancer. Cisplatin may be used both as first and second line therapy.

55. Cisplatin is a drug bought by and used in hospitals for the treatment of life-threatening diseases. It is a mature and genericised product that has been used for decades for the treatment of cancers in the EU. Cisplatin is an old generation drug among platinum compounds. One of the limitations of its treatment is the build-up of cisplatin resistance, in which case it has to be replaced by another drug.

Furthermore, carboplatin, a newer generation platinum compound has fewer side effects compared to cisplatin.

56. For the purposes of this decision and due both to the fact that indications for cisplain and carboplatin are only partially overlapping and to the buying patterns of hospitals, drugs based on cisplatin are considered to constitute a separate product market.

57. In the Czech Republic, of all drugs based on the molecule cisplatin, the combined share of the parties in 2007 would amount to [60-70]% (Teva: [20-30]%, Barr: [30-40]%) and the only competitor would be Ebewe with [30-40]%.

58. In Hungary the parties would have a combined market share in 2007 of [60-70]% (Teva: [10-20]%, Barr: [40-50]%), Ebewe would be the only other competitor with [30-40]%.

59. In the Slovak Republic, the parties' combined market share in 2007 would be [50-60]% (Teva: [10-20]%, Barr: [30-40]%). The only remaining competitor would be Ebewe with [40-50]%.

60. In Slovenia, the parties' combined market share in 2007 would be [90-100]% (Teva: [0-5]%, Barr: [80-90]%) and the only competitor would be the innovator BMS with [5-10]%.

61. The merger would therefore reduce the number of suppliers from three to two in all four countries.

62. In light of the high combined market shares of the parties, the level of concentration in the markets and the barriers to entry in genericised oncology markets in the affected countries, the proposed concentration would raise serious doubts on the markets for drugs based on cisplatin in the Czech Republic, Hungary, the Slovak Republic and Slovenia.

L1B (Antimetabolites) – Flourouracil, Methotrexate

63. The ATC3 category L1B includes the molecules folic acid analogues (eg methotrexate), pyrimidine analogues (e.g. capecitabine, carmofur, cytarabine, fluorouracil, tegafur) and purine analogues (e.g. fludarabine, mercaptopurine, tioguanine).

Fluorouracil – Czech Republic

64. Fluorouracil is an antimetabolite chemotherapy agent that has been used for 40 years as an anti-cancer treatment. It is used for the treatment of different types of cancers, most typically for colorectal cancer of the colon or for breast cancer. Fluorouracil may be used as monotherapy or in combination with many other anticancer agents typically in the metastatic stage. In breast cancer fluorouracil is often used in combination with doxorubicin and cyclophosphamide, or epirubicin and cyclophosphamide, or with methotrexate and cyclophosphamide. In

colorectal cancer often used in combination with calcium folinate and oxaliplatin or irinotecan, but other combinations are also used, including combinations with monoclonal antibody treatments. It may be used as first or second line therapy.

65. Fluorouracil is a drug bought by and used in hospitals for the treatment of life-threatening diseases. It is a mature and genericised product that has been used for decades for the treatment of cancers in the EU.

66. For the purposes of this decision and due both to the fact that indications for fluorouracil and other molecules in the L1B class are only partially overlapping and to the buying patterns of hospitals, fluorouracil is considered to be a separate relevant product market.

67. Of all drugs based on the molecule fluorouracil, the combined share of the parties in 2007 would amount to [40-50]% (Teva: [30-40]%, Barr: [10-20]%) in the Czech Republic. Ebewe has [50-60]% of the market. The merger would therefore reduce the number of suppliers from three to two.

68. In light of the high combined market shares of the parties, the level of concentration in the markets and the barriers to entry in genericised oncology markets in the affected countries, the proposed concentration would raise serious doubts on the markets for drugs based on fluorouracil in the Czech Republic.

Methotrexate – Czech Republic and Hungary

69. Methotrexate is an antimetabolite chemotherapeutic agent, but appears to have a distinct mechanism of action from fluorouracil.[10] Methotrexate has been used for a number of decades in the treatment of a large number of cancers, including trophoblastic neoplasms (choriocarcinoma and hydatidiform mole), breast cancer, certain forms of lymphoma and certain forms of leukaemia. The use of methotrexate is now generally less common than in the past but it is still used for acute lymphatic leukaemia. It has been used as a monotherapy but methotrexate is more typically used in combination with other drugs. For the treatment of breast cancer, methotrexate has been used in combination with cyclophosphamide and fluorouracil. According to the parties, methotrexate may be combined with calcium folinate (or alternatives) in the treatment of almost any cancer.[11] Methotrexate has significant indications for non-oncology applications as well.

---

[10] Fluorouracil is an analogue of uracil, a component of ribonucleic acid. The drug is believed to function as an antimetabolite. After intracellular conversion to the active deoxynucleotide, it interferes with the synthesis of DNA by blocking the conversion of deoxyuridylic acid to thymidylic acid by the cellular enzyme thymidylate synthetase. Flourouracil may also interfere with RNA synthesis. Methotrexate is an antimetabolite which acts principally by competitively inhibiting the enzyme, dihydrofolate reductase. In the process of DNA synthesis and cellular replication, folic acid must be reduced to tetrahydrofolic acid by this enzyme, and inhibition by methotrexate interferes with tissue cell reproduction.

[11] Except in the case of intrathecal use (where methotrexate may be used for cerebral/meningeal leukemia).

70. Methotrexate is a drug bought by and used in hospitals for the treatment of life-threatening diseases. It is a mature and genericised product that has been used for decades for the treatment of cancers in the EU.

71. For the purposes of this decision and due both to the fact that indications for methotrexate and other molecules in the L1B class are only partially overlapping and to the buying patterns of hospitals, methotrexate is considered to be a separate relevant product market.

72. Of all drugs based on the molecule methotrexate, the combined share of the parties in 2007 would amount to [90-100]% (Teva: [5-10]%, Barr: [80-90]%) in the Czech Republic. The only other two competitors are Ebewe ([5-10]%) and Medac ([0-5]%). The merged entity would have a very high combined market share, more than ten times the one of its nearest competitor.

73. In Hungary, the merger would lead to a combined market share in 2007 of [70-80]% (Teva: [10-20]%, Barr: [50-60]%). The merger would significantly strengthen the position of the market leader, Barr. Only two significantly smaller competitors would remain in the market: Ebewe with [10-20]% and Orion with [5-10]%.

74. In light of the high combined market shares of the parties, the level of concentration in the markets and the barriers to entry in genericised oncology markets in the affected countries, the proposed concentration would raise serious doubts on the markets for drugs based on methotrexate in the Czech Republic and Hungary.

L2B (Cytostatic Hormone Antagonists) – Tamoxifen

75. The ATC3 category L2B contains cytostatic hormone antagonists. It is subdivided into four ATC4 categories. The ATC4 category L2B1 refers to cytostatic anti-oestrogens and includes substances such as tamoxifen, mepitiostane, epitiostanol, toremifene.

Tamoxifen – Slovak Republic

76. Tamoxifen is an oestrogen receptor modulator. Its action is different from most other chemotherapeutic agents and is specific to oestrogen receptor positive breast cancer. The drug may be used alone or in combination with most other chemotherapeutic agents (except anastrozole) but it is frequently used alone and for long term treatment. Tamoxifen may be used as first or second line therapy but is most frequently used as part of a first line therapy.

77. Tamoxifen is a drug used for the treatment of a life-threatening disease. It is a mature and genericised product that has been used for decades in Europe for the treatment of cancers.

78. For the purposes of this decision and due both to the fact that indications for tamoxifen and other molecules in the L2B class are only partially overlapping and

to the buying patterns of hospitals, tamoxifen is considered to be a separate relevant product market.

79. Of all drugs based on the molecule tamoxifen, the combined market share of the parties in the Slovak Republic in 2007 would amount to [60-70]% (Teva: [5-10]%, Barr: [60-70]%). Ebewe has the remaining [30-40]% market share.

80. In light of the high combined market shares of the parties, the level of concentration in the markets and the barriers to entry in genericised oncology markets in the affected countries, the proposed concentration would raise serious doubts on the market for drugs based on tamoxifen in the Slovak Republic.

Markets outside the field of oncology with serious doubts

A11X (Other vitamins) / Riboflavin and Pyridoxine - Poland

81. Riboflavin and pyridoxine are two vitamins that belong to the ATC3 category A11X "Other vitamins". Products in this category comprise plain vitamin B3 (nicotinamide), plain vitamin B6 (pyridoxine), plain vitamin E and all other vitamins, plain and in combination. It should be noted that ATC categories with an "X" combine together various products where the therapeutic links are less clear than in other categories.

82. Within the ATC3 class A11X both parties manufacture OTC products based the molecule riboflavin and products sold on prescription based on the molecule pyridoxine. According to the parties, riboflavin can be used to treat or mitigate a specific condition or deficiency, e.g. a severe depletion of vitamin B2 that can escalate to a disease known as ariboflavinosis, while pyridoxine can be used to treat or mitigate a specific condition or deficiency, e.g. a severe depletion of vitamin B6.

83. The parties argue that specific indications for a particular vitamin play a very little role for vitamins sold OTC because they are essentially purchased as food supplements to a normal complete diet. Vitamins sold OTC in Poland are sold through pharmacies on the one hand and retail stores like supermarkets and drug stores ("mass market") on the other hand. According to the parties, marketing efforts are the key driver for the sales of vitamin products.

84. The Commission market investigation indicated that the ATC3 approach for A11X is not appropriate. A number of respondents confirmed that the molecules riboflavin and pyridoxine have different indications, i.e. they are used to treat different vitamin deficiencies and prophylaxis, as the parties stated themselves. But the parties' allegation that the indication plays a minor role for vitamin products was not confirmed in respect of these products. Respondents indicated that products based on riboflavin cannot be substituted by products based on another molecule. The same applies for pyridoxine. Moreover, respondents indicated that even though there are no specific barriers to entry, market entry could take up to three years.

85. Therefore, the Commission concludes, for the purposes of this decision, that drugs based on riboflavin and pyridoxine constitute separate relevant product markets.

86. Teva sells two prescription products; one based on pyridoxine and one based on nicotinamide. Barr sells three prescription products, one based on pyridoxine, one based on nicotinamide and one based on riboflavin.

87. Based on the molecule level, irrespective of the sales channel, the combined market shares of the parties are [90-100]% for riboflavin (Teva: [10-20]%, Barr: [80-90]%) and [90-100]% for pyridoxine (Teva: [20-30]%, Barr: [70-80]%). The parties' combined market share for nicotinamide is far below 35%.

88. The Commission therefore concludes that serious doubts arise concerning the Polish markets for riboflavin and pyridoxine respectively.

Markets outside the field of oncology – no serious doubts

A10B (Oral antidiabetics) / Metformin - Poland

89. The molecule metformin belongs to the ATC3 class A10B – Oral Antidiabetics, and the ATC4 class A10B2 (Biguanide antidiabetics). It is an oral anti-diabetic drug used for the treatment of type 2 diabetes,[12] particularly for the treatment of overweight and obese people and those with normal kidney function, and evidence suggests metformin may be the best choice for people with heart failure. The drug is also used in the treatment of polycystic ovary syndrome.

90. The parties believe that the appropriate market definition is the ATC3 class A10B, as all oral antidiabetics can be substituted against one another.

91. In previous decisions,[13] the Commission has not concluded on the market definition for oral antidiabetics. In the present case the product market definition can also be left open.

92. The combined market share of the parties based on ATC3 would be far below 15%. For drugs based on the molecule metformin in Poland the combined share of the parties would be [40-50]% (Teva [40-50]%; Barr [0-5]%).

93. At molecule level there is one generic competitor with products based on the molecule metformin, namely Menarini with a market share of [30-40]%, and the originator Merck KGAA with a market share of [10-20]%. The market share of

---

12 Type 1 diabetes results from the destruction of insulin producing cells in the pancreas and insulins are used in the treatment of Type 1 diabetes. Type 2 diabetes, which tends to occur among older age groups, consists of insulin resistance and progressive failure of insulin production by the pancreas.

13 Cases COMP/M.1846 - Glaxo Wellcome/SmithKline Beecham, para. 208 seq.; COMP/M.1378 - Hoechst/Rhone Poulenc, decision 9 August 1999, para. 55; COMP/M.631 - Upjohn/Pharmacia, decision 28 September 1995, para. 5.

the originator increased from [0-5]% in 2005 to almost [10-20]% in 2007. The price for the innovator's product is only slightly higher than the price for the generic products. The market share of the generic competitor Menarini also increased slightly from below [30-40]% in 2005 to almost [30-40]% in 2007, while Barr's market share decreased from almost [0-5]% in 2005 to below [0-5]% in 2007. Teva's market share also decreased from almost [50-60]% to [40-50]%. In addition, the increment added by Barr is marginal.

94. The Commission therefore concludes that no serious doubts arise.

A11B OTC (Multivitamins without minerals) - Poland

95. The ATC3 class A11B comprises all multivitamin combinations that do not contain minerals. Several therapeutic indications can be associated with multivitamin products, partly as a result of marketing segmentation such as children/senior people or sportive/active people. Such vitamins are usually sought for their qualities in the prevention of diet deficiencies, as well as in strength and immunity enhancement. According to the parties, specific indications for a particular vitamin play very little role for vitamins sold OTC, because they are essentially purchased as food supplements to a normal complete diet.

96. According to the parties, vitamin B1 and combinations (OTC) in Poland are sold through two distribution channels: pharmacies on the one hand and the mass market (supermarkets and drug stores) on the other.

97. The Commission market investigation confirmed the ATC3 approach. However, the market investigation indicated that these products are also sold in the mass market. Respondents indicated that market entry as a food supplement would be fast. Otherwise market entry would take longer. According to one reply, competition is intensive in this market.

98. The combined market share of the parties in 2007 (sales to pharmacies only) amounted to [50-60]% (Teva: [40-50]%, Barr: [10-20]%). The largest competitors were Merck KGAA ([10-20]%), Vitamex ([10-20]%) and Warzawa ZF Polfa ([10-20]%). Total sales in this market amounted to EUR […] in 2007.

99. The parties' products are not each other's closest competitors. Sales via other sales channels than pharmacies are not included in the market shares mentioned above. There is also a degree of competitive constraint from the mass market on pharmacy sales. There are no specific barriers to entry and in case a product is sold as a food supplement, market entry is likely to be faster than for generic OTC products in general.

100. The Commission therefore concludes that no serious doubts arise.

A11C Prescription– (Vitamins A and D including combinations of the two) - Slovenia and Germany

101. The ATC3 class A11C comprises all vitamins A and D including combinations of the two. This class also includes combinations of vitamin A with vitamin E, cinacalcet for hyperparathyroidism and products containing halibut or cod liver oil.

102. The parties submit that, although their products belong to the same ATC3 class, they cannot be considered as substitutes for the following reasons: Barr's product Plivit D3 (colecalciferol) is an oral solution of plain vitamin D. Teva's product Alpha D3 (alfacalcidol) is not a synthetic vitamin D but a synthetic active metabolite of vitamin D which is already hydroxylated.[14] According to the parties, Teva's product Alpha 3D contains the molecule alfacalcidol and is used for diseases like osteoporosis or different types of adult rickets, while Barr's product Plivit D3 contains the molecule colecalciferol and is used to prevent rickets in infants and young children, as food supplement in case of inadequate nutrition or a lack of sun and for pregnant and nursing women. Both products are prescription drugs.

103. The market investigation indicated that the molecules alfacalcidol and colecalciferol have different indications. Respondents also stated that products from other ATC3 classes may be used for the treatment of osteoporosis. There are no specific barriers to entry.

104. The market definition can be left open.

105. In Slovenia the combined market share of the parties in 2007,[15] based on ATC3, amounted to [40-50]% (Teva: [30-40]%, Barr: [10-20]%). The largest competitors were Roche ([20-30]%), Amgen ([10-20]%) and KrKa ([10-20]%). Total sales in this market amounted to EUR […] in 2007.

106. The parties' products are not each other's closest competitors in this ATC3 class as their products are based on different molecules. In addition, there are a number of additional competitors in this market.

107. The Commission therefore concludes that no serious doubts arise in Slovenia.

108. In Germany the combined market share of the parties based on ATC3 would be below 15%. Based on the molecule alfacalcidol, the combined share of the parties would be [50-60]% (Teva [30-40]%, Barr: [20-30]%). It should be noted that in

14 Hydroxylation is any chemical process that introduces one or more hydroxyl groups (-OH) into a compound (or radical) thereby oxidizing it. In biochemistry, hydroxylation reactions are often facilitated by enzymes called hydroxylases.

15 According to the parties, in Slovenia this ATC3 class is not split into OTC and prescription products. However, the parties estimate that the estimated market shares without OTC products would change less than 0.5% for all market players.

Germany Barr distributes and sells Teva's branded generic product Bonidol under the brand name Doss.

109. The main competitor to the parties at molecule level is the originator Leo Pharma with a market share of [30-40]%. There are three additional competitors who are active in parallel imports. These parallel importers all have market shares below [5-10]%. The unit price of Leo Pharma's product is EUR […], Teva's product EUR […] and Barr's product EUR […]. The prices of the parallel importers range between EUR […] and EUR[…].

110. It may be concluded that there is a certain degree of price competition between products based on alfacalcidol in Germany. The originator's price lies between the parties' respective prices. Barr's price is higher than Teva's and Leo Pharma's price. There are products based on alfacalcidol with a lower price than Teva's. Barr is only manufacturing Teva's product and Teva gets a part of the price at which the product is approved for sale in Germany. Even on the basis of a narrow market definition based on the molecule alfacalcidol, price competition in Germany will not be constrained by the merger.

111. The Commission therefore concludes that no serious doubts arise in Germany.

A11D (Vitamin B1 and combinations) - Poland

112. The ATC3 class A11D comprises plain vitamin B1, vitamin B1 and combinations with vitamin B6 and/or vitamin B12 and other vitamin B1 combination.

113. The parties argue the market should be defined based on the ATC3 level.

114. In a previous decision the Commission analysed vitamins B1 at the ATC3 level.[16]

115. The parties' products contain the same molecule, namely thiamine. For this molecule it depends on the dosage whether the product is sold OTC or on prescription. Teva sells two products OTC and one on prescription. Barr's product is only sold on prescription.

116. The market investigation has indicated that the molecule thiamine has the same applications as the molecule cocarboxylase and that some patients could switch to other products in case of a price increase. There are no specific barriers to entry. Cocarboxylase is the molecule included in competitor Sanitas' product. There is no indication that the market definition ought to be based on the molecule level.

117. In Poland the combined market share of the parties in 2007, based on ATC3, would be [10-20]% (Teva: [0-5]%, Barr: [10-20]%). The largest competitors were Sanitas ([40-50]%) and Wörwag ([30-40]%). If only prescription products in this ATC3 class are included, the combined market share of the parties would be [10-

16 See for instance, case COMP/M.950 – Hoffmann La Roche/Boehringer Mannheim, decision of 4 February 1998, para 12.

20]% (Teva: [0-5]%, Barr: [10-20]%). There are competitors with substantially higher market shares than those of the parties in the ATC3 class A11D.

118. The Commission therefore concludes that no serious doubts arise.

A12A - Calcium products - in Poland

119. The ATC3 class A12A includes single and combination products predominantly used for osteoporosis or calcium deficiency, even they may be indicated for other diseases as well.

120. The parties propose to define the market on the basis of the ATC3 level.

121. In the present case the product market definition can be left open.

122. The OTC product of Teva contains Vicalvit D, the molecules calcium and colecalciferol. Barr's OTC products Calperos and Calcium Pliva both contain calcium. There is a third product of Barr containing colecalciferol.

123. The market investigation indicated that ATC3 is the right approach for the definition of the relevant product market. The A12A class contains calcium products which can be regarded as substitutable. All products in this class are generic. Market entry with a calcium product as food supplement is possible within a couple of months, while entry as an OTC pharmaceutical product would require two to three years.

124. In Poland the combined market share of the parties in 2007, based on ATC3, would be [30-40]% (Teva: [0-5]%, Barr: [30-40]%). The largest competitors were Polfa Lodzkie ZF ([20-30]%) and Unipharm ([10-20]%).

125. The market is completely genericised with a number of competitors, there are no specific entry barriers for the OTC market and the parties' products are not each other's closest competitors within this ATC3 group.

126. The Commission therefore concludes that no serious doubts arise.

C10A (Cholesterol and triglyceride regulating preparations) / Pravastatin - Hungary

127. The molecule pravastatin belongs to the ATC3 category C10A – cholesterol and triglyceride regulating preparations. This category comprises products relating to the cardiovascular system and includes all drugs reducing cholesterol and triglycerides only. Within the ATC3 category the molecule pravastatin belongs to the ATC 4 class C10A1 (statins). It is used to lower cholesterol (Hypercholesterolemia) and prevent cardiovascular diseases.

128. The parties argue that the ATC3 level is the appropriate product market definition.

129. In previous decisions,[17] the Commission, based on the results of the market investigation, carried out the assessment at the ATC3 level C10A.

130. In the present case the product market definition can be left open.

131. The combined market share of the parties based on ATC3 would be below 15%. Based on the molecule pravastatin in Hungary the combined share of the parties would be [30-40]% (Teva [20-30]%; Barr [5-10]%). Barr entered the market in […] and gained market share in the last […] while Teva's market share decreased from [40-50]% in 2005 to [20-30]% in 2007. At the same time, the market share of the parties' competitor Apotex increased.

132. Even at the molecule level there are several competitors with generic products based on the molecule pravastatin, like Zentiva with a market share of [50-60]% and Apotex with a market share of [10-20]%.

133. According to the parties, pravastatin was partially de-listed by Hungarian authorities on 1 January 2008 and the products prescribed under the normative system are not reimbursed anymore. The parties submit that as a consequence, the use of pravastatin has decreased.

134. The Commission, therefore concludes that no serious doubts arise.

J1F (Macrolides and similar types) /Azithromycin - Lithuania and Poland

135. Azithromycin is an azalide, a subclass of macrolide antibiotics. Azithromycin is one of the world's best-selling antibiotics. Drugs based on this molecule are used to treat certain bacterial infections, most often those causing middle ear infections, tonsillitis, throat infections, laryngitis, bronchitis, pneumonia and sinusitis. This molecule is also effective against certain sexually transmitted infectious diseases.

136. Azithromycin belongs to the ATC3 class J1F (Macrolides and similar types). The ATC3 class J1F is part of a broader category of systemic antibacterials (J1), which are classes of semi-synthetically or fully synthetically prepared antibiotics. The J1F comprises drugs against infectious diseases. The Commission has previously considered the ATC3 class J1F as the appropriate definition of the relevant product market.[18]

137. The parties do not consider that products based on azithromycin constitute a separate relevant product market since, in the parties' view, all macrolides compete against each other.

---

17 See e.g. Case COMP/M.1878 – Pfizer/Warner-Lambert, para 26 seq..

18 In case COMP/M.3354 – Sanofi-Synthélabo/Aventis, the Commission considered defining a separate product market for drugs used for dental infections but the market division did not support making such a distinction.

138. In Lithuania, both parties market drugs based on azithromycin. The parties accounted for approximately [50-60]% of total sales of drugs based on this molecule in 2007 (Teva [0-5]%, Barr [50-60]%). On the basis of the ATC3 classification – i.e. J1F-Prescription[19] - the parties accounted for [20-30]% of total sales in Lithuania in 2007 (Teva [0-5]%, Barr [10-20]%). Teva entered the Lithuanian market in […].

139. Even if only drugs based on azithromycin are assumed to belong to the relevant product market, the notified operation is unlikely to give rise to competition concerns in Lithuania because the increment is relatively minor and there are two other providers of drugs based on azithromycin, namely Zentiva with a share of [40-50]% and Novartis with [0-5]%. The merger only marginally strengthens Barr's market position and the merged firm would face competition from Zentiva but also from major pharmaceuticals firm Novartis. The Commission market investigation has not indicated any competition concerns as regards drugs based on azithromycin or other drugs belonging to the ATC class J1F-Prescription in Lithuania.

140. The Commission therefore concludes that the notified transaction does not raise any competition concerns regardless of whether the analysis is made at ATC3 level – as previous Commission cases suggest - or at molecule level. The definition of the product market definition may therefore be left open.

141. In Poland, both parties market drugs based on azithromycin. The parties accounted for approximately [50-60]% of total sales of drugs based on this molecule in 2007 (Teva [0-5]%, Barr [50-60]%). On the basis of the ATC3 classification – i.e. J1F-Prescription[20] - the parties accounted for [10-20]% of total sales in Poland in 2007 (Teva [0-5]%, Barr [10-20]%).

142. Even if only drugs based on azithromycin are assumed to belong to the relevant product market, the notified operation is unlikely to give rise to competition concerns in Poland since the increment is relatively minor and there are 16 other providers of drugs based on azithromycin in Poland. The merger only marginally strengthens Barr's market position and the merged firm would face competition from a large number of companies including major pharmaceutical companies such as Abbot ([10-20]% of total sales), Sanofi-Aventis ([10-20]%) and Pfizer ([10-20]%). The Commission market investigation has not indicated any competition concerns as regards drugs based on azithromycin or other drugs belonging to the ATC class J1F-Prescription in Poland.

143. The Commission therefore concludes that the notified transaction does not raise any competition concerns regardless of whether the analysis is made at ATC3 level – as previous Commission cases suggest - or at molecule level. The definition of the product market definition may therefore be left open.

---

19 In Lithuania, JIF-products are only sold RX, so the distinction OTC/RX does not affect market shares.

20 In Poland, JIF-products are only sold RX, so the distinction OTC/RX does not affect market shares.

N3A – Antiepileptics / Gabapentin - Czech Republic

144. The molecule gabapentin belongs to the ATC3 category N3A – Anti-epileptics, indicated for neuropathic pain and epilepsy, which also includes products for non-epileptic convulsions, e.g. in pregnancy.

145. In the Czech Republic both Teva and Barr (Pliva) market one product based on the molecule gabapentin.

146. The parties argue the market should be defined based on the ATC3 level.

147. In previous decisions,[21] the Commission has left open the question whether the definition of the relevant product market corresponded to the ATC3 class N3A.

148. In the present case the product market definition can also be left open.

149. The combined market share of the based on ATC3 would be below 15%. Based on the molecule gabapentin in the Czech Republic the combined share of the parties would be [30-40]% (Teva [10-20]%; Barr (Pliva) [20-30]%). In the last three years, the market share of Teva has increased while the market share of Barr (Pliva) has declined slightly.

150. Even on the molecule level there are strong competitors with products based on the molecule gabapentin, like Pfizer with a market share of [30-40]%, Apotex with a market share of [10-20]% and Chiesi with a market share of [5-10]%. The unit prices for the parties' products and Pfizer's product are almost identical, while Apotex's and Chiesi's prices are significantly higher. Pfizer's market share is almost as high as the combined share of the parties and there are no indications that price competition would become less intensive after the merger.

151. The Commission therefore concludes that no serious doubts arise.

N5C (Tranquillisers) / Medazepam - Hungary

152. According to the parties, the molecule medazepam is classified in Hungary under the ATC 3 class N5C (tranquillisers). However, it can also be classified under N5B (hypnotics/sedatives). It is a benzodiazepine derivative. It possesses anxiolytic, anticonvulsant, sedative and skeletal muscle relaxant properties.

153. In Hungary Teva markets two products based on the molecule medazepam and Barr markets one.

154. The parties believe that the appropriate product market definition comprises at least all benzodiazepines.

---

21 Case COMP/M.4402 – UCB/Schwarz Pharma, decision of 21. November 2006, para 17.

155. In a previous decision[22], the Commission left open whether the ATC3 class N5B (hypnotics/sedatives) should be further subdivided into comparatively expensive modern hypnotics that have light addictive effect and no residue in the morning (non-benzodiazepines) and older hypnotics which are offered more at a moderate price, but have strong potential for causing addiction and have prolonged effects.

156. The market investigation confirmed that the products in the ATC3 class N5C in Hungary have common therapeutic indications. The investigation also confirmed that in certain cases products belonging to different ATC3 classes, may be used as sedatives instead of N5C products. The market test also indicated that medazepam is not the first choice in this therapeutic class in Hungary.

157. The combined market share of the parties based on ATC3 would be below 15%. Based on benzodiazepines it would also be below 15%. Based on the molecule medazepam, in Hungary the combined share of the parties would be significantly higher. In the last three years, the parties' market shares based on molecules were relatively stable.

158. As there are strong indications that the relevant product market should be defined on a broader basis than the molecule level, it can be concluded that no serious doubts arise.

N6A – Anti-depressants and mood stabilizers / Doxepin - Poland

159. The molecule doxepin belongs to the ATC 3 class N6A - Anti-Depressants and Mood Stabilizers, and the ATC 4 class N6A9 - all other antidepressants. All drugs in the ATC4 class N6A9 are prescription products

160. In Poland, Teva and Barr market one product each based on the molecule doxepin.

161. According to the parties, this ATC4 class comprises all antidepressants that do not fall under other categories. The drugs classified in this class mainly have the same uses as those classified in N6A4 and N6A5, the two latter classes comprising more recently approved antidepressants. The main indication for doxepin is depression. Doxepin can also be used for its sedative, hypnotic or anxiolytic properties when symptoms of insomnia and anxiety are combined with depression. However, older tricyclic drugs like doxepin have been increasingly replaced by newer drugs.

162. The parties believe that the appropriate market definition is the ATC3 class N6A. They admit that the ATC4 classes within the N6A class reflect differences in drug generation and chemical structure and action rather than differences in indications. Therefore the ATC4 classes N6A2 (herbal) and N6A3 (indication for bipolar disorders) might be excluded from the market definition based on ATC3.

22 See case COMP/M.3751 – Novartis/Hexal.

163. In previous decisions[23] the Commission, stated that third parties have not indicated that another market definition than the ATC 3 class N6A should be used as the appropriate market definition.

164. In the present case it can be left open whether the market ought to be defined on the basis of the ATC3 class, the ATC3 class excluding the ATC4 classes N6A2 (herbal) and N6A3 (indication for bipolar disorders) or on the ATC4 class N6A9. There are no indications that the market should be defined at the molecule level.

165. The combined market share of the parties in 2007 based on ATC3 would be just below 15%. In the ATC3 class excluding the ATC4 classes N6A2 (herbal) and N6A3 (indication for bipolar disorders) the combined market share would be only slightly higher. In the ATC4 class N6A9 the combined market share of the parties would be [20-30]% (Teva [10-20]%, Barr [5-10]%). As there was no indication for a market definition based on the molecule level, the higher combined market share of the parties – which was stable in the last three years – in this respect is irrelevant.

166. The Commission therefore concludes that no serious doubts arise.

Markets in the United Kingdom

167. Considering the results of the market investigation in generisised oncology markets and the indications that under certain circumstances relevant product markets were likely to be limited to finished dose pharmaceuticals based on the same molecule, the Commission investigated other horizontal overlaps where both Teva and Barr market finished dose pharmaceuticals based on the same molecule. The molecule-level analysis resulted in a number of such molecule overlaps in the United Kingdom, where the merging parties represent more than 35% of the total sales of drugs based on a particular molecule and the increment exceeds 1%.

168. The following drugs are described below:

(1) M5B (Bone calcium regulators) / Alendronic acid;

(2) J1C (Broad spectrum penicillins) / Amoxillin-clauvulanic acid;

(3) C7A (Beta blocking agents, plain) / Carvedilol;

(4) R6A (Systemic Antihistamines) / Cetirizine;

(5) J2A (Antimycotics for systemic use) / Fluconazole;

(6) C2A (Antihypertensives, non-herbal origin / Moxonidine;

---

23 See case COMP/M.1878 – Pfizer/Warner-Lambert, para 26 seq.The ATC3 class was also used as a basis in COMP/M.3571 – Novartis/Hexal.

(7) A4A (Antiemetics and antinauseants) / Ondansetron;

(8) C10A (Cholesterol and triglyceride regulating preparations) / Pravastatin; and

(9) C3A (Diuretics) / Torasemide.

169. Alendronic acid is a bisphosphonate drug used for osteoporosis and several other bone diseases. Both parties market drugs based on alendronic acid in the United Kingdom. The parties accounted for [30-40]% of total sales in 2007 (TEVA [30-40]% and BARR [0-5]%). Alendronic acid belongs to the ATC3 class M5B – Bone calcium regulators. On the basis of the ATC3 classification, the merging parties accounted for less than 15% of total sales in the United Kingdom in 2007. The parties maintain that 11 competing providers of drugs based on this molecule will remain in the United Kingdom after the merger.

170. Amoxillin-clauvulanic acid is a semi-synthetic penicillin effective against a broad spectrum of gram-positive and gram-negative bacteria. Both parties market drugs based on amoxillin-clauvulanic acid in the United Kingdom. The parties accounted for [40-50]% of total sales in 2007 (TEVA [20-30]% and BARR [10-20]%). Amoxillin-clauvulanic acid belongs to the ATC3 class J1C – Broad spectrum penicillins. On the basis of the ATC3 classification, the merging parties accounted for less than 15% of total sales in the United Kingdom in 2007.[24] The parties maintain that ten competing providers of drugs based on this molecule will remain in the United Kingdom after the merger.

171. Carvedilol is a non-selective beta blocker indicated in the treatment of mild to moderate congestive heart failure. Both parties market drugs based on carvedilol acid in the United Kingdom. The parties accounted for [80-90]% of total sales in 2007 (TEVA [30-40]% and BARR [40-50]%). Carvedilol belongs to the ATC3 class C7A – Beta blocking agents, plain). On the basis of the ATC3 classification, the merging parties accounted for less than 15% of total sales in the United Kingdom in 2007. The parties maintain that five competing providers of drugs based on this molecule will remain in the United Kingdom after the merger.

172. Cetirizine is an antihistamine which treats cold or allergy symptoms such as sneezing, itching, watery eyes, or a runny nose. Both parties market drugs based on cetirizine acid in the United Kingdom. The parties accounted for [30-40]% of total sales in 2007 (Teva [30-40]% and Barr [0-5]%). Cetirizine belongs to the ATC3 class R6A – Systemic Antihistamines. On the basis of the ATC3 classification, the merging parties accounted for less than 15% of total sales in the United Kingdom in 2007.[25] The parties maintain that 13 competing providers of drugs based on this molecule will remain in the United Kingdom after the merger.

---

24 In case COMP/M.1846 Glaxo Wellcome/SmithKline Beecham, the Commission considered that the ATC3 class appeared to be the most appropriate market definition.

25 In case COMP/M.1878 Pfizer/Warner-Lambert, the Commission stated that the market investigation had not indicated that another market definition than the ATC3 class R6A should be used. In case COMP/M.3751 Novartis/Hexal, the Commission considered the merging parties' argument that the

173. Fluconazole is an antifungal drug used in the treatment and prevention of superficial and systemic fungal infections. Both parties market drugs based on cetirizine acid in the United Kingdom. The parties accounted for [40-50]% of total sales in 2007 (Teva [20-30]% and Barr [20-30]%). Fluconazole belongs to the ATC3 class J2A - Antimycotics for systemic use. On the basis of the ATC3 classification, the merging parties accounted for less than 15% of total sales in the United Kingdom in 2007. The parties maintain that 15 competing providers of drugs based on this molecule will remain in the United Kingdom after the merger.

174. Moxonidine is a centrally acting antihypertensive drug used for the treatment of mild to moderate essential hypertension. Both parties market drugs based on moxonidine in the United Kingdom. The parties accounted for [30-40]% of total sales in 2007 (Teva [20-30]% and Barr [10-20]%). Moxonidine belongs to the ATC3 class C2A – Antihypertensives, non-herbal origin. On the basis of the ATC3 classification, the merging parties accounted for less than 15% of total sales in the United Kingdom in 2007.[26] The parties maintain that three competing providers of drugs based on this molecule will remain in the United Kingdom after the merger.

175. Ondansetron is a 5-HT3 receptor antagonist used mainly as an antiemetic to treat nausea and vomiting following chemotherapy. Both parties market drugs based on ondansetron in the United Kingdom. The parties accounted for [40-50]% of total sales in 2007 (Teva [0-5]% and Barr [40-50]%). Ondansetron belongs to the ATC3 class A4A – Antiemetics and antinauseants. On the basis of the ATC3 classification, the merging parties accounted for less than 15% of total sales in the United Kingdom in 2007.[27] The parties maintain that 15 competing providers of drugs based on this molecule will remain in the United Kingdom after the merger.

176. Pravastatin is a member of the drug class of statins, used for lowering cholesterol and preventing cardiovascular disease. Both parties market drugs based on pravastatin in the United Kingdom. The parties accounted for [60-70]% of total sales in 2007 (Teva [60-70]% and Barr [0-5]%). Pravastatin belongs to the ATC3 class C10A - Cholesterol and triglyceride regulating preparations. On the basis of the ATC3 classification, the merging parties accounted for less than 15% of total

---

R6A market should be sub-divided into two separate product markets, one for non-sedative antihistamines and one for sedative antihistamines. The Commission market investigation did not confirm this possible sub-division, since most respondents argued that non-sedative and sedative histamines were substitutable with each other. However, the Commission left the precise market definition open since it did not affect the competitive assessment. See also case COMP/M.4402 UCB/Schwartz, para 13 ff.

26 See e.g. case COMP/M.3853 Solvay/Fournier, decision 18 July 2005, where the ATC3 class C2A was considered as the relevant product market because respondents to the market investigation did not suggest an alternative market definition.

27 In case COMP/M.1846 Glaxo Wellcome/SmithKline Beecham, the Commission considered whether the relevant product market should be extended to include both drugs classified in ATC3 class A4A and ATC3 class A3F – Gastroprokinetics. However, the Commission stated that there were clear indications that such an extension should not be made. The Commission left the market definition open.

sales in the United Kingdom in 2007.[28] The parties maintain that eight competing providers of drugs based on this molecule will remain in the United Kingdom after the merger.

177. Torasemide is a pyridine-sulfonylurea type loop diuretic mainly used in the management of edema associated with congestive heart failure. It is also used at low doses for the management of hypertension. Both parties market drugs based on torasemide in the United Kingdom. The parties accounted for [40-50]% of total sales in 2007 (Teva [20-30]% and Barr [10-20]%). Torasemide belongs to the ATC3 class C3A – Diuretics. On the basis of the ATC3 classification, the merging parties accounted for less than 15% of total sales in the United Kingdom in 2007.[29] The parties maintain that three competing providers of drugs based on this molecule will remain in the United Kingdom after the merger.

178. Referring among other things to the previous Commission decisions, indicating that the ATC3 class is the most appropriate basis for defining the relevant product markets for the products above, the parties consider that defining relevant product markets for these products based on molecule would be too narrow. Such a definition does not sufficiently reflect competition between drugs prescribed for the same indications.

179. However, even if the products in United Kingdom listed above were to be analysed under the presumption that the relevant product markets were limited to drugs based on the same molecule, the parties maintain that these markets – which are all subject to generic competition - should not give cause for competitive concern.

180. Firstly, the parties emphasise the fact that almost all the drugs listed above are sold through retail channels (pharmacies) and not through hospitals. There are two exceptions - fluconazole and ondansetron – where the drugs are sold to hospitals to some extent.

181. Secondly, the parties believe that pharmaceutical markets in the United Kingdom are among the most competitive markets in the EU. Generic penetration is very high in the UK compared to other European countries. Generic pharmaceuticals account for approximately 30% of all pharmaceuticals sales. In the United Kingdom, 80% of prescriptions are written generically by doctors. (that is to say that practitioners normally prescribe drugs using the INN name and not the brand name of a specific drug). Since there is no requirement for prior price approval before a drug can be brought to market, new entrants may penetrate the United Kingdom market faster than in other EU Member States.

---

28 In case COMP/M.1878 Pfizer/Warner-Lambert, the Commission's competitive assessment was based on the ATC3 class C10 since the market investigation had not suggested that any other market definition was more appropriate.

29 In case COMP/M.3354 Sanofi-Synthélabo/Aventis, the Commission assessed the transaction at ATC3 level C3A because no respondent to the Commission market investigation had indicated that the relevant product market should be defined differently.

182. Thirdly, in the United Kingdom, buyers are sophisticated and may exert countervailing buyer power. As regards pharmacies – the most important distribution channel for all the products listed above – demand is more concentrated than in other Member States due to the fact that pharmacy chains are allowed. The largest chains such as Alliance Boots, Lloyds, Rowlands, Superdrug and Sainsbury together account for almost half the pharmacies market.[30] In the hospital segment, the Purchasing and Supply Agency ("PASA") of the National Health Service ("NHS") systematically organises tenders and, in the parties' view, the hospital channel in the United Kingdom is the most competitive in Europe.

183. Finally, the parties allege that pharmaceutical markets in the United Kingdom are dynamic and volatile with a flow of new entrants.[31]

184. The Commission market investigation, has largely confirmed the parties' description of pharmaceuticals markets in the United Kingdom. The number of competing products after the merger varies between three and 15 and for those molecules where there are only two competitors in addition to the merged firm - moxonidine and torasemide – the parties' joint market shares are [30-40]% and [40-50]% respectively. The remaining competitors at molecule level are therefore likely to have the ability to restrain any anti-competitive behaviour from the merged firm. In the other molecule-based markets, there are a larger number of competitors – and some of them have negligible market shares – but buyers of drugs based on these molecules have a wide choice of alternative suppliers to switch to, which makes it unlikely that the merged entity would be able to profitably raise prices after the merger, in particular in view of the fact that the demand-side of the market is relatively concentrated.

185. Moreover, the Commission market investigation has confirmed the importance and efficiency of generic competition in the United Kingdom. According to a recent report from the Office of Fair Trading, doctors are encouraged to write prescriptions using the drugs chemical name, whether or not the product in question is out of patent, unless there are specific clinical reasons not to do so.[32] Generic prescribing (where the drug is prescribed generically and a generic is available has increased from approximately 12% in 1995 to approximately 25% in 2005. In 2005, approximately 70% of prescriptions were written generically (i.e. both in cases where generics are available and where only the originator product is available).[33]

186. According to the same Office of Fair Trading report, the reimbursement scheme successfully encourages generic competition. Prices for the vast majority of generic drugs are set by the Department of Health and are based on a calculation

---

30 Office of Fair Trading 2007 Report into Distribution.

31 "The UK Pharmaceuticals Market", submission by Teva of 26 November 2008.

32 The British National Formulary prints advice about generic prescribing with each drug entry.

33 "The Pharmaceutical Price Regulation Scheme", p. 20, Office of Fair Trading Market Study 2007, available at: http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft885.pdf

that incorporates the volume-weighted average prices charged be generics manufacturers in the United Kingdom. The use of average prices among manufacturers aligns the reimbursement of generic drugs with the market conditions where they are sold. This process maintains the incentives for individual pharmacies to procure generic drugs efficiently, as reimbursement is based on average prices and pharmacies can negotiate with suppliers to secure a better than average price. This scheme has led to strong competitive pressure on generics prices, with prices in the United Kingdom held to be among the lowest in Europe.[34]

187. In addition, several respondents to the market investigation indicated that generic competition functions relatively well also in the hospital sector. One hospital stated that hospitals in the United Kingdom have operated generic substitution for 30 years. Any hospital prescription with a brand name will be substituted to a generic drug by the pharmacist. In tenders, no originator drug will be used unless the price is lower than any generic competition.[35] Another hospital stated that it would choose the generic drug if the indications and licences are the same as the original drug.[36] A third hospital responded that it would always choose the generic drug provided that it meets all quality requirements. This hospital does not tender drugs individually but through a consortium of hospitals.[37]

188. For the reasons set out above – in particular the number of competing suppliers after the merger and the well-functioning system for generic competition via pharmacies as well as via hospitals - the Commission concludes that the notified transaction does not raise any competition concerns as regards the provision in the United Kingdom of drugs based on the molecules alendronic acid, amoxillin-clauvulanic acid, carvedilol, cetirizine, fluconazole, moxonidine, ondansetron, pravastatin and torasemide. The exact definition of the relevant product market – ATC level 3 or molecule level - may be left open since it does not affect the competitive assessment.

---

34 "The Pharmaceutical Price Regulation Scheme", p. 32, Office of Fair Trading Market Study 2007, available at: http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft885.pdf

35 Reply by [*hospital*] of 14 November 2008 to Commission request for information.

36 Reply by Royal Surrey County Hospital NHS Trust of 14 November 2008 to Commission request for information [Non-confidential reply].

37 Reply by North Middlesex University Hospital Trust of 18 November to Commission request for information [Non-confidential reply].

C. APIs – Horizontally Affected Markets and Vertically Affected Markets

RELEVANT PRODUCT MARKETS

189. In previous decisions the Commission has considered that APIs form a separate market which is upstream of the market of the finished pharmaceutical products.[38] The market investigation in this case has confirmed this approach.

RELEVANT GEOGRAPHIC MARKET

190. The Commission has previously considered that the markets for the provision of APIs are wider than the markets for finished dose pharmaceuticals and possibly worldwide. The market investigation in this has confirmed that the relevant geographic market is likely to be worldwide in scope.

HORIZONTALLY AFFECTED MARKETS

191. Both Teva and to a lesser extent, Barr, manufacture APIs. Teva produces […] different APIs, of which […] are sold externally to third parties. Barr manufactures […] APIs of which […] are sold to third parties on the merchant market. […] APIs are produced by both Teva and Barr. Applying the 35% threshold for affected markets which could potentially give rise to competition concerns, the notified transaction results in one horizontally affected market, namely mupirocin.

Mupirocin

192. Mupirocin is an antibiotic used for topical treatment of superficial infections.[39] In 2007, the parties estimated their joint market share to approximately [30-40]% (Teva [10-30]%, Barr [10-20]%). According to the parties, ten providers of Mupirocin are active in Europe and, in addition, there is competition from Chinese producers. Teva expects that more companies will enter this market within the next two years. The parties maintain that they face strong competition from Alpharma ApS and GlaxoSmithKline Worthing.

193. The Commission market investigation has not identified any particular competition concerns concerning mupirocin. Most respondents indicated that they pursue a policy of dual sourcing for APIs. Switching suppliers is relatively easy. While market entry by a company that does not already produce APIs is likely to take several years and require substantial investments to obtain the necessary regulatory approvals (such as GMP-compliance[40]), entry barriers are lower for

38 See for instance case COMP/M.3394 Johnson & Johnson/Johnson & Johnson MSD Europe and case COMP.M.3751 Novartis/Hexal.

39 According to the notification, mupirocin is used in products belonging to the following ATC3-classes: D3A, D6A D7B and R1A.

40 Good Manufacturing Practice or GMP (also referred to as 'cGMP' or 'current Good Manufacturing Practice') is a term that is recognised worldwide for the control and management of manufacturing and quality control testing of pharmaceutical products, medical devices and foods.

existing API-producers that wish to add another API to their existing product portfolio. The time of entry depends on the particular API but entry was estimated at two to three years by several respondents. A number of API-producers indicated that they currently have spare production capacity and that they could increase production without substantial investments, for example by increasing production from five to seven days per week or by moving from two to three shifts.

194. For these reasons, the Commission concludes that the notified transaction does not raise any competition concerns as regards horizontal overlaps for APIs.

VERTICALLY AFFECTED MARKETS

195. Since APIs are important inputs to finished dose pharmaceuticals and both Teva and Barr produce APIs and sell them to third parties (the merchant market), the proposed transaction gives rise to a number of vertically affected markets – i.e. markets where Teva produces the API and Barr is active in the downstream market where the API is used or vice versa.

196. When identifying vertically affected markets which may give rise to serious doubts, the Commission has focused on vertical relationships where:

(i.) either party has a market share of more than 30% in an upstream API-market and the other party has a market share of more than 5% in an ATC3 class containing that particular API, or

(ii.) either party has a market share of more than 25% in a downstream ATC3 class and the other party has market share of more than 5% of a corresponding upstream API-market.[41]

Assessment

197. The parties have identified 28 downstream vertically affected markets where Teva's market share exceeds 30% in the upstream API-market and Barr has a market share of more than 5% in a downstream ATC3 class. Moreover, the parties have identified three downstream vertically affected markets where Barr has a market share of more than 30% in an upstream API-market and Teva has a market share of more than 5% in a downstream ATC3 class. In addition, there are four upstream vertically affected markets where Teva has a market share of more than 25% in downstream ATC3 class and Barr has a market share in an upstream API-market. Finally, the parties have identified 18 upstream vertically affected markets where Barr has a market share of more than 25% in a downstream ATC3 class and Teva has a market share above 5% in an upstream API-market. In total, this results in 53 vertically affected markets. It should be noted that the parties have calculated the market shares for the upstream API markets on the basis of both internal and external sales. If only the merchant market were taken into

41 As is the case for horizontally affected markets, the Commission has used the ATC3 class as a starting point for the demarcation of the downstream product market for finished dose pharmaceuticals.

account, the parties consider it likely that the number of vertically affected markets would be reduced significantly.

198. The parties argue that the notified operation will neither give rise to input foreclosure (i.e. the merged firm raises downstream rivals' costs by restricting their access to an important input), nor to customer foreclosure (i.e. the merged firm forecloses upstream rivals' access to their downstream customers). The parties emphasise the fact that in all but six cases, the API manufactured by one party upstream is different from the API used by the other party in the downstream ATC3 class for finished dose pharmaceuticals. Similarly, in all but five cases, the downstream party in a given ATC3 class does not use the API manufactured by the other party at the upstream level. In these cases there is no direct vertical relationship between the parties.

199. The Commission considers that, in those cases where there is no direct vertical relationship between the parties (because the upstream API is different from the API used in the finished dose pharmaceutical downstream), the producer upstream is unlikely to successfully engage in input foreclosure and the producer downstream is unlikely to successfully engage in customer foreclosure.

200. As regards the downstream affected markets, the Commission considers that the merged firm would in all likelihood lack the ability to engage in input foreclosure because neither Teva, nor Barr supplies their downstream competitors with APIs.[42] Even if the merged firm would stop supplying its customers (or supply them on less favourable terms) it would not affect the markets in which the merged firm is active at the downstream level. In such a scenario input foreclosure would be even more unlikely if the relevant downstream market would be narrower than ATC3 (i.e. ATC4 or molecule level).

201. As regards the upstream affected markets, the Commission considers that the notified operation is unlikely to raise competition concerns because the upstream markets for the provision of APIs are likely to be worldwide whereas the downstream markets for finished dose pharmaceuticals are national. This means that even if the merged firm holds a large share of a given national pharmaceuticals market, this share would represent only a fraction of the total worldwide demand for the API in question. Consequently, even if the merged firm would try to foreclose a competing APIs producer, he would still have numerous alternatives to sell the API in other parts of the world.

202. No respondent to the Commission market investigation has indicated that the notified operation would lead to any vertical competition concerns. Moderate entry barriers for existing API suppliers, the frequent use of dual sourcing for APIs, the current spare capacity in the API-industry and increasing competition from producers in China and India also makes any vertical foreclosure strategy unlikely to succeed.

---

42 Teva states that there is one exception that may have implications in the EEA: Teva supplies […] with […]. However, […] is covered by a patent owned by […]. Teva is the exclusive supplier […] for this API.

203. For these reasons, the Commission concludes that the notified transaction is unlikely to raise any competition concerns as regards vertical foreclosure.

D. Conclusion – Serious Doubts

204. For the reasons set out above, the Commission concludes that the notified operation gives rise to serious doubts as regards its compatibility with the common market and the EEA-agreement for the following markets for the provision of finished dose pharmaceuticals:

Oncology

(1) Paclitaxel in the Czech Republic;

(2) Paclitaxel in Poland;

(3) Calcium folinate in the Czech Republic;

(4) Calcium folinate in Poland;

(5) Carboplatin in the Czech Republic;

(6) Carboplatin in Hungary;

(7) Carboplatin in Slovenia;

(8) Cisplatin in the Czech Republic;

(9) Cisplatin in Hungary;

(10) Cisplatin in the Slovak Republic;

(11) Cisplatin in Slovenia;

(12) Fluorouracil in the Czech Republic;

(13) Methotrexate in the Czech Republic;

(14) Methotrexate in Hungary;

(15) Tomoxifen in Slovakia;

Non-oncology

(16) A11X (Other vitamins) / Riboflavin in Poland;

(17) A11X (Other vitamins / Pyrodoxine in Poland.

V. MODIFICATION TO THE PROPOSED OPERATION

A. Description of the Commitments

205. In order to remove the serious doubts resulting from the proposed transaction, Teva formally submitted commitments to the Commission on 1 December 2008. The commitments were modified on 3 December 2008 and – following the market test – the commitments were modified further on 14 December 2008.

206. In the field of oncology Teva commits to divest:

(1) Barr's calcium folinate business in the Czech Republic;

(2) Teva's carboplatin business in the Czech Republic;

(3) Teva's cisplatin business in the Czech Republic;

(4) Teva's fluorouracil business in the Czech Republic;

(5) Teva's methotrexate business in the Czech Republic;

(6) Teva's paclitaxel business in the Czech Republic;

(7) Teva's carboplatin business in Hungary;

(8) Teva's cisplatin business in Hungary;

(9) Teva's methotrexate business in Hungary;

(10) Teva's calcium folinate business in Poland;

(11) Teva's paclitaxel businesses in Poland;

(12) Teva's cisplatin business in Slovakia;

(13) Teva's tamoxifen business in Slovakia;

(14) Teva's carboplatin business in Slovenia;

(15) Teva's cisplatin business in Slovenia.

In markets outside the field of oncology, Teva commits to divest:

(16) Teva's pyridoxine business in Poland;

(17) Teva's riboflavin business in Poland.

207. The businesses to be divested include: (i.) all tangible and intangible assets (including IPRs), (ii.) all licenses, permits and authorisations, (iii.) all contracts, leases commitments and customer orders, (iv.) all customer, credit and other records (v.) reasonable technical assistance and (vi.) an option to hire members of sales forces necessary to maintain the competitiveness of the divestment businesses.

B. Assessment of the Commitments

208. The market test of the commitments was positive overall but some potential issues concerning the switching of supply to alternative sites were raised. According to respondents, switching could take from one to three years and would require the assistance and good cooperation of the seller during the transitional period. The market test has also given more specific indications regarding the need for sales staff and how their transfer could be facilitated.

209. In order to address the issues raised in the market test, the parties have modified the commitments in the following manner:

– The duration of the transitional supply agreement has been extended to three years and additional guarantees have been included with respect to pricing and order volumes on the one hand and the assistance provided by the seller on the other. Provisions have also been included to allow the Commission to monitor the cooperation from the seller following the divestment until the switching of production is completed.

– Concrete procedures regarding the hiring of personnel have been specified for the oncology products, including the number and type of sales personnel that the Purchaser would have access to in each country.

210. Based on the indications from the market test, the Commission also concluded that the viability of the Divestment Businesses depends to a significant extent on the Purchaser. As the oncology experience of the Purchaser was indicated as a key factor for viability, the parties modified the Commitments to include as a Purchaser criterion for the oncology divestments an existing presence in oncology pharmaceuticals in the EEA. Moreover, given the relatively small size of the respective Divestment Businesses the Commitments were modified to include the criteria of a single Purchaser for the oncology Divestment Businesses and of a single Purchaser for the Non-oncology Divestment Businesses.

211. The Commission therefore considers that the modified commitments are sufficient to eliminate all serious doubts as to the compatibility of the transaction with the common market.

212. These divestitures are accepted on the basis that they will be transferred as a viable going concern to the Purchaser(s) and will thereby remove the entire overlap in the 17 markets listed in paragraph 204 above.

213. In order to ensure that Teva complies with these commitments, the Commission attaches conditions and obligations to this decision. The commitments set out in Sections B and C and Schedules I to XVII of the commitments annexed to the present decision constitute conditions, since only by fulfilling them may the structural change on the relevant markets be achieved so as to eliminate the serious doubts identified by the Commission. The other commitments constitute obligations, since they concern the implementing steps necessary to achieve the structural change intended to eliminate the serious doubts identified by the Commission.

VI. CONCLUSION

214. For the reasons set out above, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and the EEA Agreement, subject to full compliance with: (i.) the conditions in Sections B and C and Schedules I to XVII of the commitments annexed to the present decision, and (ii.) the obligations in the other Sections of the commitments. This decision is adopted in application of Articles 6(1)(b) and 6(2) of Council Regulation (EC) No 139/2004.

215. The full text of these commitments is annexed to this decision. These commitments form an integral part of this decision.

For the Commission,

[*signed*]
Vladimir ŠPIDLA
Member of the Commission

Case M. 5295 – Teva / Barr
COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2), of Council Regulation (EEC) No. 139/2004 as amended (the "***Merger Regulation***"), Teva Pharmaceutical Industries Limited ("***Teva***") hereby provide the following Commitments (the "***Commitments***") in order to enable the European Commission (the "***Commission***") to declare the acquisition of Barr Pharmaceuticals Inc. ("***Barr"***) (collectively the "***Parties"***), compatible with the common 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 (EEC) No 139/2004 and under Commission Regulation (EC) No 447/98.

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 (EEC) No 139/2004.

Barr: Barr Pharmaceutical Inc. is a corporation incorporated under the laws of Delaware (U.S.A), with its registered office at 225 Summit Avenue Montvale, NJ 07645, U.S.A. and registered with the Commercial/Company Register under number SRV 030845130 - 3726561 File.

Closing: the transfer of the legal title of the Divestment Business to the Purchaser.

Divestment Business: the business or businesses as defined in the 17 attached Schedules that Teva commits to divest.

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 sell the Divestment Business to a Purchaser […].

Effective Date: the date of adoption of the Decision.

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

Hold Separate Manager: the person appointed by Teva for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

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.

Personnel: all personnel currently employed by the Parties and working for each Divestiture Business, including staff seconded to the Divestiture Business.

Purchaser: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Teva: Teva Pharmaceutical Industries 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 Commercial/Company Register at [•] under number [•].

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

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

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 as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 19. To carry out the divestiture, Teva commits to find a purchaser and to enter into a final binding agreement for the sale of the Divestment Business within the First Divestiture Period. If Teva has not entered 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 27 in the Trustee Divestiture Period.

2. Teva shall be deemed to have complied with this commitment if, by the end of the 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 19 and if the closing of the sale of the Divestment Business takes place within a period not exceeding […] after the approval of the purchaser and the terms of sale by the Commission.

3. 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.

Structure and definition of the Divestment Business

4. The Divestment Businesses consist in

i. Barr's calcium folinate business in the Czech Republic;

ii. Teva's carboplatin business in the Czech Republic;

iii. Teva's cisplatin business in the Czech Republic;

iv. Teva's fluorouracil business in the Czech Republic;

v. Teva's methotrexate business in the Czech Republic;

vi. Teva's paclitaxel business in the Czech Republic;

vii. Teva's carboplatin business in Hungary;

viii. Teva's cisplatin business in Hungary;

ix. Teva's methotrexate business in Hungary;

x. Teva's calcium folinate business in Poland;

xi. Teva's paclitaxel businesses in Poland;

xii. Teva's cisplatin business in Slovakia;

xiii. Teva's tamoxifen business in Slovakia;

xiv. Teva's carboplatin business in Slovenia;

xv. Teva's cisplatin business in Slovenia;

xvi. Teva's pyridoxine business in Poland;

xvii. Teva's riboflavin business in Poland.

Businesses i to xv will be transferred altogether to a single Purchaser; Businesses xvi and xvii will also be transferred altogether to a single Purchaser; it being understood that the same Purchaser may acquire all Businesses. These Businesses are described in more detail in the attached Schedules and include:

(a) 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; including in particular the marketing authorizations and the information contained in the relevant registration dossiers, which contain 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: Nonclinical Study Reports;
- Module 5: Clinical Study Reports;

(b) all licenses, permits and authorizations issued by any governmental organization for the benefit of the Divestment Business;

(c) all contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business (items referred to under (a)-(c) hereinafter collectively referred to as "***Assets***");

(d) for Business i, a best effort obligation to obtain the assignment of the contract manufacturing agreement entered into by Barr for the manufacture of the product,

(e) the benefit, for a period of three years, on a reasonable cost plus basis to be agreed with the Purchaser, of a supply arrangement for the relevant products and/or reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the relevant Divestiture Businesses, as detailed in the Schedules,

(f) for Businesses i to xv, an option for the Purchaser to hire the following Personnel of the Parties :

(i) for Poland, […] sales representatives and […] contract manager;

(ii) for the Czech Republic, […] sales representatives and […] contract manager;

(iii) for each of Slovakia and Hungary, […] sales representatives and […] contract manager;

(iv) for Slovenia, […] sales representative and […] contract manager.

5. For the avoidance of doubt, the Divestment Businesses shall, *inter alia*, not include:

(a) any manufacturing facilities of the Parties;

(b) intellectual property other than intellectual property predominantly relating to the Divestment Businesses that would not be covered by paragraph 4 (a);

(c) the Teva and Barr names and logo in any form;

(d) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that a Purchaser shall obtain a copy of the same and shall be permitted access to the original of such books and records upon reasonable request during normal business hours; and

(e) general books of account and books of original entry that comprise the Parties' or an Affiliated Undertaking's permanent accounting or tax records.

SECTION C. RELATED COMMITMENTS

Preservation of Viability, Marketability and Competitiveness

6. From the Effective Date until Closing, the Parties 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.

7. In particular the Parties undertake:

(a) not to carry out any act upon their own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) to make available sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans and maintain the marketing and sales efforts devoted to the Divestment Business at their current level.

Hold-separate obligations of Parties

8. Until Closing, Teva shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable entity separate from the businesses retained by the Parties. Teva shall appoint a Hold Separate Manager who shall be responsible for the management of the Divestment Business, under the supervision of the Monitoring Trustee. The Hold Separate Manager shall manage the Divestment Business independently and in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by the Parties.

9. Teva commits, from the Effective Date until Closing, to the maximum extent possible to keep the Divestment Business separate from the businesses it is retaining and to ensure that Personnel of the Divestment Business – including the Hold Separate Manager – have no involvement in any business retained and vice versa. Teva shall also ensure that the Personnel does not report to any individual outside the Divestment Business.

Ring-Fencing

10 Teva shall implement all necessary measures to ensure that it does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Business. In particular, the participation of the Divestment Businesses in a central information technology network shall be restricted to the extent possible, without compromising the viability of the Divestment Business. Teva may obtain information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or whose disclosure to Teva is required by law.

Personnel

11. The Parties shall use their reasonable best efforts to the extent permitted by law, to facilitate the transfer to the relevant Purchaser (if possible by collective transfer) of any of the Personnel listed under paragraph 4(f) above desired by such Purchaser (collectively the "***Employees***"). The Parties shall provide relevant contact details for the Employees as desired by the Purchaser, or otherwise make the Employees available to the Purchaser subject to compliance with applicable laws. Prior to Closing, the Parties shall facilitate interviews between such Personnel and the Purchaser(s), shall not discourage such employee from participating in such interviews, and shall not interfere in employment negotiations between such Personnel and the Purchaser(s).

12. With respect to each Employee who receives an offer of employment from the Purchaser (conditional on or following the Closing), the Parties shall do the following: (i) not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Employee from being employed by the Purchaser(s), and not offer any incentive to the Employee to decline employment with the Purchaser; (ii) if the Employee accepts such offer of employment from the Purchaser(s), the Parties shall cooperate with the Purchaser(s) in effecting transfer of the Employee to the employ of the Purchaser(s) and the Parties shall amend or waive the relevant provisions of employment agreements, stock options and

other employee benefit arrangements of Personnel so that they do not suffer adverse consequences as a result of their negotiations with, or acceptance of an offer from, the Purchaser.

13. Each of the Parties undertakes, subject to customary limitations, that in relation to Personnel who are hired by (as opposed to seconded to) the Purchaser(s), it will not solicit and will procure that its Affiliated Undertakings do not solicit, such Personnel for a period of 12 months after Closing or after the date of termination of employment of such Personnel by the Parties (as applicable).

Due Diligence

14. 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.

Reporting

15. Teva shall submit written reports in English on potential purchasers of the Divestment Business 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).

16. Teva shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of an information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

SECTION D. THE PURCHASER

17. 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) be a pharmaceutical company having the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors;

    (c) 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, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business (the before-mentioned criteria for the purchaser hereafter the "***Purchaser Requirements***");

    (d) for Businesses i to xv, be a pharmaceutical company active in the oncology field in at least one country of the EEA.

18. The final binding sale and purchase agreement shall be conditional on the Commission's approval. When Teva has reached an agreement with a 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 Divestment Business is being sold in a manner consistent with the Commitments. For the

approval, the Commission shall verify that the purchaser fulfils the Purchaser Requirements and that the Divestment Business is being sold 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

I. Appointment Procedure

19. 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 divestment agreement […] 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.

20. The 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 sale value of the Divestment Business, the fee shall also be linked to a divestiture within the Trustee Divestiture Period.

Proposal by the Parties

21. No later than […] 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 […] 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 20 and shall include:

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

    (b) the outline of a work plan which describes how the 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

22. 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 […] of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by the Parties

23. If all the proposed Trustees are rejected, Teva shall submit the names of at least two more individuals or institutions within […] of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 19 and 22.

Trustee nominated by the Commission

24. 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.

II. Functions of the Trustee

25. The 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 Trustee or Teva, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

26. 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:

(a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Parties, in accordance with paragraphs 7 to 9 of the Commitments;

(b) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 8 of the Commitments;

(c) (i) in consultation with Teva, determine all necessary measures to ensure that Teva does not after the effective date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Business, in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business, and (ii) decide whether such information may be disclosed to Teva as the disclosure is reasonably necessary to allow Teva to carry out the divestiture or as the disclosure is required by law;

(d) monitor the splitting of assets between the Divestment Business and Teva or Affiliated Undertakings;

(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, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

(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 Divestment Business in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process;

(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. The report shall cover the operation and management of the Divestment Business so that the Commission can assess whether the business is held in a manner consistent with the Commitments and 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) within […] after receipt of the documented proposal referred to in paragraph 18, submit to the Commission a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale 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

27. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell […] price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding divestment agreement in accordance with the procedure laid down in paragraph 18. The Divestiture Trustee shall include in the divestment agreement such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the divestment such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of Teva, subject to the Parties' unconditional obligation to divest […] in the Trustee Divestiture Period.

28. 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.

III. Duties and obligations of the Parties

29. 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 Teva's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Teva and the Divestment Business shall provide the Trustee upon request with copies of any document. Teva and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

30. Teva shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. Teva shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. 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.

31. Teva shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, Teva shall cause the documents required for effecting the sale and the Closing to be duly executed.

32. 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 Trustee, its employees, agents or advisors.

33. 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 32 shall apply mutatis mutandis. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Teva during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

IV. Replacement, discharge and reappointment of the Trustee

34. 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.

35. If the Trustee is removed according to paragraph 34, the 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 20-25.

36. Beside the removal according to paragraph 34, 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 Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

SECTION F. THE REVIEW CLAUSE

37. 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 […] before the expiry of that period, showing good cause. Only in exceptional circumstances shall Teva be entitled to request an extension within the […] of any period.

……

On behalf of Teva

Name:

Title:

SCHEDULE - (I)

BARR PHARMACEUTICAL'S CALCIUM FOLINATE BASED PRODUCT

LEUCOVORIN - CZECH REPUBLIC

1. Divestment Business consists of Barr Pharmaceutical's (or an Affiliated Undertaking) rights, title and interests in Leucovorin in the Czech Republic (currently marketed under the brand name Leucovorin CA Lach) including the right to develop, manufacture and use Leucovorin with a view to its sale in any form and for any indication whatsoever in the Czech Republic. Leucovorin is an adjuvant used in cancer chemotherapy. For the avoidance of doubt, Divestment Business does not contain any rights to sell Leucovorin outside the Czech Republic.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in the Czech Republic;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, exclusive, and royalty free license to use the Leucovorin CA Lach trademark in the Czech Republic;

   (d) the transfer of the marketing authorization for Leucovorin in the Czech Republic including all relevant dossiers relating to the current and/or pending marketing authorizations available to Barr;

   (e) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Czech Republic; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(e) hereinafter collectively referred to as "Assets of Divestment Business").

3. Teva commits on behalf of Barr to make its best efforts to obtain the assignment of the contract manufacturing agreement entered into between Pliva (an Affiliated Undertaking of Barr) and […] or at the option of the Purchaser, Barr shall enter into a supply

arrangement with the Purchaser for the non-exclusive supply of Leucovorin in the Czech Republic, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Barr to the Purchaser of Leucovorin in the Czech Republic for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva commits on behalf of Barr to make its best efforts to cooperate with the Purchaser for the transfer of the production of Calcium folinate to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva commits on behalf of Barr to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Barr shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Leucovorin in the Czech Republic for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Barr provide technical assistance to the Purchaser expeditiously. Barr 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Ownership or use of Leucovorin CA Lach trademark outside of the Czech Republic;

    (c) Raw materials;

    (d) Any research and development, clinical data and studies or intellectual property relating to Leucovorin after Closing;

    (e) All marketing authorizations currently held by the Parties outside the Czech Republic for Leucovorin;

    (f) Monies owed to the Parties by customers for the purchase of Leucovorin, and monies owed by the Parties to suppliers for materials used in the productions of Leucovorin.

SCHEDULE - (II)

TEVA PHARMACEUTICAL INDUSTRIES' CARBOPLATIN BASED PRODUCTS - CZECH REPUBLIC

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its carboplatin product ("***Carboplatin***") in the Czech Republic (currently marketed under the brand name Carboplatin Teva) including the right to develop, manufacture and use Carboplatin with a view to its sale in any form and for any indication whatsoever in the Czech Republic. Carboplatin is a chemotherapy drug derived from Cisplatin. For the avoidance of doubt, Divestment Business does not contain any rights to sell Carboplatin outside the Czech Republic.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in the Czech Republic;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) the transfer of the marketing authorization for Carboplatin in the Czech Republic including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (d) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Czech Republic; including in particular the information contained in the registration dossier, 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;

      (items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Carboplatin in the Czech Republic, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Carboplatin in the Czech Republic or a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Carboplatin to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Carboplatin in the Czech Republic or a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Raw materials;

    (c) Any research and development, clinical data and studies or intellectual property relating to Carboplatin after Closing;

    (d) All marketing authorizations currently held by the Parties outside the Czech Republic for Carboplatin;

    (e) Monies owed to the Parties by customers for the purchase of Carboplatin, and monies owed by the Parties to suppliers for materials used in the productions of Carboplatin.

SCHEDULE - (III)

TEVA PHARMACEUTICAL INDUSTRIES' CISPLATIN BASED PRODUCTS - CZECH REPUBLIC

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its cisplatin product ("***Cisplatin***") in the Czech Republic (currently marketed under the brand name Cisplatin Teva) including the right to develop, manufacture and use Cisplatin with a view to its sale in any form and for any indication whatsoever in the Czech Republic. Cisplatin is a platinum-based chemotherapy drug used to treat various types of cancers. For the avoidance of doubt, Divestment Business does not contain any rights to sell Cisplatin outside the Czech Republic.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in the Czech Republic;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) the transfer of the marketing authorization for Cisplatin in the Czech Republic including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (d) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Czech Republic; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Cisplatin in the Czech Republic, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Cisplatin in the Czech Republic for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Cisplatin to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Cisplatin in the Czech Republic for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Raw materials;

    (c) Any research and development, clinical data and studies or intellectual property relating to Cisplatin after Closing;

    (d) All marketing authorizations currently held by the Parties outside the Czech Republic for Cisplatin;

    (e) Monies owed to the Parties by customers for the purchase of Cisplatin, and monies owed by the Parties to suppliers for materials used in the productions of Cisplatin.

SCHEDULE - (IV)

TEVA PHARMACEUTICAL INDUSTRIES' FLUOROURACIL BASED PRODUCTS

FLUOROURACIL TEVA - CZECH REPUBLIC

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its fluorouracil product ("***Fluorouracil***") in the Czech Republic (currently marketed under the brand name Fluorouracil Teva) including the right to develop, manufacture and use Fluorouracil with a view to its sale in any form and for any indication whatsoever in the Czech Republic. Fluorouracil is a pyrimidine analog, which is used as a drug in the treatment of cancer. For the avoidance of doubt, Divestment Business does not contain any rights to sell Fluorouracil outside the Czech Republic.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in the Czech Republic;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) the transfer of the marketing authorization for Fluorouracil in the Czech Republic including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (d) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Czech Republic; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Fluorouracil in the Czech Republic, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of

Fluorouracil in the Czech Republic for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Fluorouracil to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Fluorouracil in the Czech Republic for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Raw materials;

    (c) Any research and development, clinical data and studies or intellectual property relating to Fluorouracil after Closing;

    (d) All marketing authorizations currently held by the Parties outside the Czech Republic for Fluorouracil;

    (e) Monies owed to the Parties by customers for the purchase of Fluorouracil, and monies owed by the Parties to suppliers for materials used in the productions of Fluorouracil.

SCHEDULE - (V)

TEVA PHARMACEUTICAL INDUSTRIES' METHOTREXATE BASED PRODUCTS - CZECH REPUBLIC

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its methotrexate product ("***Methotrexate***") in the Czech Republic (currently marketed under the brand name Methotrexate Teva) including the right to develop, manufacture and use Methotrexate with a view to its sale in any form and for any indication whatsoever in the Czech Republic. Methotrexate is an antimetabolite and antifolate drug used in treatment of cancer and autoimmune diseases. For the avoidance of doubt, Divestment Business does not contain any rights to sell Methotrexate outside the Czech Republic.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in the Czech Republic;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) the transfer of the marketing authorization for Methotrexate in the Czech Republic including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (d) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Czech Republic; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Methotrexate in the Czech Republic, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Methotrexate in the Czech Republic for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Methotrexate to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Methotrexate in the Czech Republic for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Raw materials;

    (c) Any research and development, clinical data and studies or intellectual property relating to Methotrexate after Closing;

    (d) All marketing authorizations currently held by the Parties outside the Czech Republic for Methotrexate;

    (e) Monies owed to the Parties by customers for the purchase of Methotrexate, and monies owed by the Parties to suppliers for materials used in the productions of Methotrexate.

SCHEDULE - (VI)

TEVA PHARMACEUTICAL INDUSTRIES' PACLITAXEL BASED PRODUCTS

PAXENE, PACLITAXEL TEVA AND ONXOL - CZECH REPUBLIC

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its paclitaxel products ("***Paclitaxel***") in the Czech Republic (currently marketed under the brand names Paxene, Paclitaxel Teva and Onxol) including the right to develop, manufacture and use Paclitaxel with a view to its sale in any form and for any indication whatsoever in the Czech Republic. Paclitaxel is a mitotic inhibitor used in cancer chemotherapy. For the avoidance of doubt, Divestment Business does not contain any rights to sell Paclitaxel outside the Czech Republic.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in the Czech Republic;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, exclusive, and royalty free license to use the Paxene, Paclitaxel Teva and Onxol trademarks in the Czech Republic;

   (d) the transfer of the marketing authorization for Paclitaxel in the Czech Republic including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (e) an irrevocable, exclusive, assignable, sub-licensable, exclusive, and royalty free license for the transfer of 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 Czech Republic; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(e) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Paclitaxel in the Czech Republic, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Paclitaxel in the Czech Republic for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Paclitaxel to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Paclitaxel in the Czech Republic for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Ownership or use of Paxene, Paclitaxel Teva and Onxol trademarks outside of the Czech Republic;

    (c) Raw materials;

    (d) Any research and development, clinical data and studies or intellectual property relating to Paclitaxel after Closing;

    (e) All marketing authorizations currently held by the Parties outside the Czech Republic for Paclitaxel;

    (f) Monies owed to the Parties by customers for the purchase of Paclitaxel, and monies owed by the Parties to suppliers for materials used in the productions of Paclitaxel.

SCHEDULE - (VII)

TEVA PHARMACEUTICAL INDUSTRIES' CARBOPLATIN BASED PRODUCT

CARBOPLATIN-TEVA - HUNGARY

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its carboplatin product ("***Carboplatin***") in Hungary (currently marketed under the brand name Carboplatin-Teva) including the right to develop, manufacture and use Carboplatin with a view to its sale in any form and for any indication whatsoever in Hungary. Carboplatin is a chemotherapy drug derived from Cisplatin. For the avoidance of doubt, Divestment Business does not contain any rights to sell Carboplatin outside Hungary.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in Hungary;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) the transfer of the marketing authorization for Carboplatin in Hungary including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (d) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Hungary; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Carboplatin in Hungary, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of

Carboplatin in Hungary for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Carboplatin to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Carboplatin in Hungary for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Raw materials;

    (c) Any research and development, clinical data and studies or intellectual property relating to Carboplatin after Closing;

    (d) All marketing authorizations currently held by the Parties outside Hungary for Carboplatin;

    (e) Monies owed to the Parties by customers for the purchase of Carboplatin, and monies owed by the Parties to suppliers for materials used in the productions of Carboplatin.

SCHEDULE - (VIII)

TEVA PHARMACEUTICAL INDUSTRIES' CISPLATIN BASED PRODUCTS - HUNGARY

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its cisplatin product ("***Cisplatin***") in Hungary (currently marketed under the brand name Cisplatin Teva) including the right to develop, manufacture and use Cisplatin with a view to its sale in any form and for any indication whatsoever in Hungary. Cisplatin is a platinum-based chemotherapy drug used to treat various types of cancers. For the avoidance of doubt, Divestment Business does not contain any rights to sell Cisplatin outside Hungary.

2. Divestment Business includes:

(a) the sale of existing product inventory, sales and promotional material in Hungary;

(b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

(c) the transfer of the marketing authorization for Cisplatin in Hungary including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

(d) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Hungary; including in particular the information contained in the registration dossier, 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;

(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Cisplatin in Hungary, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Cisplatin in Hungary for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Cisplatin to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Cisplatin in Hungary for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Raw materials;

    (c) Any research and development, clinical data and studies or intellectual property relating to Cisplatin after Closing;

    (d) All marketing authorizations currently held by the Parties outside Hungary for Cisplatin;

    (e) Monies owed to the Parties by customers for the purchase of Cisplatin, and monies owed by the Parties to suppliers for materials used in the productions of Cisplatin.

SCHEDULE - (IX)

TEVA PHARMACEUTICAL INDUSTRIES' METHOTREXATE BASED PRODUCTS

METHOTREXAT-TEVA - HUNGARY

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its methotrexate product ("***Methotrexate***") in Hungary (currently marketed under the brand name Methotrexat-Teva) including the right to develop, manufacture and use Methotrexate with a view to its sale in any form and for any indication whatsoever in Hungary. Methotrexate is an antimetabolite and antifolate drug used in treatment of cancer and autoimmune diseases. For the avoidance of doubt, Divestment Business does not contain any rights to sell Methotrexate outside Hungary.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in Hungary;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) the transfer of the marketing authorization for Methotrexate in Hungary including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (d) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Hungary; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Methotrexate in Hungary, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of

Methotrexate in Hungary for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Methotrexate to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Methotrexate in Hungary for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Raw materials;

    (c) Any research and development, clinical data and studies or intellectual property relating to Methotrexate after Closing;

    (d) All marketing authorizations currently held by the Parties outside Hungary for Methotrexate;

    (e) Monies owed to the Parties by customers for the purchase of Methotrexate, and monies owed by the Parties to suppliers for materials used in the productions of Methotrexate.

SCHEDULE - (X)

TEVA PHARMACEUTICAL INDUSTRIES'S CALCIUM FOLINATE BASED PRODUCT

RESCUVOLIN - POLAND

1. Divestment Business consists of Teva Pharmaceutical Industries (or an Affiliated Undertaking) rights, title and interests in its calcium folinate product ("***Calcium folinate***") in Poland (currently marketed under the brand name Rescuvolin) including the right to develop, manufacture and use Calcium folinate with a view to its sale in any form and for any indication whatsoever in Poland. Calcium folinate is an adjuvant used in cancer chemotherapy. For the avoidance of doubt, Divestment Business does not contain any rights to sell Calcium folinate outside Poland.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in Poland;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, exclusive, and royalty free license to use the Rescuvolin trademark in Poland;

   (d) the transfer of the marketing authorization for Calcium folinate in Poland including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (e) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Poland; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(e) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Calcium folinate in Poland, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the reasonable continuous supply by Teva to the Purchaser of Calcium folinate in Poland for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Calcium folinate to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Calcium folinate in Poland for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Ownership or use of Rescuvolin trademark outside of Poland;

    (c) Raw materials;

    (d) Any research and development, clinical data and studies or intellectual property relating to Calcium folinate after Closing;

    (e) All marketing authorizations currently held by the Parties outside Poland for Calcium folinate;

    (f) Monies owed to the Parties by customers for the purchase of Calcium folinate, and monies owed by the Parties to suppliers for materials used in the productions of Calcium folinate.

SCHEDULE - (XI)

TEVA PHARMACEUTICAL INDUSTRIES' PACLITAXEL BASED PRODUCTS

PACLITAXIN AND PAXENE - POLAND

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its paclitaxel products ("***Paclitaxel***") in Poland (currently marketed under the brand names Paclitaxin and Paxene) including the right to develop, manufacture and use Paclitaxel with a view to its sale in any form and for any indication whatsoever in Poland. Paclitaxel is a mitotic inhibitor used in cancer chemotherapy. For the avoidance of doubt, Divestment Business does not contain any rights to sell Paclitaxel outside Poland.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in Poland;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, exclusive, and royalty free license to use the Paclitaxin and Paxene trademarks in Poland;

   (d) the transfer of the marketing authorization for Paclitaxel in Poland including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (e) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Poland; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(e) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Paclitaxel in Poland, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Paclitaxel in Poland for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Paclitaxel to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Paclitaxel in Poland for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Ownership or use of Paclitaxin and Paxene trademarks outside of Poland;

    (c) Raw materials;

    (d) Any research and development, clinical data and studies or intellectual property relating to Paclitaxel after Closing;

    (e) All marketing authorizations currently held by the Parties outside Poland for Paclitaxel;

    (f) Monies owed to the Parties by customers for the purchase of Paclitaxel, and monies owed by the Parties to suppliers for materials used in the productions of Paclitaxel.

SCHEDULE - (XII)

TEVA PHARMACEUTICAL INDUSTRIES' CISPLATIN BASED PRODUCTS - SLOVAKIA

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its cisplatin product ("***Cisplatin***") in Slovakia (currently marketed under the brand name Cisplatin Teva) including the right to develop, manufacture and use Cisplatin with a view to its sale in any form and for any indication whatsoever in Slovakia. Cisplatin is a platinum-based chemotherapy drug used to treat various types of cancers. For the avoidance of doubt, Divestment Business does not contain any rights to sell Cisplatin outside Slovakia.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in Slovakia;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) the transfer of the marketing authorization for Cisplatin in Slovakia including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (d) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Slovakia; including in particular the information contained in the registration dossier, 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;

      (items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Cisplatin in Slovakia, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Cisplatin in Slovakia for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Cisplatin to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Cisplatin in Slovakia for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Raw materials;

    (c) Any research and development, clinical data and studies or intellectual property relating to Cisplatin after Closing;

    (d) All marketing authorizations currently held by the Parties outside Slovakia for Cisplatin;

    (e) Monies owed to the Parties by customers for the purchase of Cisplatin, and monies owed by the Parties to suppliers for materials used in the productions of Cisplatin.

SCHEDULE - (XIII)

TEVA PHARMACEUTICAL INDUSTRIES'S TAMOXIFEN BASED PRODUCT

TAMOPLEX - SLOVAKIA

1. Divestment Business consists of Teva Pharmaceutical Industries (or an Affiliated Undertaking) rights, title and interests in its tamoxifen product ("***Tamoxifen***") in Slovakia (currently marketed under the brand name Tamoplex) including the right to develop, manufacture and use Tamoxifen with a view to its sale in any form and for any indication whatsoever in Slovakia. Tamoxifen is an orally active selective estrogen receptor modulator that is used in the treatment of breast cancer. For the avoidance of doubt, Divestment Business does not contain any rights to sell Tamoxifen outside Slovakia.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in Slovakia;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, exclusive, and royalty free license to use the Tamoplex trademark in Slovakia;

   (d) the transfer of the marketing authorization for Tamoxifen in Slovakia including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (e) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Slovakia; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(e) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Tamoxifen in Slovakia, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Tamoxifen in Slovakia for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Tamoxifen to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Tamoxifen in Slovakia for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Ownership or use of Tamoplex trademark outside of Slovakia;

    (c) Raw materials;

    (d) Any research and development, clinical data and studies or intellectual property relating to Tamoxifen after Closing;

    (e) All marketing authorizations currently held by the Parties outside Slovakia for Tamoxifen;

    (f) Monies owed to the Parties by customers for the purchase of Tamoxifen, and monies owed by the Parties to suppliers for materials used in the productions of Tamoxifen.

SCHEDULE - (XIV)

TEVA PHARMACEUTICAL INDUSTRIES' CARBOPLATIN BASED PRODUCTS

CARBOSIN 152 - SLOVENIA

1. Divestment Business consists of Teva Pharmaceutical industries' (or an Affiliated Undertaking) rights, title and interests in its Carboplatin product ("***Carboplatin***") in Slovenia (currently marketed under the brand name Carbosin 150) including the right to develop, manufacture and use Carboplatin with a view to its sale in any form and for any indication whatsoever in Slovenia. Carboplatin is a chemotherapy drug derived from Cisplatin. For the avoidance of doubt, Divestment Business does not contain any rights to sell Carboplatin outside Slovenia.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in Slovenia;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, exclusive, and royalty free license to use the Carbosin 150 trademark in Slovenia;

   (d) the transfer of the marketing authorization for Carboplatin in Slovenia including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (e) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Slovenia; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(e) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Carboplatin in Slovenia, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Carboplatin in Slovenia for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Carboplatin to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Carboplatin in Slovenia for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Ownership or use of Carbosin 150 trademark outside of Slovenia;

    (c) Raw materials;

    (d) Any research and development, clinical data and studies or intellectual property relating to Carboplatin after Closing;

    (e) All marketing authorizations currently held by the Parties outside Slovenia for Carboplatin;

    (f) Monies owed to the Parties by customers for the purchase of Carboplatin, and monies owed by the Parties to suppliers for materials used in the productions of Carboplatin.

SCHEDULE - (XV)

TEVA PHARMACEUTICAL INDUSTRIES' CISPLATIN BASED PRODUCTS

PLATOSIN - SLOVENIA

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its cisplatin product ("***Cisplatin***") in Slovenia (currently marketed under the brand name Platosin) including the right to develop, manufacture and use Cisplatin with a view to its sale in any form and for any indication whatsoever in Slovenia. Cisplatin is a platinum-based chemotherapy drug used to treat various types of cancers. For the avoidance of doubt, Divestment Business does not contain any rights to sell Cisplatin outside Slovenia.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in Slovenia;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, exclusive, and royalty free license to use the Platosin trademark in Slovenia;

   (d) the transfer of the marketing authorization for Cisplatin in Slovenia including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (e) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Slovenia; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(e) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Cisplatin in Slovenia, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Cisplatin in Slovenia for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Cisplatin to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Cisplatin in Slovenia for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Purchaser will be given an option to hire the Personnel listed in paragraph 4(f) of the Commitments.

10. The Divestment Business shall not include:

    (a) Any manufacturing facility;

    (b) Ownership or use of Platosin trademark outside of Slovenia;

    (c) Raw materials;

    (d) Any research and development, clinical data and studies or intellectual property relating to Cisplatin after Closing;

    (e) All marketing authorizations currently held by the Parties outside Slovenia for Cisplatin;

    (f) Monies owed to the Parties by customers for the purchase of Cisplatin, and monies owed by the Parties to suppliers for materials used in the productions of Cisplatin.

SCHEDULE - (XVI)

TEVA PHARMACEUTICAL INDUSTRIES' PYRIDOXINE BASED PRODUCTS

VITAMIN B6 - POLAND

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its pyridoxine product ("***Pyridoxine***") in Poland (currently marketed under the brand name Vitamin B6) including the right to develop, manufacture and use Pyridoxine with a view to its sale in any form and for any indication whatsoever in Poland. Pyridoxine is a drug that helps to assist in the balancing of sodium and potassium as well as promoting red blood cell production. For the avoidance of doubt, Divestment Business does not contain any rights to sell Pyridoxine outside Poland.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in Poland;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, exclusive, and royalty free license to use the Vitamin B6 trademark in Poland;

   (d) the transfer of the marketing authorization for Pyridoxine in Poland including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (e) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Poland; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(e) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Pyridoxine in Poland, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Pyridoxine in Poland for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Pyridoxine to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Pyridoxine in Poland for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Divestment Business shall not include:

   (a) Any manufacturing facility;

   (b) Ownership or use of Vitamin B6 trademark outside of Poland;

   (c) Raw materials;

   (d) Any research and development, clinical data and studies or intellectual property relating to Pyridoxine after Closing;

   (e) All marketing authorizations currently held by the Parties outside Poland for Pyridoxine;

   (f) Monies owed to the Parties by customers for the purchase of Pyridoxine, and monies owed by the Parties to suppliers for materials used in the productions of Pyridoxine.

SCHEDULE - (XVII)

TEVA PHARMACEUTICAL INDUSTRIES' RIBOFLAVIN BASED PRODUCTS

VITAMIN B2 - POLAND

1. Divestment Business consists of Teva Pharmaceutical Industries' (or an Affiliated Undertaking) rights, title and interests in its riboflavin product ("***Riboflavin***") in Poland (currently marketed under the brand name Vitamin B2) including the right to develop, manufacture and use Riboflavin with a view to its sale in any form and for any indication whatsoever in Poland. Riboflavin is an easily absorbed micronutrient with a key role in maintaining health in humans and animals. For the avoidance of doubt, Divestment Business does not contain any rights to sell Riboflavin outside Poland.

2. Divestment Business includes:

   (a) the sale of existing product inventory, sales and promotional material in Poland;

   (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;

   (c) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, exclusive, and royalty free license to use the Vitamin B2 trademark in Poland;

   (d) the transfer of the marketing authorization for Riboflavin in Poland including all relevant dossiers relating to the current and/or pending marketing authorizations available to Teva;

   (e) an irrevocable, exclusive, assignable, sub-licensable, exclusive, 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 Poland; including in particular the information contained in the registration dossier, 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;

   (items referred to under (a)-(e) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Riboflavin in Poland, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of

Riboflavin in Poland for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches.

5. Teva shall make its best efforts to cooperate with the Purchaser for the transfer of the production of Riboflavin to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.

6. Teva shall submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.

7. At the option of the Purchaser, Teva shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Riboflavin in Poland for a period of three years on a reasonable cost plus basis to be agreed with the Purchaser.

8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that Teva provide 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.

9. The Divestment Business shall not include:

   (a) Any manufacturing facility;

   (b) Ownership or use of Vitamin B2 trademark outside of Poland;

   (c) Raw materials;

   (d) Any research and development, clinical data and studies or intellectual property relating to Riboflavin after Closing;

   (e) All marketing authorizations currently held by the Parties outside Poland for Riboflavin;

   (f) Monies owed to the Parties by customers for the purchase of Riboflavin, and monies owed by the Parties to suppliers for materials used in the productions of Riboflavin.