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Case No COMP/M.3493 - YAMANOUCHI / FUJISAWA

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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

Brussels, 18-VIII-2004

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PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying Parties

Dear Sir/Madam,

Subject: Case No COMP/M.3493 - Yamanouchi / Fujisawa
Notification of 14 July 2004 Article 4 of Council Regulation (EC) No. 139/2004[1]

1. On 14 July 2004, the Commission received a notification of a proposed concentration whereby the Japanese undertakings Yamanouchi Pharmaceutical Co., Ltd ("Yamanouchi") and Fujisawa Pharmaceutical Co., Ltd ("Fujisawa") enter into a full merger within the meaning of Article 3(1)(a) of the Merger Regulation.

I. THE PARTIES AND THE OPERATION

2. Both **Yamanouchi** and **Fujisawa** are active in the research and development ("R&D"), manufacture and sale of pharmaceutical products for the treatment of human illnesses and diseases. […]

3. The transaction takes the form of a statutory merger under Japanese law, with Yamanouchi as the surviving entity. The operation, therefore, constitutes a concentration under the Merger Regulation.

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1 OJ L 24, 29.1.2004 p. 1

II. COMMUNITY DIMENSION

4. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion (Yamanouchi EUR 3,194 million, Fujisawa EUR 2,923 million)[2]. Each of the parties has a Community-wide turnover in excess of EUR 250 million (Yamanouchi EUR 515 million, Fujisawa EUR 394 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.

III. COMPETITIVE ASSESSMENT

A. Relevant Product Markets

(i) Overview

With an annual turnover of approximately EUR 3 billion each, Yamanouchi and Fujisawa are medium-sized pharmaceutical companies. In the EEA, the merger gives rise to limited horizontal and vertical overlap in the following markets.

(ii) Horizontal Effects

5. The parties argue that the relevant product markets should be defined according to third-level Anatomical Therapeutic Chemical classification ("ATC 3"), as the narrowest possible market definition. On this basis, horizontal overlap arises in the following markets:

- Germany: C8A (Calcium antagonist, plain); J1F (Macrolides and similar type)
- Ireland: A2B (Antiulcerants); D10A (Topical anti-acne preparations)
- Italy: A3A (Plain antispasmodics and anticholinergics)

6. In addition, there are overlaps between a number of Phase III R&D projects awaiting authorisation of Yamanouchi and products currently sold in the EEA by Fujisawa, and vice versa. Such overlap occurs in the following ATC 3 areas:

- M1A (Anti-rheumatics, non-steroidal), currently sold by Fujisawa
- G4B (Other urological products), currently sold by Fujisawa
- J2A (Systemic agents for fungal infections), currently sold by Yamanouchi
- R3A (B2-stimulants), currently sold by Yamanouchi in Spain (as well as by Fujisawa in Germany)

7. Whether ATC 3 is indeed an appropriate aggregation level for market definition purposes in these product areas can be left open, as no competition concerns arise under

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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). To the extent that figures include turnover for the period before 1.1.1999, they are calculated on the basis of average ECU exchange rates and translated into EUR on a one-for-one basis.

either ATC 3 or any wider or narrower (e.g. ATC 4, where available) product market definition.

(iii) Vertical Effects

8. Both Yamanouchi and Fujisawa produce a number of active ingredients that are used for pharmaceutical products in downstream markets where the other party also sells products. Vertical overlap occurs in the following areas:

Yamanouchi products used in downstream market where Fujisawa is active:

- Famatodine: used in A2B (Antiulcerants)
- Formoterol fumarate : used in R3A (B2 stimulants)
- Cefotetan used in J1D (Cephalosporins)

Fujisawa products used in downstream market where Yamanouchi is active:

- Ceftizoximine sodium used in J1D (Caphalosporins)
- Cefixime used in J1D (Caphalosporins)
- Cefdinir used in J1D (Caphalosporins)
- Prifinium bromide used in A3A (Plain antispasmodics and anticholinergics)
- Nilvaldipine used in C8A (Calcium antagonists, plain)
- Thioctic acid amide used in A16A (Other alimentary tract and metabolism products)

9. In previous decisions, the Commission concluded that active ingredients form a separate market which is upstream to the market for finished pharmaceutical products. However, as the transaction raises no competition concerns the exact definition of the relevant product market can be left open.

B. Relevant Geographic Market

(i) Horizontal Markets

10. The parties appear to agree with the Commission's past practice that the relevant geographic market for pharmaceutical products is national.

11. For R&D, the parties argue that the market is worldwide in scope. However, even on an EEA-basis, the transaction does not lead to any competition concerns.

(ii) Vertical Markets

12. The parties submit that the active ingredient markets are at least EEA-wide and may be European-wide or even worldwide in scope. However, the exact market definition can be left open as no competition concerns arise even under an EEA-wide market definition.

C. Assessment

(i) Horizontal Effects

13. The operation gives rise to one affected market at the final product level, namely the market for D10A (Topical anti-acne preparations) in Ireland, where Yamanouchi has a market share of [30-40]% and Fujisawa has a market share of [0-10]% (parties' estimates by value based on 2003 figures by Intercontinental Medical Statistics ("IMS")). However, a number of major competitors operate in Ireland, and they are likely to be able to substantially increase their supplies in response to a small price increase in this relatively small national market:

D10A, Ireland

Company	**Market share (by value)**
Yamanouchi/Fujisawa	[30-40]%
Galderma	[20-30]%
Pharmacia & Upjohn	[10-20]%
Boots Healthcare	[0-10]%
Schwarz Pharma	[0-10]%
Quinoderm	[0-10]%
Janssen Cilag	[0-10]%
Monmouth Pharm	[0-10]%

14. On the basis of the parties' market share estimates, the HHI in this market is just below 2000 ([…]) and the delta is [well below 250]. The market investigation included a number of customers and competitors in Ireland, who confirmed that no competition concerns will arise from the notified transaction.

15. Further horizontal overlap arises in Italy, where the combined market share for A3A amounts to [10-20]% ([10-20]% + [0-10]%). In the remaining markets with horizontal overlap (A2B in Ireland; C8A and J1F in Germany), the parties' combined market shares range from [0-10]%. The market investigation indicates that no significant competitive effects arise in these areas.

16. As far as existing products are concerned, an ATC 4 classification exists for only one of the above product areas, A2B. However, the parties' product portfolios do not overlap on an ATC 4 basis as they are active in different product classifications (Yamanouchi: A2B4, Fujisawa: A2B2), according to the parties. The market investigation has found no indications that competition concerns may arise under any other possible market definition, either narrower or wider than ATC 3.

17. As regards overlap between advanced R&D activities and existing products, the respective party's market shares for the relevant current products remains below 25% in all cases, at both the ATC 3 and ATC 4 level. (In fact, market shares are below 10%, except in M1A where Fujisawa has [10-20]% in Ireland. At the ATC 4 level, the only overlap between existing and pipeline products occurs in Spain, where Yamanouchi has [0-10]% in R3A3 and Fujisawa has a corresponding pipeline product.) This conclusion holds both on the basis of a worldwide and an EEA market. As a result, the market investigation found no indications that the transaction may significantly impede effective competition in any part of the Common Market.

(ii) Vertical Effects

18. Both Yamanouchi and Fujisawa have significant market shares (between 30% and 99%) in the active ingredients listed in the market definition section above, mainly because of past or current patent rights. However, the arising vertical overlap is marginal.

19. There is no supply relationship between the parties for active ingredients manufactured by Yamanouchi and Fujisawa's current market share remains significantly below 25% (and also below 15%) in all related downstream products in all EEA countries. That is, Fujisawa's products are based on active ingredients other than those produced by Yamanouchi in those countries where it is active at the downstream level.

20. Likewise, there is no supply relationship between the parties for active ingredients manufactured by Fujisawa and Yamanouchi's current market share remains significantly below 25% in all related downstream products in all EEA countries. Yamanouchi's highest downstream market share arises in Italy, where it has approximately [10-20]% market share in the A3A category (with a product based on active ingredients other than those supplied by Fujisawa). Apart from Italy, Fujisawa's downstream market shares are well below 10%.

21. As result, the market investigation has found no indications that the merged company would find it profitable, or indeed technically feasible, to engage in a foreclosure strategy based on its strong (patent-related) positions in some active ingredients and the related downstream market presence.

IV. CONCLUSION

22. 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)
Franz FISCHLER
Member of the Commission