EN

Case No COMP/M.3928 - TEVA / IVAX

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 24/11/2005

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24/11/2005

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PUBLIC VERSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying party

Dear Sir/Madam,

Subject: Case No COMP/M.3928 – Teva/Ivax
Notification of 18.10.2005 pursuant to Article 4 of Council Regulation No 139/2004[1]

1. On 18.10.2005, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which the undertaking Teva Pharmaceutical Industries Limited ("Teva", Israel) acquires within the meaning of Article 3(1)(b) of the Council Regulation control of the whole of the undertaking Ivax Corporation and its various subsidiaries (together "Ivax", USA) by way of purchase of shares.

[1] OJ L 24, 29.1.2004 p. 1.

2. After examination of the notification, the Commission has concluded that the notified operation falls within the scope of the Merger Regulation and does not raise serious doubts as to its compatibility with the common market and with the functioning of the EEA Agreement.

I. THE PARTIES

3. Teva is a global pharmaceutical company with its corporate headquarters in Israel. It specializes in the development, production and marketing of generic pharmaceuticals as well as active pharmaceutical ingredients (API's). It also develops, manufactures and sells proprietary pharmaceuticals products.

4. IVAX is a multinational company with headquarters in the United States. It is engaged in the research, development, manufacturing and marketing of branded and generic pharmaceuticals and veterinary products in the U.S. and internationally. Approximately 66 % of its revenues are generated from the sale of generic products.

II. THE OPERATION

5. On the basis of an agreement signed on 25.07.2005, Teva intends to acquire by share deal, through Ivory Acquisition Sub, Inc., a wholly owned subsidiary, sole control of Ivax.

III. CONCENTRATION

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

IV. COMMUNITY DIMENSION

7. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion[2] (Teva 3,857 million Euro, Ivax 1,446 million Euro). Each of Teva and Ivax have a Community-wide turnover in excess of EUR 250 million, but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension.

V. COMPETITIVE ASSESSMENT

Horizontally related markets

RELEVANT PRODUCT MARKETS

8. In previous decisions[3], the Commission noted that medicines may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Chemical" classification (ATC), devised by European Pharmaceutical Marketing Research

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[2] Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover (OJ C66, 2.3.1998, p25).

[3] COMP M.3751-Novartis/Hexal, COMP M.3544-Bayer Healthcare/Roche, COMP M.3354-Sanofi-Synthelabo/Aventis

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 up to four levels. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed. The third ATC level allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use. This level is generally used as the starting point for defining and enquiring about market definition in competition cases. However, it is appropriate to carry out analyses at other ATC levels, or a combinations thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level, and that, therefore, there are indications that the third ATC level does not lead to a correct market definition.

Prescribed/non-prescribed (OTC)

9. The Commission has in the past[4] defined separate markets for OTC (as opposed to prescription) pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distributing tend to differ between these categories, even if the active ingredients are identical. OTC products may be advertised to the public at large. Doctors do not need to intervene in the purchase of these products. Consumers make their own choice and bear the costs of their purchase, generally leading to a higher price elasticity of demand. By contrast, prescription pharmaceuticals need to be prescribed by a doctor, whose intervention is thus essential in the choice of the product. Pricing for prescription products is influenced by the public health care system, who pays (part of) the purchase price via reimbursement. Marketing, therefore, is targeted at prescribers, that is, doctors and hospitals. "Semi-ethical" products are OTC drugs for which reimbursement can be obtained if they are purchased on prescription.

Originator medicines/generics

10. In previous decisions[5], the Commission indicated that generics can efficiently substitute originator drugs after patent expiry, especially if the regulatory background pushes for switching and that originator medicines and generics belong to the same product market.

RELEVANT GEOGRAPHIC MARKETS

11. The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope, despite the trend towards harmonisation at a European level.

12. The results of the investigation suggest that the Commission should not deviate from its previous practice in assessing pharmaceutical markets at the national level and that the same approach is appropriate for generic products. At this stage, despite the presence of large European wholesalers, the competition still takes place at national level.

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4 COMP M.3751-Novartis/Hexal, COMP M.3544-Bayer Healthcare/Roche, COMP/M.3394-Johnson & Johnson/ Johnson & Johnson MSD Europe

5 COMP M3751- Novartis/Hexal

13. The more specific characteristics of each affected market will be described in the assessment part of this decision.

14. In previous decisions[6] the Commission concluded that active ingredients form a separate market which is upstream of the market of the finished pharmaceutical products.

15. The Commission has also found that active ingredients markets are, from a geographic scope, larger than markets for finished pharmaceutical products and may be worldwide.

16. Ten vertically affected upstream markets will be created with respect to the active ingredients.

ASSESSMENT

Horizontally affected markets

17. Based on ATC 3 categories, the concentration will create only 5 horizontally affected markets in the area of medicines, namely the ATC 3 categories L1C (Czech Republic), J1E (UK), R3D (UK and Ireland) and R3A (UK).

18. In each of the five affected ATC 3 markets, the increase in market share resulting from the transaction is limited (ranging between [0% - 5%].

Vinca Alkaloids & Other Plant Products (L1C-prescribed) (Oncology)-Czech Republic

19. The parties state that pharmaceutical products of the L1C class are part of the broader category of antineoplastics and immunomodulating agents (L1). The L1 class includes all preparations mainly indicated for the treatment of cancers (oncology) and all packs specifically produced for use in anticancer therapy e.g. special anticancer packs of antibiotics.

20. The Commission's approach is to distinguish the markets according to the various types of cancer (prostate cancer[7], colorectal cancer and non-Hodgkins lymphoma[8]) or according to their mode of action[9].

21. The only overlap existing between Teva and IVAX's products is in the treatment of lung cancer. The notifying party considers that, although belonging to the L1C category, Teva's and IVAX's products are not substitutes as they are used to treat different cell types. In any case, the precise definition of the market can be left open since, in any alternative product market definition, the proposed operation will not impede competition.

22. If the prescribed L1C segment is considered, the parties have a combined market share (2004) in the Czech Republic of [10% - 20%] (Teva [0% - 5%], Ivax [10% -20%]). Other competitors are Sanofi-Aventis [20% - 30%], Bristol-Meyers SQB [20% - 30%],

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6 COMP M.3751- Novartis/Hexal, COMP M.3394 – Johnson&Johnson/Johnson&Johnson MSD Europe, decision 29.03.2004

7 M.2312-Abbott/BASF

8 M.1846-Glaxo Wellcome/SmithKline Beecham

9 M.1878-Pfizer/Warner-Lambert,

Pfizer [10% – 20%], Pierre Fabre [0% - 10%], GSK [0% - 10%] and others [0% - 5%]. Furthermore on a wider market definition for medicines used for the treatment of lung cancer the parties' combined market share does not exceed 15%.Even at ATC 4 level, the concentration will not lead to competition problems.

23. In the light of the foregoing, the Commission has concluded that no competition concerns are likely to arise on this market. The market investigation has not revealed that the transaction would raise competition problems on this market.

Trimethoprim and Similar Formulations (J1E-prescribed) - UK

24. The J1E category consists of antibiotics. Antibiotics are antibacterial agents that inhibit the growth of certain micro-organisms. Systemic antibiotics (J1) are classes of semi-synthetically prepared antibiotics, which followed the development of penicillin into second and third generation products. The products available in the J1E ATC category in the UK consist only of trimethoprim, co-trimoxazole and sulfamethoxazole. The latter two products are always sold in combination with trimethoprim. Within the J1E category, the parties supply only trimethoprim.

25. However, the parties argue that the relevant product market is wider than the J1E category comprising J1 at ATC level 2 and G4A (Quinolone derivatives). If one considers the therapeutic indications, trimethropim and similar formulations are used in the UK to treat urinary-tract infection ("UTI"). Four other medicines from the G4A category were also approved for treating UTI. In any case, the precise definition of the market can be left open since, in any alternative product market definition, the proposed operation will not impede competition.

26. If one were to consider the ATC 3 category of J1E products, the parties have a combined market share (2004) of [20% -30%] [Teva (20% - 30%), Ivax (0% - 5%)]. Other competitors are GSK [20% - 30%], Alpharma [10% - 20%], Solvay [0% - 10%] and others. Even at ATC 4 level, the concentration will not lead to competition problems.

27. Should the market be defined as including all products indicated for the treatment of UTI (J1 and G4A), the parties combined market share would amount to [0% - 10%] and would therefore not be an affected market.

28. In the light of the foregoing, the Commission has concluded that no competition concerns are likely to arise on this market. The market investigation has not revealed that the transaction would raise competition problems on this market.

Respiratory Products (R3D and R3A) (prescribed) – UK and Ireland

29. Teva's and IVAX's activities overlap at ATC level 3 in the R3D and R3A categories only in the UK. Medicines belonging to these categories are asthma-related respiratory medicines and may broadly be categorized into short-acting treatments (or "relievers") and treatments for long-term management of the illness (or "preventers"). R3D (Corticoids) are used for prophylactic and long-term management of asthma. They are required to be taken on a regular basis (i.e. daily) as part of a preventative treatment. R3A (B2 Stimulants) are used to relieve asthma symptoms. R3A and R3D products are also prescribed in combination with other products. R3A can be used in combination with R3B and R3F, whereas R3D can be used in combination with R3F.

30. The parties argue that it is therefore possible to segment the relevant markets as follows:

    (i) Asthma relievers/antibronchodilation products where the following ATC 3 categories should be combined: R3A, R3B and R3F; and

    (ii) Asthma preventers/ Anti-inflammatory: R3D and R3F

31. In any case, the precise definition of the market can be left open since, in any alternative product market definition, the proposed operation will not impede competition.

32. The transaction will only lead to affected markets if one considers only the R3A and R3D segments. On the R3A and R3D segment, the combined market share in the UK of the parties amount to respectively [10% - 20%] [Teva (0% - 5%), Ivax (10% - 20%)]and [20% - 30%] [Teva (0% - 5%), Ivax (20% - 30%)] with limited increments. In Ireland, Ivax is present on the R3D market (market share [20% - 30%]), but Teva is not active in the R3 category in Ireland and so no overlapping activities exist.

33. Based on both the ATC 3 category and the alternative market definitions proposed by the parties (asthma relievers and asthma preventers), the concentration will not result in affected markets. Even at ATC 4 level, the concentration will not lead to competition problems.

34. In the light of the foregoing, the Commission has concluded that no competition concerns are likely to arise on this market. The market investigation has not revealed that the transaction would raise competition problems on this market.

Vertically related markets

35. Based on the parties' information, Teva has a world-wide market share in excess of 25% for several of its active ingredients, but IVAX's share does not exceed 25 % in relation to any active ingredients. Therefore, vertically affected markets arise only in relation to Teva's upstream active ingredient manufacturing activities and IVAX's downstream use of these ingredients to produce certain finished dose pharmaceuticals.

36. The parties have identified ten vertically affected markets where market shares (2004) are above 25%: allopurinol, amitriptyline, atenolol, beclamethasone, diltiazem, doxepin, gemfibrozil, loperamide, nifuroxazide, triamcinolone. However, on all relevant downstream ATC 3 categories, the combined market shares of parties are below [25% - 35%].

<u>Allopurinol</u>

37. Teva has a worldwide market share (2004) in allopurinol of [35% - 45%]. The parties have indicated that approximately nine other competitors, including Egis and Vera Lab, are active on the market. On the relevant downstream ATC-3 market where Ivax is active (prescribed M4A in the France, Ireland, UK, the parties' combined market shares (2004) are below [10% - 20%].

Amitriptyline

38. Teva has a market share (2004) of [25% - 35%] in amitriptyline. The parties have indicated that approximately eleven other competitors, including Anphar Laboratories and Dipharma, are active on the market. On the relevant downstream ATC-3 market where Ivax is active (prescribed N6A in France, Poland, UK), the parties' combined market shares (2004) are below [0% - 10%].

Atenolol

39. Teva has a market share (2004) of [25% - 35%] in atenolol. The parties have indicated that approximately fourteen other competitors, including IPCA, SIMS and Ariane, are active on the market. On the relevant downstream ATC-3 markets where Ivax is active (prescribed C7A in France and UK), the parties' combined market shares (2004) are below [5% - 15%].

Beclomethanazone

40. Teva has a market share (2004) of [40% - 50%] in beclomethanazone. The parties have indicated that approximately twelve other competitors, including GSK and Farmabios, are active on the market. On all the relevant downstream ATC 3 markets where Ivax is active (prescribed R3D, R1A in various member states), the market share (2004) of the parties is below [25% - 35%].

Diltiazem

41. Teva has a market share (2004) of [25% - 35%] in diltiazem. The parties have indicated that approximately fifteen other competitors, including Tanabe and Zambon Group, are active on the market. On the relevant downstream ATC 3 markets where Ivax is active (prescribed C8A in France and UK), the market share (2004) of the parties is below [0% - 10%].

Doxepin

42. Teva has a market share (2004) of [30% - 40%] in doxepin. The parties have indicated that approximately eight other competitors, including Dipharma and Sifavitor, are active on the market. On the relevant downstream ATC 3 markets where Ivax is active (prescribed N6A in France, Poland and UK), the market share (2004) of the parties is below [0% - 10%].

Gemfibrozil

43. Teva has a market share (2004) of [40% - 50%] in gemfibrozil. The parties have indicated that approximately ten other competitors, including Pfizer and Dipharma, are active on the market. On the relevant downstream ATC 3 markets where Ivax is active (prescribed C10A in Sweden and UK), the market share (2004) of the parties is below [0% - 10%].

Loperamide

44. Teva has a market share (2004) of [50% - 60%] in loperamide. The parties have indicated that approximately ten other competitors, including Sifavitor and Isochem, are active on the market. On the relevant downstream ATC 3 markets where Ivax is

active (OTC A7H in the UK), the market share (2004) of the parties is below [0% - 10%].

Nifuroxazide

45. Teva has a market share (2004) of [50% - 60%] in nifuroxazide. The parties have indicated that other competitors, including Coprima, Isochem and Shuzhau, are active on the market. On the relevant downstream ATC 3 markets where Ivax is active (prescribed A7A in France), the market share (2004) of the parties is below [5% - 15%].

Triamcinolone

46. Teva has a market share (2004) of [35% - 45%] in triamcinolone. The parties have indicated that approximately seven other competitors, including Pfizer Centre Source and Farmabios, are active on the market. On the relevant downstream ATC 3 markets where Ivax is active (prescribed D7A in Czech Republic and Slovakia), the market share (2004) of the parties is below [5% - 15%].

Conclusions on vertical relationships

47. In respect of all of Teva's active ingredient products, the parties state that there will be little or no change in the supply structure as a result of the transaction, so no foreclosure issues can arise. For most of Teva's active ingredients, IVAX's share in the downstream market is minimal [0% - 5%]. Hence, even if all active ingredient sales to IVAX were to be internalized post-merger, this would not significantly affect the customer base of Teva's competitors.

48. In relation to Allupurinol and Beclomethasone, for which IVAX's relevant downstream market share is somewhat higher [20% - 30%], Ivax already purchases all of its requirements from Teva so that the transaction will not lead to a change in the supply structure. No incentives or actual sales are changed and, hence, no foreclosure issues should arise.

49. Moreover, there are a large number of suppliers in each vertically affected market so that no producer of downstream products would find it difficult to source any of these active ingredients post-transaction. The parties argue that Teva active ingredients are commodities, which are out of patent and are relatively easy to manufacture. There are no specific barriers to entry, as evidenced by the recent arrival of a significant number of new producers from India and China.

50. With regard to vertical relations between Teva and Ivax, it can be concluded that no competition concerns arise from the transaction, as there are limited market shares downstream or alternative suppliers upstream. The market investigation has not revealed that the transaction would raise competition problems on the vertically affected markets.

Pipeline products

51. The Commission has previously specified that pipeline products are products that are not yet on the market, but which are at an advanced stage of development, i.e. the latest stage of clinical testing (phase III)[10].

52. Given that they are primarily generic companies, Teva and Ivax have only a small number of innovative medicines in their pipelines and the only area in which there exists some overlap is multiple sclerosis (MS). Both parties are seeking to develop an oral therapy for MS as part of a wave of R&D aimed at creating second-generation treatments for MS. However, the pipeline products of Teva are only in phase II.

53. In 2005, Ivax and Serono SA, jointly initiated a phase III study of Mylinax, a potential oral treatment product for MS. In addition, the parties state that a large number of competitors are working to develop second-generation treatments for MS including four phase III projects and 27 projects in phase II. In the relevant ATC category of the products which can be used to treat MS (L3A-prescribed), only Teva is active with a market share of only [10% - 20%].

VI. CONCLUSION

54. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with 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
Charlie McCREEVY
Member of the Commission

[10] M.3751-Novartis/Hexal ; M.2517-Bristol-Myers Squibb/Du Pont ; M.1878-Pfizer/Warner-Lambert