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*Case No IV/M.555 -
GLAXO / WELLCOME*

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**REGULATION (EEC) No 4064/89
MERGER PROCEDURE**

Article 6(1)(b) NON-OPPOSITION
Date: 28/02/1995

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.2.1995

MERGER PROCEDURE
ARTICLE 6(1)b DECISION

PUBLIC VERSION

To the notifying party

Dear Sirs,

Subject : Case No IV/M.555 - GLAXO/WELLCOME
Notification of 30th January 1995 pursuant to Article 4 of Council Regulation
No 4064/89.

1. On 30th January 1995 Glaxo plc ("Glaxo") notified a public bid for the acquisition of Wellcome plc ("Wellcome").
2. After examination of the notification, the Commission has concluded that the notified operation falls within the scope of Council Regulation No. 4064/89 and does not raise serious doubts as to its compatibility with the common market.

I. THE PARTIES AND THE OPERATION

3. The case was notified on 30th January 1995. The proposed operation consists in the acquisition, by way of a public bid, of Wellcome by Glaxo, both of which are U.K. pharmaceutical companies.

II. CONCENTRATION

4. The takeover of Wellcome by Glaxo by way of a public bid is a concentration within the meaning of article 3(1) (b) of the merger regulation.

III. COMMUNITY DIMENSION

5. The combined worldwide turnover of the parties exceeds 5.000 million ECU. The aggregate Community wide turnover of each party exceeds 250 million ECU. They do not achieve more than two-thirds of their turnover in one and the same Member State. The operation therefore has a Community dimension.

IV. THE RELEVANT MARKETS

A. Relevant Product Market

6. Medicines can be broken down into therapeutic classes according to the Anatomical Therapeutic Classification ("ATC") which is recognized and used by the World Health Organization. This classification, previously used by the Commission,¹ enables medicines to be grouped according to their composition and therapeutic properties.
7. The third level classes of the ATC classification provide a grouping of medicines according to their therapeutic indications, that is, their intended use and therefore may be accepted as an operational market definition. It may be necessary, however, to carry out analyses at other levels of ATC classification where it is appropriate to group particular 3rd level categories together, for example. This will be the case where products from different ATC classes compete as possible treatments for a specific diagnosed medical condition.
8. Furthermore, medicines may be subdivided into different segments on the basis of different criteria which may lead to distinctions, essentially from a demand-side point of view. A distinction may be made between medicines which are subject to medical prescription ("prescription-only" medicines) and medicines which are not subject to medical prescription ("non prescription" medicines). A distinction may also be made between medicines which are wholly or partially reimbursed under the health insurance system and medicines which are not reimbursed. These segments overlap to a certain extent. Most of "prescription only" medicines are reimbursed and most of "non prescription" medicines are not reimbursed. Moreover, the presence of one medicine in one segment is not permanent to the extent it is linked to decisions of competent authorities which can lead to switches between these segments.
9. In the pharmaceutical sector, in order to be complete a competition assessment will require scrutiny of products which are not yet on the market but which are at an advanced stage of development (normally after a very considerable investment of resources of time and money). The potential of such products to compete with other products, either in development or already on the

¹ Decision IV/M.072 - Sanofi/Sterling Drug (10.6.91)
Decision IV/M.323 - Procordia/Herbamont (20.04.93)
Decision IV/M.426 - Rhône Poulenc/Cooper (18.04.94)
Decision IV/M.457 - La Roche/Syntex (20.06.94)
Decision IV/M.500 - AHP/American Cyanamid (19.09.94)

market, can only be assessed by reference to their characteristics and intended use. In some areas, any such attempt at product market definition may be problematical (in the HIV/Aids area, for example.)

10. On the basis of the screening of the products sold by Glaxo and Wellcome by reference to the ATC classification, the notifying party has identified the following affected markets:
- Antiemetics-antinauseants.
 - Systemic antibiotics.
 - Anti-migraine treatments.

Anti-emetics

11. The ATC has a category A4A covering a range of anti-emetic products. However, certain products from ATC category A3F may be considered reasonable substitutes for A4A products, according to data supplied to the Commission by a number of large pharmaceutical companies. The exact definition of this product market may be left open, since even on the narrowest definition no competition problems arise from the proposed merger (see below).

Systemic Antibiotics

12. The combined market shares of Glaxo and Wellcome for all systemic antibiotics in any Member State is below 10% except Finland where it is [...]². In any case, it seems likely, on the basis of data supplied to the Commission by a number of large pharmaceutical companies that not all systemic antibiotics are inter-substitutable. However, at the third level of the ATC classification, there is no significant overlap as Glaxo and Wellcome market different products which do not directly compete with each other (see Assessment below).

Anti-Migraine Treatments

13. Glaxo considers the ATC classification for anti-migraine products ("N2C") as too narrow. They propose another approach to market definition based on ICD code 346, which includes a wider number of medicines such as non-narcotic analgesics, narcotic analgesics, antiemetics, anti-hypertensives (beta-blockers) and tranquillizers (benzodiazepines)³. However, on the basis of data supplied to the Commission by pharmaceutical companies, it would seem that for most of the above-mentioned products the degree of substitutability with specific anti-migraine "N2C" products is very low or non-existent.

² Business secret deleted. Between 10 % and 20 %

³ It has been suggested by the notifying party that, in a case where a particular ATC category would constitute an excessively arbitrary market definition, the "International Classification of Diseases" (ICD), which is maintained by the World Health Organisation and which classifies medicines with respect to diseases, may provide an alternative pragmatic framework of reference.

14. More specifically, Glaxo has launched a successful anti-migraine product "Imigran" in the EU (since 1991). Imigran has achieved very high market shares in a number of EU Member States and is marketed at a very much higher price than other antimigraine products. In view of its therapeutic characteristics and its high market shares and price, Imigran would currently appear to be a unique product for acute attacks of migraine, at least as far as a significant proportion of migraine patients are concerned.

B. Geographic reference Market

15. The harmonisation of technical legislation within the Community and the entry into force on 1.1.1995 of new marketing authorization procedures for medicines represent the completion of the Single Market Programme from the point of view of scientific and technical requirements for medicines. Since the beginning of 1995 pharmaceutical companies have the option (and indeed the obligation for biotechnology products) to submit an application for authorization of new medicines to the European Medicines Evaluation Agency (EMEA), which later will make a recommendation to the Commission, whose decision is binding on all Member States.
16. The sale of medicines is influenced by the administrative or purchasing policies adopted in Member States by national health services. For example, some countries take direct or indirect measures to influence prices and there are different levels of reimbursement by the social security system for different categories of medicine. For these reasons pharmaceutical prices may differ from one Member State to another. In addition there exists widespread different branding and sizing strategies and distribution systems, which further indicate national market characteristics.
17. If from a pricing point of view markets in the EU remain essentially national, the situation is different with respect to R&D. From the point of view of medical Research and Development of new medicines, pharmaceutical firms compete on a wider basis and generally have world-wide R&D strategies.
18. For the above reasons the impact of this concentration has to be assessed in relation to national markets and, in the area of R&D, to European Union or even World-wide markets.

V. ASSESSMENT

The three affected markets to be assessed are:

1. Anti-emetics
19. For anti-emetics, the parties propose two alternative market definitions. Wellcome's position at EU level is very small, under either product market definition, with shares below [...] ⁴ in the last three years. At national level,

⁴ Business secrets deleted. Less than 5%

Wellcome's market share is below [...] ⁵ in any Member State, excepting Denmark ([...] ⁶ in 1994). In Denmark, Glaxo has a significant share ([...] ⁷), giving a combined share of [...] ⁸.

20. Wellcome only has one product in this area, Valoid (brand name of cycline), with total sales below Ecu 1.5 million. The majority of these sales are outside the EEA, and Wellcome has not actively promoted Valoid for some time in the EEA. Cycline is off-patent and generic versions are available. Furthermore, Valoid does not directly compete with Glaxo's main medicine in this sector, Zofran. Valoid is predominantly used outside the hospital environment, whereas Zofran is essentially used intravenously in hospitals to treat nausea and vomiting caused by chemotherapy and post-operative nausea.

The main competitors in these areas are large, research based pharmaceutical firms like Sandoz, Solvay, Johnson and Johnson, Boehringer Ingelheim.

2. Antibiotics

21. Wellcome's sales of prescription systemic antibiotics represent a small percentage of its sales of medicines (less than 10%) according to its annual report. It also has sales of topical antibiotics sold on non-prescription status. Sales of antibiotics by Glaxo concentrate on cephalosporins, where it faces competition from Lilly, Hoechst and a number of other companies. At the third ATC level, the parties do not have any significant overlap in their activities, and it seems therefore that Glaxo and Wellcome are not direct competitors in the area of antibiotics. Wellcome markets one systemic antibacterial, whose sales have been falling since its patent expired in 1984. It also markets a number of topical antibacterials, off-patent and sold basically as non-prescription medicines. Glaxo's sales of antibiotics concentrate on cephalosporins, predominantly injectables, which tend to be sold in hospital environments.
22. Under a broad product market definition, the market shares of the parties at national and EU level are low. Their share in the EU for all systemic antibiotics are very low ([...] ⁹ for Glaxo in 1994 and [...] ¹⁰ for Wellcome in the same year). Their combined market share is below 10% in any Member State of the EU, excepting Finland (where Glaxo has a share of [...] ¹¹ and Wellcome of less than [...] ¹²). Under a narrower approach to market definition, the parties' activities would not overlap.

3. Anti-migraine

⁵ Business secrets deleted. Less than 5%
⁶ Business secrets deleted. Less than 10%
⁷ Business secrets deleted. Between 40 % and 50 %
⁸ Business secrets deleted. Between 50 % and 60 %
⁹ Business secrets deleted. Less than 10 %
¹⁰ Business secrets deleted. Less than 5 %
¹¹ Business secrets deleted. Between 10 % and 20 %
¹² Business secrets deleted. Less than 5 %

23. With regard to anti-migraine drugs, Glaxo's product (Imigran), which was launched in 1991, appears to have introduced a new therapeutic approach. Prices for Imigran are several times higher than those of other medicines traditionally used for the treatment of migraine attacks. This might lead to the conclusion that Imigran could constitute a market in itself.
24. However, in the notification, Glaxo considers the ATC classification for anti-migraine products as unsuitable. They propose two other approaches. One is based on the estimate of the potential market on the basis of average migraine attacks suffered by an estimate of population suffering migraine. The other one is based on diagnosis ICD code 346, which includes a wider number of drugs such as non-narcotic analgesics, narcotic analgesics, antiemetics, anti-hypertensives (beta-blockers) and tranquillizers (benzodiazepines). Under this approach, suggested by the notifying party, Glaxo's share of sales in the EU amount to [...] ¹³ by prescription counts and to [...] ¹⁴ by value. The share has been progressing significantly in the last 3 years, due to the fact that Imigran has been launched recently. Glaxo's largest shares in national markets by value are [...] ¹⁵ in the UK, [...] ¹⁶ in the Netherlands, [...] ¹⁷ in Sweden, [...] ¹⁸ in Finland. By prescription count, shares are below [...] ¹⁹ in all cases.
25. Market shares for Imigran are considerably higher if the market is defined on the basis of ATC third level code N2C. These range from [...] ²⁰ in those countries where Imigran is normally reimbursed.
26. Although market shares and relative prices of Imigran might suggest the existence of a possible dominant position, the first issue to address with respect to the proposed concentration is not so much whether dominance for Imigran can be established, but rather whether the acquisition of Wellcome by Glaxo would lead to the creation or, if dominance was pre-existing, reinforcement of such a position.
27. Wellcome has one anti-migraine drug on the market, Migril, which is Wellcome's brand for ergotamine. Ergotamine has been off-patent for over twenty years and is supplied in generic and branded form by a number of other companies, including large pharmaceutical groups. Sales of Migril in the EU represent approximately Ecu 4.2 million and its share of ATC class N2C in any national market in the EU is below [...] ²¹ with the exception of France ([...] ²²) and Ireland ([...] ²³). The price of a typical daily dosage of Migril costs

¹³ Business secrets deleted. Less than 10 %

¹⁴ Business secrets deleted. Between 30 % and 40 %

¹⁵ Business secrets deleted. Between 60 % and 70 %

¹⁶ Business secrets deleted. Between 70 % and 80 %

¹⁷ Business secrets deleted. Between 70 % and 80 %.

¹⁸ Business secrets deleted. Between 50 % and 60 %

¹⁹ Business secrets deleted. Less than 40 %

²⁰ Business secrets deleted. 40 % to 90 %

²¹ Business secrets deleted. Less than 5 %

²² Business secrets deleted. Less than 10 %

²³ Business secrets deleted. Between 10 % and 20 %

approximately [...] ²⁴ times less than Glaxo's Imigran. It does not seem therefore that, even if the product is considered to be in the same product market as Imigran, the removal of Wellcome's product as a possible competitor to Imigran could raise serious concerns under the merger regulation.

28. Both Glaxo and Wellcome carry out research in the area of antimigraine products, and they both have antimigraine drugs in clinical trials (compound 311C for Wellcome and a number of products for Glaxo, the most advanced being naratriptan). Wellcome's product is in phase III clinical trials, and, subject to the necessary reservations and uncertainties regarding the successful marketing authorization of a new medicine, it is expected to reach the market during 1997. The mode of action/pharmacological profile of 311C is similar to that of Imigran and may, therefore, compete closely with it. It is being developed for the treatment of migraine attacks as opposed to prophylactic treatment of migraines.
29. To remove any possible doubts as to the compatibility of the notified transaction with the common market, Glaxo has undertaken to grant an exclusive licence to a third party to accomplish the development and market independently either Wellcome's 311C or Glaxo's naratriptan. Glaxo reserves itself the right to choose which compound to licence after it has had access to the necessary information to evaluate the results obtained so far during the clinical trials of Wellcome's compound.
30. In any event the Commission has examined in its enquiry whether there are other compounds in a similar situation to that of Wellcome's 311C, in order to verify that the acquisition of Wellcome by Glaxo would not result in a significant reduction of potential competition within the market for anti-migraine products.
31. The enquiry has specifically focused on products with the same mode of action/pharmacological profile being developed as direct competitors of Glaxo's Imigran for the treatment of attacks. The Commission has had confirmation that several pharmaceutical firms currently have compounds of these characteristics under research and development. Some of these companies are large multinational groups ranking among the top pharmaceutical firms worldwide. Among them there would appear to be at least two which have progressed with their R&D programmes in this field, like Wellcome, up to Phase III of clinical trials, i.e. trials in larger patient groups with the purpose of determining the short- and long-term safety/efficacy balance of formulations of the active ingredient, as well as to assess its overall and relative therapeutic value. The latter companies have indicated that their compounds could reach the market before the end of the decade. Although it should also be observed that in the pharmaceutical sector uncertainties always remain about the materialization of potential competition into successfully competing products, even for compounds in Phase III of clinical trials, the identified potential competitors are in a very similar situation to that

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Business secrets deleted. Between 10 and 20

of Wellcome, and the effect of the removal of Wellcome as a possible competitor of Glaxo's Imigran is therefore limited.

Non-affected markets.

32. Wellcome's main area of strength is in the area of antivirals. Wellcome markets Retrovir, the leading drug in the therapy of HIV and AIDS. There are very few products approved so far in this area which fight the virus itself. Information on sales of these antivirals is limited, but the notifying party estimates that Retrovir would account for nearly [...] ²⁵ of the sales of antiretroviral drugs used in France, the other available drug being DDI.

Glaxo does not have an antiretroviral drug itself. However, it is developing a treatment (known as 3TC), which Glaxo believes will be licensed (if at all) only for use with Wellcome's Retrovir, as a complementary product.

33. The proposed concentration will combine the R&D resources and expertise of two leading firms in this area. Nevertheless, in the absence of a definitive treatment for HIV/AIDS, the combination Glaxo/Wellcome is not likely to inhibit to a significant extent the research for effective compounds for the treatment of HIV infections, being undertaken by other pharmaceutical companies.

There are no other fields of overlap in R&D raising competition concerns.

VI. CONCLUSION

34. 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 functioning of the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of Council Regulation No 4064/89.

For the Commission,

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Business secrets deleted. Between 75 % and 85 %