EN

Case No COMP/M.2312 - ABBOTT / BASF

Only the English text is available and authentic.

REGULATION (EEC) No 4064/89
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 28/02/2001

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COMMISSION OF THE EUROPEAN COMMUNITIES

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In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EEC) No 4064/89 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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
6(1)b DECISION

To the notifying party

Dear Sirs,

Subject: Case No COMP/M.2312 - ABBOTT/BASF
Your notification of 26.01.2001 pursuant to Article 4 of Council Regulation No 4064/89[1]

1. On 26.01.2001**,** the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EEC) No 4064/89 ("the Merger Regulation") by which the Abbott Group ("Abbott") acquires within the meaning of Article 3(1)(b) of the Council Regulation the worldwide pharmaceutical business of BASF Aktiengesellschaft (jointly referred to as "BASF").

2. After examination of the notification, the Commission has concluded that the notified operation falls within the scope of the Merger Regulation as amended 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. Abbott (USA) is a global health care company listed on the New York, Chicago, Pacific and London exchanges. It develops, manufactures and markets pharmaceutical, nutritional, hospital and diagnostic products. It has more than 135 manufacturing, distribution and R&D facilities in more than 130 countries.

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[1] OJ L 395, 30.12.89 p.1; corrigendum OJ L 257 of 21.09.90, p.13; Regulation as last amended by Regulation (EC) No 1310/97 (OJ L 180, 09.07.97, p.1, corrigendum OJ L 40, 13.02.98, p.17).

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4. BASF (Germany) is a global company active in chemical, health and nutrition, and oil and gas sectors. It is listed on the Frankfurt, London and Zurich stock exchanges. The pharmaceutical division of its Health & Nutrition segment manufactures drugs for treating thyroid deficiencies, obesity-related disorders, diseases of the cardiovascular and central nervous systems analgesics and pharmaceutical active ingredients.

II. THE OPERATION

5. The notified operation consists of an acquisition by Abbott of the worldwide pharmaceutical business of BASF consisting, among other things, of BASF Pharmaceutical Corporation, Knoll AG and Knoll GmbH. Abbott will acquire from BASF 100% of the voting securities of BASF's pharmaceutical subsidiaries, and also certain assets of BASF consisting of patents, patent applications and perpetual patent licences. The acquired business includes BASF's pharmaceutical products, as well as BASF active ingredients which are used for BASF pharmaceutical products or for both BASF and third party pharmaceutical products.

III. CONCENTRATION

6. By the proposed operation, Abbott will acquire sole control over BASF's worldwide pharmaceutical business. Therefore the operation is a concentration.

IV. COMMUNITY DIMENSION

7. Abbott and BASF have a combined aggregate world-wide turnover in excess of EUR 5,000 million (in 1999 Abbott: EUR 12.4 billion, BASF: EUR 2.2 billion). Each of them have a Community-wide turnover in excess of EUR 250 million (in 1999 Abbott: EUR […] billion, BASF: EUR […] million), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The operation does not qualify for co-operation with the EFTA surveillance authority pursuant to the EEA Agreement.

V. COMPETITIVE ASSESSMENT

A. Relevant product markets

8. The economic sector concerned in this case is the pharmaceutical business. In several recent pharmaceutical cases (M.1378 Hoechst/Rhône-Poulenc, M. 1397 Sanofi/Synthélabo, M.1403 Astra/Zeneca, M.1835 Monsanto/Pharmacia & Upjohn, M.1846 Glaxo Wellcome/SmithKline Beecham, M.1878 Pfizer/Warner-Lambert), the Commission has found that product markets in the pharmaceutical industry can be grouped into existing pharmaceutic specialities, active substances and future products. In the present case, the parties' activities overlap only in pharmaceutic specialities and future products.

1. Pharmaceutic specialities

9. Pharmaceutical products are used for the treatment of human illnesses and diseases. Prescription/ethical medicines are pharmaceutical products exclusively accessible by way of medicinal prescription and subject, for the main part, to reimbursement through social security schemes. OTC drugs are "over-the-counter" pharmaceutical products certain of which can be prescribed by a doctor and may be reimbursable through a social security scheme.

10. In its previous decisions, 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 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 level (ATC 3) allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use, and can therefore be used as an operational market definition. These groups of products generally have the same therapeutic indication and cannot be substituted by products belonging to other ATC 3 classes.

11. The Commission has in earlier decisions considered that it may be appropriate in certain cases to carry out analyses at other levels of the ATC classification. For example, it may be necessary to combine certain groups of pharmaceutic specialities or it may also be appropriate to apply a narrower market definition.

12. In this case, the parties have provided data on the basis of the ATC 3 classification level. In human pharmaceuticals, the parties have overlapping activities in 3 treatment areas. These treatment areas are haematinics.iron & combinations (B3A), macrolides & similar type (J1F) and other therapeutic products (V3A).

a) Haematinics.iron & combinations (B3A)

13. The parties have submitted that haematinics.iron & combinations (B3A) should be assessed at the ATC 3 level. The Commission's investigation supports this view.

b) Macrolides & similar type (J1F)

14. The parties have submitted that macrolides & similar type (J1F) should be assessed at the ATC 3 level. Some third parties have, however, indicated that the assessment could also be carried out at the more general level or in combination of several classifications. The reasons for this are according to third parties that marcolide antibiotics compete generally with other antibiotics, such as penicillins and cephalosporins, and that many bacterial infections can be treated by a range of antibiotics.

15. It is not necessary, however, to reach a conclusion on the exact market definition in this case because in all alternative market definitions considered, the operation would not lead to the creation or strengthening of a dominant position.

c) Other therapeutic products (V3A)

16. The parties have submitted that their products, which are relevant for the assessment of this case, are in fact completely different and do not materially overlap. The parties have submitted that Abbott's product Neo Synephrine is used to maintain blood pressure during inhalation anaesthesia while BASF's products Calciumfolinat and Calciumlevofolinat are antidotes/modulators in cancer therapy using methotrexate. The parties argue that a third level ATC overlap only appears because of the catch-all nature of class V3A. A number of third parties have confirmed in their replies to the Commission's questionnaires that the parties' products are intended for different indications and do not overlap.

17. It is not necessary, however, to reach a conclusion on the exact market definition in this case because in all alternative market definitions considered, the operation would not lead to the creation or strengthening of a dominant position.

2. Future products

18. In the pharmaceuticals industry, a full assessment of the competitive situation requires examination of the products which are not yet on the market but which are at an advanced stage of development. As noted in the Ciba-Geigy/Sandoz decision[2], R&D projects undergo three different phases of clinical testing: Phase I marks the start of clinical testing on humans, currently some eight to ten years before a product is marketed. Statistically, projects in phase I generally have no more than a 10% chance of being successful. Phase II, some four to five years before the product is marketed, involves working out the proper dose for the patient and defining the areas of application. The success of phase II is generally acknowledged to be approximately 30%. Phase III, starting three years before the product is marketed, involves establishing the product's effectiveness on larger groups of patients. The risk of failure in phase III is reported to be over 50%.

19. Regarding future products, the Commission has to look at R&D potential in terms of its importance for existing markets, but also for future market situations. The relevant markets for future products often cannot be defined in the same manner as for existing products, except if the future products intend to replace existing products. The potential for these products to enter into competition with other products which are either at the development stage or already on the market can be assessed by reference to their characteristics and intended therapeutic use. Market definition can thus be based either on the existing ATC classes or it can be guided primarily by the characteristics of future products as well as by the indications to which they are to be applied.

20. In the current transaction, the parties overlap in the development of future products only to a very limited extent and they submit that there are no affected markets. However the Commission considers that BASF and Abbot have respectively a pipeline and an existing product in the treatment of arthritis and both parties have pipeline products in the area of endothelin-A receptor antagonists. These will be discussed further below.

a) Treatment of arthritis

21. BASF's primary pipeline product, D2E7, is a fully human monoclonal antibody for the treatment of rheumatoid arthritis (RA). It works by neutralising tumour necrosis factor alpha which is a protein that accumulates disproportionately in the joints resulting in inflammation, swelling and joint damage. D2E7 interrupts the process that leads to rheumatoid arthritis. D2E7 is currently undergoing Phase III trials and is expected to be launched in the EU in 2003. It is expected to be labelled for severe cases of RA and is intended to be a disease-modifying treatment.

22. Abbott currently markets an anti-inflammatory, meloxicam, which is labelled for the relief of symptoms of osteoarthritis and is classified under M1A in the ATC system.

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[2] IV/M.737 – Ciba-Geigy/Sandoz, Commission decision of 4.2.1998

Abbott claims that meloxicam, a non-steroidal anti-inflammatory drug is for treatment of the inflammation symptoms and does not treat the disease itself.

23. The market test has confirmed that the two products are completely different in terms of medical use. Human monoclonal antibody is developed to treat RA and it is classified in the M1C ATC Class (specific anti-rheuma product). An anti-inflammatory does not treat RA but is used to relieve pain and is classified as M1A. On the basis of the investigation, the Commission has concluded that the two products are not competing with each other and, therefore, belong to separate product markets.

24. Abbott also has a pipeline product, ABT-963, a Cox-2 inhibitor, in early phase I clinical trials. This is intended for the treatment of symptoms of RA and osteoarthritis and is not a disease-modifier like D2E7. Therefore there would not be any overlap with BASF future product D2E7.

25. On the basis of the foregoing, the Commission considers that the treatment of arthritis does not constitute an affected market.

b) Endothelin-A receptor antagonists

26. Abbott claims that the parties' respective endothelin-A receptor antagonists are not being trialed for the same indications and could not be adapted without considerable additional time and expense.

27. BASF has a cardiovascular pipeline product, Darusentan, which is currently in Phase IIa clinical trials for congestive heart failure and hypertension indications. BASF also has another endothelin-A receptor antagonist, BSF 208075, in Phase II trials in the United States for cardiovascular indications.

28. Abbott's pipeline product, ABT-627, is in Phase III clinical trials in respect of prostate cancer indications. Abbott states that in order to be approved for cardiovascular indications, instead of prostate cancer, ABT-627 would require at least five years of further trials and considerable extra expense since development hurdles are less for oncology products. This has been widely confirmed by the market test. Abbot adds that BASF's cardiovascular products are currently at least two years behind Abbott's cancer product and Phase II trials would have to be repeated if it were to be suitable for cancer indications. Abbott considers that, consequently, even if both products reached the market, no competition between these products is likely in the short or medium term.

29. The precise market definition can be left open for the purpose of the present assessment since no competition concerns arise in the area of endothelin-A receptor antagonists, whatever market definition is considered.

B. Relevant geographic markets

1. <u>Pharmaceutic specialities</u>

30. The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope, despite the trend towards standardisation at a European level. The sale of medicines is influenced by the administrative procedures or purchasing policies which the national health authorities have introduced in Member States. Some countries exercise a direct or indirect influence on prices, and there are different levels of reimbursement by the social security system for different categories

of medicines. For this reason, the prices for medicinal products may differ from one Member State to another. In addition, there are far reaching differences in terms of brand and pack-size strategies and in distribution systems. These differences lead to national market characteristics.

31. The results of the investigation in this case do not suggest that the Commission should deviate from its previous practice in assessing pharmaceutical markets at the national level. Therefore, the markets for pharmaceutic specialities affected by the concentration will be regarded as national.

2. Future products

32. To the extent that products not yet on the market must be taken into account on the basis of research and development in particular areas, the said national restrictions do not have the same degree of effectiveness than for existing pharmaceuticals. Normally, a characteristic of such products is that they have not yet been registered. Because research and development is normally global, the consideration of future markets should therefore at least focus on the territory of the Community and possibly on world-wide markets.

C. Assessment

1. Pharmaceutic specialities

a) Haematinics.iron & combinations (B3A)

33. The activities of the parties in this product category overlap only in Belgium where the combined market share of the parties will be [30-40%], with an increment of [5-10%] (BASF). The new entity would face competition in particular from Grünenthal, who is the market leader with [30-40%] of the market, and from Trenker, who currently has [20-30%] of the sales in this category. Therefore, in view of these market shares, the Commission considers that the transaction is unlikely to lead to the creation or strengthening of a dominant position.

b) Macrolides & similar type (J1F)

34. The only overlap between the parties' activities in this narrow product category occurs in Spain, where the parties would jointly attain a market share of [25-35%], with an increment of [<1%] (BASF). Pfizer has [10-20%] of the market and Aventis [5-15%]. Should a wider market definition be used, the investigation shows that the parties' market shares would be even lower.

35. In view of the parties' market position and in particular the small increment of market share, the Commission considers that the transaction will not lead to the creation or strengthening of a dominant position.

c) Other therapeutic products (V3A)

36. Both parties are active in this product category only in Austria. Should the parties' products be considered to overlap, the combined market share would be [10-20%] with an increment of [<1%] (Abbott). The Commission considers that the parties' market position is unlikely to lead to adverse effects on competition on this market.

Conclusion

37. On the basis of the foregoing and supported by the investigation conducted in this case, the Commission considers that the operation as notified will not lead to the creation or strengthening of a dominant position as a result of which effective competition would be significantly impeded in any national market in pharmaceutic specialities.

2. Future Products

38. There has been a global move to consolidation within the pharmaceuticals industry in recent years in response to a rapidly changing business environment characterised by efforts to react to health-care costs containment, increasing R&D costs, new therapies, and the desire to achieve both synergies and economies of scale. Size is an increasingly important competitive factor in the pharmaceutical industry. It allows firms to leverage increasing R&D costs across a broader range of products and to spread the risk inherent in every new research project over a large capital base. The greater resources of a larger company can be used to fund additional R&D projects, to devote more resources to long term projects and to increase spending on already advanced projects to accelerate the development process.

39. Notwithstanding the ongoing consolidation in the global pharmaceutical industry, the industry remains largely fragmented with no single pharmaceutical company accounting for more than 8% of the 1999 world market. GlaxoSmithKline rank first in the world with 7.3% of worldwide pharmaceutical sales, followed by Pfizer (6.7%), AstraZeneca and Aventis.

40. Abbott and BASF are also both strong players in the research and development, manufacture and supply of human pharmaceuticals. Their merger will create the 14th largest pharmaceutical company in the world. However, on world-wide basis, the new entity will remain subject to strong competition from numerous multinational companies. In addition to GlaxoSmithKline and Pfizer, Merck&Co, Brystol-Myers Squibb, Novartis, Pharmacia, Hoffman-La Roche, Johnson & Johnson, American Home Products and Eli Lilly continue to be larger competitors.

41. Research and development is an important element in competition among pharmaceutical companies. The global pharmaceutical market is characterised by a significant number of players undertaking significant R&D. Manufacturers meet this challenge by focusing on innovation. Frequently this research is carried out in-house by the pharmaceutical companies themselves, but important R&D also occurs through numerous academic and commercial laboratories. Because the investments required for pharmaceutical R&D can be financed only if a company is able to generate the necessary cash flow during the relevant period of patent protection of the product development, the pharmaceutical companies consider that it is essential to launch the products on the markets of large industrialised countries as quickly as possible. The survival of large pharmaceutical companies depends on the profitability of a small number of products and also on the regular renewal of a portfolio of patents on new pharmaceutical products.

42. Abbott claims that its larger size will ensure that sufficient resources are available to bring new products, such as the pipeline D2E7 rheumatoid arthritis product to the market and to invest in new R&D.

43. With regard to *endothelin-A receptor antagonists*, the investigation has confirmed that the products being directed in two different therapeutic ways, it would be very difficult

to trial them for the same indication. If so, that would request a full development (from Phase I) and would take at least [5-10] years and would cost around € 50 Million .

44. Even if it was possible to adapt any oral endothelin-A receptor antagonist to both oncology and cardiovascular indications, the proposed operation would not raise any competition concerns since the market investigation has confirmed that there are over 10 known endothelin-A receptor antagonists being developed by Abbott's competitors (Actelion/Roche, Vanguard/Roche, Texas Biotech/Icos, Merck & Co, Takeda, GlaxoSmithKline, Shionogi, Yamanouchi and Pfizer) for a variety of indications ranging from congestive heart failure to prostate cancer. Additional compounds are also undergoing preclinical evaluation by several pharmaceutical companies.

Conclusion

45. In view of the above elements, the Commission considers that the operation will not create or strengthen a dominant position as a result of which effective competition would be significantly impeded in any national market in future pharmaceutical products.

VII. CONCLUSION

46. 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 (EEC) No 4064/89.

For the Commission,