EN

Case No COMP/M.4198 -
BAYER / SCHERING

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 24/05/2006

In electronic form on the EUR-Lex website under document number 32006M4198

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

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24-V-2006

SG-Greffe(2006) D/202763

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 Where possible the information omitted has been replaced by ranges of figures or a general description.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

To the notifying party

Dear Sir/Madam,

Subject: Case No COMP/M.4198 Bayer/ Schering
Notification of 12/04/2006 pursuant to Article 4 of Council Regulation No 139/2004[1]

1. On 12.04.2006, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004[2] by which the undertaking Bayer Aktiengesellschaft ("Bayer", Germany) acquires within the meaning of Article 3(1)(b) of the Council Regulation a sole control of the undertaking Schering AG ("Schering", Germany) by way of a public offer.

I. THE PARTIES

2. Bayer is a publicly listed international diversified group active in health care, crop science and polymer products. Bayer AG is the management holding company of the Bayer Group, which includes approximately 280 consolidated subsidiaries. Its business operations are organised in three subgroups: Bayer HealthCare, Bayer CropScience and Bayer MaterialScience.

1 OJ L 24, 29.1.2004 p. 1.

2 OJ L24, 29.01.2004 p.1

3. Schering is a publicly listed global pharmaceutical company, which is active in five global core business areas: Gynecology and Andrology; Diagnostic Imagining; Specialised Therapeutics; Oncology; and Dermatology. The Schering AG Group is comprised of over 150 subsidiaries worldwide.

II. THE CONCENTRATION

4. On 23.03.2006, Bayer has publicly announced its intention to commence a voluntary public offer, through its wholly owned subsidiary Dritte BV GmbH. The notified operation therefore confers to Bayer, exercised via Dritte, sole control over Schering. It therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

III. COMMUNITY DIMENSION

5. The undertakings concerned have a combined aggregate worldwide turnover of above 5 billion EUR (Bayer: 27,383 million EUR, Schering: 5,308 million EUR). Each of them has a Community-wide turnover in excess of 250 million EUR (Bayer: […] million EUR, Schering: […] million EUR), 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.

IV. COMPETITIVE ASSESSMENT

A. Relevant markets

1) Product markets

6. In previous decisions[3], the Commission has applied the ATC classification devised by EphMRA and has stated that the third level of the ATC classification allows medicines to be grouped in terms of their therapeutic indications and can therefore be used as an operational starting point for market definition. However, in certain cases it may be necessary to analyse pharmaceutical products at a higher, lower or mixed level or to further subdivide the ATC 3 classes on the basis of demand-related criteria. In the present case, the parties have accepted this view.

7. 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. Therefore, and as the market investigation confirmed this view, the Commission will assess OTC medicines and prescribed medicines as two separate product markets.

[3] Case COMP/M.3751 – Novartis/Hexal, decision of 27 May 2005; Case COMP/M.4007 – Reckitt Benckiser/Boots Healthcare International, decision of 6 January 2006.

[4] Case COMP/M.3751 – Novartis/Hexal, decision of 27 May 2005; Case COMP/M.4007 – Reckitt Benckiser/Boots Healthcare International, decision of 6 January 2006.

8. In previous decisions[5], the Commission has demonstrated that originator drugs were exposed to generic competition. Therefore the Commission has never made a distinction between generics and originator drugs. The parties have shared this approach and the market investigation has confirmed that drugs are exposed to generic competition.

9. The concentration will give rise to five horizontally affected markets which relate to five ATC 3 classes: G1B (gynaecological antifungals), C5A (topical anti-haemorrhoidals), D1A (antifungals, dermatological), D7B (topical corticosteroids combinations), N5B (hypnotics/sedatives).

10. In the light of a previous decision of the Commission and of the results of the market investigation, the relevant product markets could be subdivided further for D1A, D7B and N5B classes as it is set out below. On the basis of such segmentation, the concentration would also give rise to affected markets.

G1B (gynaecological antifungals)

11. G1B products include antifungal products indicated only for gynaecological conditions. The ATC classification does not further subdivide the ATC 3 class G1B on an ATC 4 level. The parties submitted that ATC3 level is appropriate to define the relevant market. The parties' view has been confirmed by all the respondents to the market investigation.

C5A (topical anti-haemorrhoidals)

12. This category includes products that are used mainly for the topical treatment of haemorrhoids. The parties submit that the ATC 3 level is appropriate to define the relevant product market. The respondents to the market investigation have confirmed the parties' view and none of the respondents submitted that the ATC 4 level would be more appropriate to define the relevant product market.

D1A (Dermatological antifungals)

13. D1A products include a range of dermatological products based on different active ingredients and different delivery modes, i.e. scalp treatments, systemic treatments (orally taken) and topical treatments. The Commission has previously noted that it might be more appropriate to further subdivide this category[6], and has excluded shampoos and scalp treatments (D1A3) from the market definition.

14. Several respondents to the market investigation submitted that the relevant product market should be subdivided further to the ATC 4 level. The products of the parties belong to the D1A1 group.

15. However the question of the exact market definition can be left open as the notified transaction would not raise serious doubts on any possible market definition.

D7B (Topical Corticosteroid)

[5] Case COMP/M.3751 – Novartis/Hexal Decision of 27 May 2005.

[6] Case COMP/M.3544 – Bayer HealthCare/Roche (OTC business), decision of 19 November 2004, para. 24 et seq.

16. Topical Corticosteroid combinations include all dermatological products containing corticosteroids in combination with one or more active ingredients, except those classified in D10A (i.e. topical anti-acne preparations).

17. A further segmentation based on the ATC4 level classifies the various corticosteroid combinations by cause of the inflammation: products classified in D7B1 are indicated for antibacterial treatment, while products classified in D7B2 are antifungals, D7B3 products contain medicines indicated for combi-treatments, and D7B4 products include other corticosteroid combinations. The products of the parties belong to the D7B2 group. However, the parties state that such segmentation would be very theoretical and would also not account for combinations which can be used to combat different causes of an inflammation at the same time. In particular the parties stress that, in most cases, medical practitioners cannot determine at the outset whether bacteria or fungi or other causes are the source of an inflammation. Therefore the corticosteroids contained in all products within D7B will ensure a treatment of the inflammation.

18. The majority of the respondents to the market investigation submitted that the relevant product market should not be subdivided further to the ATC 4 level. However a few third parties stated the contrary as there are differences in the terms of use among the four ATC4 D7B groups. In particular they indicated that the antibiotic products (D7B1) are typically not interchangeable with the antifungal products (D7B2).

19. However the question of the exact market definition can be left open as the notified transaction would not raise serious doubts on any possible market definition.

N5B (Hypnotics/Sedatives)

20. In the previous decisions, the Commission has left open the question whether the N5B segment should be further subdivided into comparatively expensive modern hypnotics that have light addictive effects and no residue in the morning (non-benzodiazepines), (benzodiazepines), but have strong potential for causing addiction and have prolonged effects.[7]

21. The parties' products are all classifiable in N5B1 (Non-barbiturates, plain) group which includes benzodiazepines indicated exclusively for the treatment of insomnia.

22. The question of the exact market definition for N5B group can be left open as the notified transaction would not raise serious doubts on any possible market definition.

2) Geographic markets

23. In previous decisions[8] the Commission held that the relevant geographic market for pharmaceutical products including OTC products was national in scope. The parties share this view which has been confirmed by the market investigation.

B. Assessment

[7] Case COMP/M.3751 – Novatis/Hexal Decision of 27 May 2005.

[8] Case COMP/M.3751 – Novatis/Hexal, decision of 27 May 2005; Case COMP/M.4007 – Reckitt Benckiser/Boots Healthcare International, decision of 6 January 2006.

24. Following the transaction, the parties would have significant market shares above 35% and with an increment above 1% in the following markets: prescription G1B in Portugal, OTC D1A1 in Austria, prescription D7B2 in Ireland. The calculation of the market shares is based on the IMS MIDAS database for 2005.

25. The remaining affected markets where the parties have overlapping activities and market shares below 35% are: prescription G1B in Greece ([20-30]%, Bayer: [10-15]%, Schering: [5-10]%), prescription N5B / N5B1 in Italy (N5B: [20-30]%, Bayer: [0-5]%, Schering: [20-30]% ; N5B1: [20-30]%, Bayer: [0-5]%, Schering: [20-30]%), OTC C5A in Italy ([20-30]%, Bayer: [15-20]%, Schering: [5-10]%), prescription D7B in Portugal ([15-20]%, Bayer: [5-10]%, Schering: [5-10]%)[9], prescription D1A / D1A1 in Spain (D1A: [15-20]%, Bayer: [15-20]%, Schering: [0-5]% ; D1A1: [20-30]%, Bayer: [15-20]%, Schering: [0-5]%).

26. In all of the above mentioned affected markets where the parties' combined market shares are under 35%, several competitors remain and they include either market leaders or companies with strong market positions. The major competitors include Johnson & Johnson, Galenica in the relevant market in Greece ; Recordati, Wyeth, Sanofi-Aventis, Boehringer Ingelheim and Solvay in the relevant markets in Italy ; Schering-Plough[10], Johnson & Johnson and Leo Pharma in the relevant markets in Portugal ; Esteve, Ferrer, Puig and Johnson & Johnson in the relevant markets in Spain. Third parties in their replies to the Commission's questionnaires have not raised any substantiated concerns on any of these markets. Therefore the Commission has concluded that the concentration is unlikely to significantly impede effective competition in those markets, which will not be further discussed in the decision.

Prescription G1B(Gynaecological antifungals) in Portugal

27. In Portugal, the parties' combined share amounts to about [40-50]% (Bayer: [30-40]%, Schering: [0-5]%). However, despite that important combined market share, the proposed concentration is unlikely to give rise to anti-competitive effects for the following reasons. Firstly, the limited overlap will not significantly strengthen the pre-merger position of Bayer. Secondly, the parties face a number of other significant competitors as inter alia Johnson & Johnson ([20-30]%), Decafarma ([10-15]%) and Pfizer ([5-10]%). Thirdly, there are no specific entry barriers. In particular, patent protection has expired, so that the products can also be produced by generic manufacturers. As a matter of fact, it can be noted that several competitors' market shares have risen over the past three years (for instance Decafarma: [0-5]% in 2003 and [10-15]% in 2005, Azevedos: [0-5]% in 2003 and [5-10]% in 2005) whereas the parties' markets shares have decreased (Bayer: [40-50]% in 2003 and [30-40]% in 2005, Schering: [0-5]% in 2003 and [0-5]% in 2005). Fourthly, the respondents to the market investigation did not raise any competition concern.

28. In the light of the foregoing, the Commission has concluded that no competition concerns are likely to arise on the prescription Portuguese G1B market.

---

[9] In Portugal, the parties' activities would not overlap if a further segmentation to the ATC 4 level (D7B2) were to be adopted, since Schering is active on the D7B1 and D7B2 segments whereas Bayer is active on the D7B3 segment.

[10] Schering Plough is an American group which is totally independent of Schering AG.

OTC D1A / D1A1 (Dermatological Antifungals / Topical Dermatological Antifungals) in Austria.

29. In Austria, Bayer's product Canesten classified in D1A is available over the counter. In most cases, Schering's product in this ATC 3 class, Travogen, is sold as a combination of Travogen (30g) and Travocort (15g). The Travogen/Travocort combination is prepared by pharmacies and requires a prescription. According to the parties the combination of Travogen/Travocort is prescribed very often, so that the majority of Travogen sales are made in the prescription segment. However the parties' activities overlap in the OTC market as Travogen is also sold alone as an OTC product.

30. On the ATC3 level the parties' combined share amount to [30-40]% (Bayer: [20-30]%, Schering: [10-15]%). The new entity will face a number of competitors as inter alia Johnson & Johnson ([20-30]%), Ratiopharm ([10-15]%), Novartis ([5-10]%), Boots ([5-10]%), Bristol Myers ([0-5]%).

31. If the ATC 4 segment (D1A1) is considered, the parties' market shares would be higher ([40-50]%, Bayer: [30-40]%, Schering: [5-10]%). However, the proposed concentration is unlikely to give rise to anti-competitive effects for the following reasons. Firstly, the new entity will face a major competitor such as Johnson & Johnson ([40-50]%). There are a number of other competitors such as Novartis, Sanofi, L'Oreal, Nycomed with market shares between [0-5]% and [0-5]%. Secondly there are no specific entry barriers. In particular, patent protection has expired, so that the products can also be produced by generic manufacturers. Thirdly the respondents to the market investigation did not raise any competition concern.

32. In the light of the foregoing, the Commission has concluded that no competition concerns are likely to arise on the OTC Austrian D1A/D1A1 markets.

Prescription D7B / D7B2 (Topical Corticosteroid/ Combinations of corticosteroids with antifungals) in Ireland

33. In Ireland, the parties are present with prescription medicines: Canesten HC (Bayer) and Travocort (Schering). On the ATC 3 level, the parties have a combined market share of [15-20]%. On such a market the new entity will face several major competitors as Leo Pharma ([30-40]%), Schering Plough ([15-20]%) and Johnson & Johnson ([10-15]%).

34. If the ATC 4 segment (D7B2) is considered, the parties' market share would result in a significant combined share of [40-50]% (Bayer: [30-40]%, Schering: [10-15]%). However, although as the result of the transaction Bayer will significantly strengthen its position, the proposed concentration is unlikely to give rise to ant-competitive effects for the following reasons. Firstly, the new entity will face competition pressure exercised by Johnson & Johnson ([40-50]%) and Schering Plough ([5-10]%). Secondly, there are no specific entry barriers. In particular, the patents on the products of Bayer and Schering have expired and generic manufacturers can easily offer competing products. Thirdly, the respondents to the market investigation did not raise any competition concern regarding a D7B2 market.

35. In the light of the foregoing, the Commission has concluded that no competition concerns are likely to arise on the Irish prescription D7B/D7B2 markets.

C. Pipeline products (future markets)

36. In the pharmaceuticals industry, a full assessment of the competitive situation requires examination of the products that are not yet on the market, but which are at an advanced stage of development.

37. In the previous decisions[11], the Commission has defined pipeline products as products that are not yet on the market, but which are at an advance stage of development, normally at the latest stage of clinical testing (phase III). According to the parties the only overlap occurs in the field of oncology, more specifically for prescription products that are classifiable in the ATC 3 category L1X. L1X products include all other antineoplastics that are not alkylating agents (L1A), antimetabolites (L1B), vinca alkaloids and other plant products (L1C), antineoplastic antibiotics (L1D). Bayer is not active on the L1X category but it is about to launch Nexavar, while Schering is already selling certain products within the oncology field (Campath and Zevalin) and has some products in phase II studies and in phase III trials (PTK/ZK and MS 275). The parties state that their market shares will remain limited even if this overlap would occur by the introduction of the new products, since Schering has very low national market shares (no more than [0-5]%) on the L1X markets.

38. Therefore, and in the absence of concerns raised by any third party during the market investigation, the concentration is unlikely to significantly impede effective competition in the L1X markets.

V. CONCLUSION

39. 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)
Neelie KROES
Member of the Commission

[11] E.g. Case COMP/M.3571 –Novartis/Hexal, Decision of 27 May 2005, p. 19, Case COMP/M.3928 – TEVA/IVAX, Decision of 24 November 2005, para. 51;.