EN

Case No COMP/M.5555 -
NOVARTIS/ EBEWE

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
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COMMISSION OF THE EUROPEAN COMMUNITIES

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PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the Notifying Party:

Dear Sir/Madam,

Subject: Case No COMP/M.5555 - NOVARTIS/ EBEWE

Notification of 18 August 2009 pursuant to Article 4 of Council Regulation No 139/2004[1]

I. INTRODUCTION

1. On 18 August 2009, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 (the "Merger Regulation") by which the undertaking Novartis AG ("Novartis", Switzerland, or the "Notifying Party") acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of the undertaking EBEWE Spezial-Pharma Holding GmbH ("EBEWE SP", Austria), collectively "the Parties", by way of purchase of shares.

II. THE PARTIES

2. Novartis is a Swiss-based pharmaceutical company active on a world-wide basis in the development, production and distribution of pharmaceutical products and animal health products.

3. EBEWE SP is a group of companies to be formed in preparation of the proposed concentration through the spin-off of all the assets of the current EBEWE Group, based in Austria, which relate to the manufacture and distribution of specialty generic pharmaceutical products, including, in particular, oncology products, as well as all of

1 OJ L 24, 29.1.2004 p. 1.

the assets of the current EBEWE Group, which relate to the contract manufacturing of finished dose pharmaceuticals - cytotoxic injectables and liquid injectable ampoules - for other pharmaceutical companies. The company EBEWE Parenta, which has sales only in the US, is also included.

III. THE OPERATION

4. The proposed concentration concerns the acquisition by Novartis through a wholly-owned Novartis affiliate of all of the shares of EBEWE SP. Upon completion of the proposed transaction, EBEWE SP will be integrated into Sandoz, the generic pharmaceutical division of Novartis.

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

IV. COMMUNITY DIMENSION

6. The concentration does not have a Community dimension within the meaning of Article 1 of the Merger Regulation as the Community–wide turnover of one of two undertakings concerned (EBEWE SP) is EUR […] (i.e. less than EUR 250 million) and EBEWE SP does not achieve an aggregate turnover of more than EUR 25 million in each of three Member States (it achieves a turnover of more than EUR 25 million only in Germany).

7. Given the multiple filing requirements in at least three Member States (and in particular Bulgaria, Germany, Italy, Cyprus, Hungary, Austria, Poland and Slovakia) and the cross-border nature of the transaction, the case was referred to the Commission under Article 4(5) of the EC Merger Regulation for the purpose of its competitive assessment. None of the Member States competent to examine the concentration indicated its disagreement with the request for referral within the period laid down by the Merger Regulation.

V. RELEVANT MARKETS

PRODUCT MARKET DEFINITION

A. *Existing pharmaceutical specialities (or "finished dose pharmaceuticals")*

8. The Commission has analysed markets for existing pharmaceutical specialities in previous decisions.[2] According to the Commission, the market for existing pharmaceutical specialities can be classified into therapeutic classes by reference to the Anatomical Therapeutic Chemical Classification ("ATC") devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS"). The ATC has 16 categories (A, B, C, D, etc.), each with four different levels, and is regularly updated. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed.

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2 See e.g. Case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2009.

9. The third level, referred to as ATC3, allows medicines to be grouped according to their therapeutic indications (i.e. their intended use) and is generally taken as the starting point for the product market definition in competition cases. However, it may be appropriate to carry out analyses also at other levels, for example at ATC4 or molecule (based on the same main active pharmaceutical ingredient or API) level[3], or across classes, if specific circumstances indicate that the ATC3 level is not the most appropriate for the purposes of the market definition.

10. In this case, the Parties argue that, for some products, a market definition based on an ATC3 level would not be appropriate and thus propose a different market definition on the basis of demand-related criteria. In particular, for oncology products, the Parties concur with the approach taken by the Commission in *Teva/Barr*.[4] In that case the Commission considered the molecule to be the relevant market for a number of genericised oncology products. The Parties argue that, given that the target is a generic company and the purchaser also has significant generic operations in oncology, the approach adopted by the Commission in *Teva/Barr* should be retained. This notwithstanding, the Parties also identified affected markets based on an ATC3 level and, where the ATC3 category is further subdivided, on the ATC4 level, as well as on the molecule level.

11. The discussion on the market definition relating to specific products follows below.

B. ***Contract manufacturing***

12. According to Commission's previous decisions, contract manufacturing of finished dose pharmaceuticals ("contract manufacturing") consists in the manufacturing under contract, on behalf of third party pharmaceutical companies, of finished pharmaceutical products which may or may not include final packaging.[5]

13. In previous decisions the Commission has left open whether contract manufacturing should be delineated further by, for example, the technology needed to produce different forms of pharmaceuticals or by type of API used.[6]

14. In a previous decision the Commission has considered the nature of the technology and know-how required to produce the pharmaceutical to be a starting point.[7]

15. According to the Parties, the proposed concentration would not give rise to affected markets in this respect. EBEWE SP supplies liquid cytotoxic injectables in the form of ampules, vials and pre-filled syringes and manufactures non-cytotoxics in the form of liquid injectable ampoules. The market investigation confirmed that cytotoxic substances need dedicated production facilities and know-how. Whether this would

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3 See e.g. Case COMP/M.5295 *Teva/Barr*, Decision of 19 December 2008.

4 COMP/M.5295 *Teva/Barr*, Decision of 19 December 2008.

5 See case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2009.

6 Ibid.

7 Case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2009, paras 187 et seq.

justify the delineation of a separate contract manufacturing market or even a further subdivision according to the form of the cytotoxic product can however be left open as the proposed transaction does not raise competition concerns irrespective of the product market definition of contract manufacturing used.

C. *APIs ("active pharmaceutical ingredients")*

16. In previous decisions the Commission has considered that APIs form separate markets which are upstream to the markets of finished pharmaceutical products.[8] The Commission has looked at each individual API as potentially constituting a relevant market by itself. However, it cannot be excluded that certain APIs may be substitutable with each other for all, or for a range of, applications. This case does not raise competition concerns irrespective of the product market definition of APIs retained.

GEOGRAPHIC MARKET DEFINITION

A. *Existing pharmaceutical specialities (or "finished dose pharmaceuticals")*

17. The Commission has found in previous decisions that the markets for existing pharmaceutical specialities are national in scope due to the existence of different regulatory controls for pharmaceutical products and differences in price setting and reimbursement mechanisms between Member States.[9] The Parties concur with this view.

18. The results of the market investigation did not indicate any need to depart from the geographic market definition used in previous Commission decisions.

B. *Contract manufacturing*

19. In previous decisions the Commission indicated that the market for contract manufacturing was at least EEA-wide and likely to be a world-wide market, but left the market definition open.[10] The market investigation in the present case supports this finding. For the purposes of the competitive assessment in this case, however, the market definition can be left open as the proposed transaction does not lead to any competition concerns irrespective of the geographic market definition of contract manufacturing used.

C. *APIs ("active pharmaceutical ingredients")*

20. The Commission has previously considered that the markets for the provision of APIs are wider than the markets for finished dose pharmaceuticals and possibly world-wide. In this case the proposed transaction does not lead to any competition concerns irrespective of the geographic market definition for APIs retained.

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8 Case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2009. See, e.g., *Johnson & Johnson/Johnson & Johnson MSD Europe*, *Novartis/Hexal*, and *Teva/Barr*.

9 See, e.g., Case COMP/M.4007 *Reckitt Benckiser/BOOT Healthcare International*; Case COMP/M.4198 *Bayer/Schering*.

10 Case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2008.

VI. COMPETITIVE ASSESMENT

A. *Existing pharmaceutical specialities (or "finished dose pharmaceuticals")*

21. In the light of previous Commission decisions[11], the Parties have identified three possible horizontally affected relevant markets where, based on the ATC3 level or,also on the ATC4 and/or molecule level (where an overlap occurs on these levels), the transaction would lead to combined market shares of at least 35% with an increment exceeding 1%. All three such possible markets relate to oncology.

22. There are in addition a number of possible markets (both in oncology and other therapeutical areas) where the combined market share of the Parties exceeds 35% but the increment is below 1% or where the combined market share of the Parties is between 15% and 35% based on an ATC3, ATC4 or a molecule level. The investigation did not uncover any competition concerns with regard to these possible markets.

23. In particular, given that the EBEWE SP businesses to be acquired by Novartis focus on oncology and, in particular, cytotoxic products, the most significant overlap in the Parties' activities occurs in generic oncology products (as also pointed out by some respondents to the market investigation). The market investigation confirmed that specific production know-how and facilities are required to produce cytotoxic products. These special requirements have already been indicated in *Teva/Barr*[12] as potentially additional barriers to entry in the case of cytotoxic products. However, the market investigation in the present case showed that, besides the Parties, there are a number of players which produce generic oncology products and have comparable production capabilities (cytotoxic manufacturing) to supply the EEA market.

24. In light of the above, it appears unlikely that the merger would raise competition concerns where the Parties' market shares do not exceed 35% and/or the overlap in their activities is marginal (<1%).

25. The markets, where the Parties' combined market shares are 35% or higher with an increment exceeding 1% to which the proposed transaction gives rise are examined hereafter.

L1D Antineoplastic Antibiotics - Germany

26. Both Parties produce and sell antineoplastic antibiotics that control or kill neoplastic cells in cancer treatment. They are therapeutic agents isolated naturally from microorganisms or synthesized chemically that kill or inhibit the growth of tumour cells. They block cell growth by interfering with DNA, the genetic material in cells. The ATC3 class L1D is

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11 Cases COMP/M.3354 *Sanofi-Synthelabo/Aventis*, Decision of 26 April 2004, para. 20; COMP/M.3751 *Novartis/Hexal*, Decision of 27 May 2005, para. 25; COMP/M.5295 *Teva/Barr*, Decision of 19 December 2008, para 23.

12 Case COMP/M.5295 *Teva/Barr*, Decision of 19 December 2008, para 37.

not subdivided into ATC4 classes. Novartis' L1D drugs are based on the main molecules bleomycin, doxorubicin, epirubicin, mitomycin and mitoxantrone, respectively, whereas EBEWE SP sold L1D drugs based on doxorubicin, epirubicin and mitoxantrone, respectively.

27. The Commission has previously examined existing drugs in the oncology sector and has stated that, for cancer treatment, defining relevant product markets for pharmaceuticals according to their ATC3 classification may not always be appropriate because treatments vary depending on the type of cancer, its location and whether the cancer is in an initial or an advanced stage. In *Teva/Barr* the role and substitutability of individual molecules were used as a basis for the competitive analysis, in particular for genericised oncology products[13]. The Parties concur with this view.

28. In this case, the exact market definition can be left open as the transaction would not give rise to competition concerns either on an ATC3 or molecule level for the reasons below.

29. The Parties did not identify any markets based on the ATC3 level L1D, where the Parties' combined market shares would amount to at least 35% with an increment exceeding 1%.

30. The transaction would give rise to only one possible market based on molecule where the combined market shares of the parties would reach 35% with an increment exceeding 1%. In Germany, the combined market share of the Parties would reach [30-40] % for the molecule mitoxantrone with an increment of [10-20]% by EBEWE SP. On this market Novartis offers the product Mitoxantron Hexal while EBEWE SP markets the products Mitoxantron NC and Neoxantron. Both Parties have increased significantly their market shares since 2006. EBEWE SP in particular acquired its [10-20]% market share within two years, adding [10-20]% in 2008 alone.

31. There are a number of competitors with products in the L1D class based on the molecule mitoxantrone. These are Meda, the originator (with a market share of [30-40]%, declining since 2006), Teva ([10-20]%, declining since 2006) and Baxter ([10-20]%, increasing since 2006). The market investigation confirmed all these as credible competitors and indicated that customers would be likely to switch to competitors in case of a price increase by the merged entity. EBEWE SP's own example of gaining its market share within a short time confirms that customers are willing to switch to alternative suppliers.

32. Based on the fact that i) the Parties would still be a distant second player to the market leader, Meda; ii) there are a number of credible alternative providers of mitoxantrone; and iii) customers would be likely to switch to these alternative providers in case of a price increase by the merged entity, the proposed transaction is unlikely to give rise to competition concerns even on the basis of a narrower molecule-based market definition relating to mitoxantrone.

V3D Detoxifying agents for anti-neoplastic treatment

33. ATC3 class V3D includes drugs based on the molecules amifostine, calcium folinate, calcium levofolinate, dexrazoxane and mesna when indicated for adjuvant therapy in antineoplastic treatment. Products containing calcium folinate and which have

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13 COMP/M.5295 *Teva/Barr*, Decision of 19 December 2008, para 18.

multiple indications are classified in this class. Calcium folinate is used in combination with other drugs in chemotherapy against cancer to prevent or reduce the side effects of chemotherapy. Within ATC3 class V3D the Parties' activities overlap only with respect to drugs based on calcium folinate. This category also includes products based on amifostine and dexrazoxane.

34. The Parties consider, in accordance with *Teva/Barr*[14], that the molecule level is the correct basis to define the product market for this class of drugs.

35. The Commission has recently found, following specific investigation of the V3D market in *Teva/Barr*,[15] that products based on the molecule calcium folinate constitute a separate market. There is no reason to deviate from this market definition in the present case.

36. Based on a market definition consisting of Calcium folinate products, the transaction does not give rise to any affected markets where the Parties' combined market share would reach 35% with an increment exceeding 1%.

M5B Bone calcium regulators – Austria, Italy

37. Both Parties produce and sell bone calcium regulators classified under the ATC3 category M5B. Calcium regulators are predominantly used to treat osteoporosis, which is a disease of bone that leads to an increased risk of fracture, but can also be used for other indications such as oncology. Pharmaceuticals in this ATC3 class are further subdivided at ATC4 level into M5B3, which includes bisphosphonates used in the treatment of osteoporosis; M5B4, which covers bisphosphonates used in oncology for the treatment of tumour-related calcium disorders; and M5B9, which consists of all non-bisphosphonate drugs similarly used to treat osteoporosis.

38. In *Sanofi-Aventis/Zentiva*[16] the Commission found that there is a high degree of substitution between all bisphosphonates and that it would therefore be inappropriate to define the relevant market at the molecule level. The Commission left open whether the relevant market should be defined as the ATC3 class M5B as a whole or be limited to bisphosphonates, that is, ATC4 classes M5B3 and M5B4 combined.

39. The Parties agree that it is not appropriate to define the relevant product market at the molecule level as bisphosphonates may be used for the treatment of both osteoporosis and tumor-related calcium disorders. The Parties also claim that the relevant product market should be determined at either the ATC3 level M5B as a whole or be limited to bisphosphonates, that is, ATC4 classes M5B3 and M5B4 combined. In neither alternative does the proposed transaction give rise to markets, where the Parties would reach 35% combined market shares with an increment exceeding 1%.

40. In the present case, the overlap between the Parties' activities occurs in the oncology-related application of biphosphonates, i.e. on the ATC4 class M5B4, and on the pamidronic acid molecule level.

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14 Case COMP/M.5295 *Teva/Barr*, Decision of 19 December 2008.

15 Case COMP/M.5295 *Teva/Barr*, Decision of 19 December 2008, para 42.

16 Case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2008, paragraph 144.

41. Although the market investigation pointed to similarities in pharmacological properties and use between all biphosphonates, the different indications (oncology vs osteoporosis use) were highlighted by several respondents. Other distinctions mentioned include the galenic form (oral vs parental) and dosage, which also seem to correspond to the different indications of biphosphonates. It appears that generic versions of pamidronic acid are considered to be the main competing products to the Parties' products. However, several respondents pointed to substitutability also with other M5B4 drugs, such as Zometa (a patented drug of Novartis based on zolendronic acid) and Bondronat (a Roche product based on ibandronic acid) as well as Clody, Difosfonal and Clasteon (clodronic acid products in Italy supplied by Chiesi Farmaceutici, Società Prodotti Antibiotici and Abiogen Pharma). Some of these products were indicated as substitutes even by some respondents who considered oncological use (M5B4) to merit the delineation of a separate product market. To a lesser extent there were also indications that M5B3 drugs may compete with the Parties' products. In any event, as can be seen from information submitted by the Parties based on IMS market share data, pamidronic acid constitutes only a small part of the entire value of M5B4 products in both countries.

42. The market definition in the present case, however, can be left open as the transaction would not give rise to any competition concerns either on the ATC3, ATC4 or molecule basis or if all biphosphonates (M4B3 and M5B4 combined) were grouped together.

i) Austria

43. In Austria the proposed transaction would lead to combined market shares of at least 35% with an increment exceeding 1% only at the molecule level. The Parties' combined market share for drugs based on the molecule pamidronic acid is [60-70]% with an increment of [10-20]% by EBEWE. The Parties' main competitors are Chiesi ([20-30]%) and Hospira ([10-20]%). Stada is also present on the market with a generic pamidronic acid product, albeit with minor sales in 2008 and no sales before that.

44. The market investigation confirmed generic pamidronic acid products of all competitors (Hospira, Chiesi and even Stada) to be credible alternatives for customers. In particular these generic pamindronic acid products were indicated by most respondents to be the main competing products to the Parties' pamindronic acid products. The market investigation also indicated that customers would likely switch to these products in case of a 10% price increase by the Parties. The ibandronic acid-based product of Roche was also mentioned by respondents, albeit to a lesser extent, as a competitor.

45. Switching may be facilitated by the fact that these products are mainly procured by hospitals through tenders (as indicated by the market investigation). The fact that switching suppliers is not only possible but not uncommon is also indicated by significant year-to-year fluctuations (amounting to as much as [10-20]%) in market shares. It can be noted to this effect that the Parties' combined market share in 2006 was [40-50]%, almost 20 percentage point less than two years later. Within the same period of time Hospira more than doubled their market share from [5-10] to [10-20]%.

46. The Parties' combined market share would be [20-30]% with a marginal increment of <1% on the basis of both the ATC3 class M5B and of all biphosphonates (M5B3 and M5B4 combined), and of [70-80]% but also with a marginal increment of <1% under

ATC4 class M5B4. High market shares in the ATC4 class M5B4 are due to a product patented by Novartis (Zometa) and not to the product where the Parties overlap. The other significant market share of [20-30]% belongs to another originator product, Bonviva (by Roche), which was indicated by the market investigation to be a credible alternative to the Parties' product. The remaining part of the market is made up of generic suppliers of pamidronic acid each with less than [0-5]% market share.

47. In light of the relatively low combined market shares and the marginal increment by EBEWE SP, the transaction is unlikely to raise competition concerns on the ATC3 level and based on all bisphosphonates combined (ATC4 levels M5B3 andM5B4). In light of the marginal increment and the presence of other, credible alternatives, the transaction is unlikely to raise competition concerns on the ATC4 level M5B4 (biophosphonates for the treatment of tumour-related calcium disorders). Based on i) the availability of other credible suppliers of generic pamidronic acid; ii) the apparent possibility and willingness of customers to switch suppliers; and iii) the competitive pressure stemming from other bone calcium regulators used in oncology, the proposed transaction is unlikely to raise competition concerns even on the narrowly defined market of pamidronic acid-based products in Austria.

ii) Italy

48. In Italy the Parties would reach a combined market share of at least 35% with an increment exceeding 1% on both the ATC4 level M5B4 and the molecule level (based on pamidronic acid).

49. On a market definition based on the ATC4 level M5B4, the Parties' combined market share would reach [50-60]% with an increment of [0-5]%. The Parties' main competitors in this segment are Prospa ([10-20]%), Abiogen Pharma ([10-20]%) and Chiesi ([10-20]%) and there is a tail end of other, smaller, competitors (Hospira, Teva, Ratiopharm, Stada)

50. With regard to the molecule level, in Italy Novartis sells bone calcium regulators based on the molecules alendronic acid, clodronic acid, pamidronic acid and zoledronic acid, whilst Ebewe sells drugs based on pamidronic acid. On a market definition based on the molecule pamidronic acid, the Parties' combined market share would reach [40-50]% with an increment of [20-30]% by EBEWE. Hospira would still remain the market leader with [40-50]% while Teva has [5-10]%.

51. In contrast, on the basis of a market definition including all biphosphonate products (ATC4 classes M5B3 and M5B4 combined), the Parties would reach a combined market share of only [10-20]% with an increment of <1% and, on the basis of ATC3 class M5B, the Parties would reach a combined market share of only [10-20]% with an increment of <1%

52. The proposed transaction, however, does not give rise to competition concerns on any possible market definition, whether based on the molecule pamidronic acid or the ATC4 class M5B4 alone.

53. With regard to a molecule-based market definition, the market investigation has shown that generic drugs based on pamidronic acid produced by the Parties' competitors, such as, for example, Hospira, Teva and Ratiopharm, are considered by respondents to be in competition with the Parties' products and thus to constitute a

valid option for buyers. The market investigation also indicated willingness on the part of customers to switch to alternative generic pamindronic acid products in case of a 10% price increase by the Parties.This finding is confirmed by the fact that some hospitals source their requirements through public bids made on the basis of the molecule needed for the therapeutic indication. As to a market definition based on ATC4 class M5B4, the bulk of the Parties' market share ([40-50]%) comes from sales of the originator drug of Novartis (Zometa) that is based on a different molecule than Ebewe's Pamidronato. Several respondents indicate a number of drugs which compete with the Parties' products, for example Bondronat (ibandronic acid) by Roche; Clody (clodronic acid) by Chiesi Farmaceutici; Difosfonal (clodronic acid) by Società Prodotti Antibiotici; and Clasteon (clodronic acid) by Abiogen Pharma.Several respondents further indicated that customers would likely switch to competing products in case of a price increase of 10% of the Parties' pamindronic acid products. Besides generic pamidronic acid products, clodronic acid products were also mentioned to this effect.

54. In view of i) the availability of other credible suppliers of both generic drugs based on pamidronic acid and alternative drugs which compete with the Parties' products under ATC4 class M5B4; and ii) the apparent possibility for customers to switch suppliers, the proposed transaction is unlikely to raise competition concerns in Italy under any of the possible product market definitions regarding bone calcium regulators.

B. ***Contract manufacturing***

55. In a previous decision, the Commission considered the nature of the technology and know-how required, as opposed to the molecule, to be a starting point for the competitive assessment of any possible affected markets[17].

56. According to the Parties, the proposed concentration will not give rise to any affected markets with regard to contract manufacturing. EBEWE SP supplies liquid cytotoxic injectables in the form of ampoules, vials and pre-filled syringes and manufactures non-cytotoxics in the form of liquid injectable ampoules. Novartis does not manufacture cytotoxic injectables for third parties (it only has captive production), but fills liquid injectable ampoules for third parties. According to the Parties, EBEWE SP's share of any potential EEA or global market for contract manufacturing in the form of filling liquid injectable ampoules is close to zero while the Parties also estimate Novartis' share of such possible market to be below [0-5]%. The proposed transaction is therefore unlikely to raise competition concerns due to the horizontal overlap in the Parties' contract manufacturing activities.

57. Furthermore, Novartis is already at present the largest customer of EBEWE SP in the area of contract manufacturing, in particular with regard to the production of cytotoxic pre-filled syringes, which is all sold to Novartis. The proposed concentration will therefore not bring about any significant change to the current situation in this respect.

58. In light of the above, the proposed transaction is unlikely to raise competition concerns in any possible horizontal or vertical contract manufacturing market between the Parties or any market downstream to the Parties' contract manufacturing activities.

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17 Case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2009, paras 187 et seq.

C. *APIs ("active pharmaceutical ingredients")*

59. There is no horizontal overlap between the Parties' activities in any API market as only Novartis manufactures APIs.

60. Novartis does not manufacture any APIs used in the products manufactured by EBEWE SP, and therefore there are no possible vertical links between the Parties' activities if both the upstream and the downstream market are defined on the molecule level. In any event, Novartis does not reach a market share of 25% or higher on an EEA-wide or worldwide basis in any of the relevant API merchant markets (Novartis estimates its market share of the relevant APIs to be around [0-5]% or less). Furthermore, there is only one downstream market where the combined market share of the Parties exceeds 25% on the ATC3 level. However, the Parties' combined market share in the ATC3 class N4A in Slovakia would only be [20-30]% with a marginal increment of [0-5]%.

61. In light of the above, the transaction is not likely to raise any competition concerns in any API market or any market downstream to the API markets where Novartis is active.

D. *Potential competition in finished dose pharmaceuticals*

62. The Commission has previously examined the issue of the competition exerted by pipeline generic products in a case involving an originator company buying a generic company[18]. In that case, the Commission considered all instances where the target had in the pipeline a generic version of a product of the acquirer. In the present case, the Parties confirmed that none of the pipeline products of EBEWE SP is a generic version of an originator Novartis drug.

63. In addition, neither Party has a market share of at least 35% in any oncology market based on a molecule where the other Party is planning to launch a product based on the same molecule in the coming 12 months. There is therefore no indication that any potential competition stemming from the pipeline product of a Party would be more significant than the competitive pressure stemming from actual competitors of the other Party.

64. Based on the above, the transaction is unlikely to lead to competition concerns due to the elimination of pipeline products.

VII. CONCLUSION

65. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of Council Regulation (EC) No 139/2004.

For the Commission,
(signed)

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18 Case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2008, para 512.

Neelie KROES
Member of the Commission