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Case No IV/M.072 - SANOFI / STERLING DRUG

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REGULATION (EEC) No 4064/89
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
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COMMISSION
OF THE EUROPEAN
COMMUNITIES

Brussels 10.6.1991

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

Registered with advice of delivery

To : Notifying parties.

Dear Sirs,

Subject : Case No IV/M072 -Sanofi/Sterling Drug.
Notification pursuant to Article 4 of Council Regulation No 4064/89.

1. The abovementioned notification concerns a series of agreements between Sanofi, a French company controlled by Elf Aquitaine, and Sterling Drug Inc ("Sterling Drug"), a wholly owned subsidiary of the Eastman Kodak company, by which Sanofi and Sterling Drug propose to combine their worldwide human prescription drug ("ethical") pharmaceutical activities (excluding Japan) and all their European human over-the-counter or non-prescription ("OTC") pharmaceutical activities.

2. After full examination of the notification the Commission has come to the conclusion that the notified operation falls within the scope of Council Regulation No 4064/89 (Merger Regulation) and does not raise serious doubts as to its compatibility with the common market.

I. THE PARTIES AND THE NOTIFIED OPERATION

3. Sanofi is currently active in three main sectors : human health, including ethical, OTC pharmaceutical and diagnostic products; agro and food business (additives, ingredients, surfactants, aromas, veterinary products and biotechnological applications); and perfumes and cosmetics. It is the second largest French pharmaceuticals manufacturer and was ranked 35th worldwide in 1989.

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Its main geographical markets are in Europe, Africa, South America and Asia. It has no direct presence in the USA as far as ethical and OTC pharmaceutical products are concerned.

4. Sterling Drug is currently active in two sectors : human health, including ethical and OTC pharmaceutical products; and household cleaning and other products. It was ranked the 37th largest pharmaceutical company worldwide in 1989. The majority of its sales are achieved in the USA, with remaining sales mainly in Europe.

5. The parties have entered into a number of agreements, collectively entitled the "Alliance", and which include the setting up of joint ventures, by which they propose to combine their ethical prescription activities worldwide, excluding Japan, and their European OTC activities. In each case the parties will combine their existing manufacturing, administration, marketing, sales, distribution and support operations. In addition, the development of new products will be decided jointly, together with their subsequent registration, manufacture etc.

6. The ethical business will be carried out under the name Sanofi Winthrop. Separate agreements cover Europe, Africa, the Middle East, China and Taiwan (Prescription Venture A) and North America, South America, Central America, Oceania and South East Asia (Prescription Venture B). The overall division of interest of the parties in each venture is as follows : 50.055% to Sanofi, 49.945% to Sterling Drug in Prescription Venture A, and 50.055% to Sterling Drug, 49.945% to Sanofi in Prescription Venture B. The OTC venture will be carried out under a name yet to be decided, under Sterling Drug's control for day to day business.

II. CONCENTRATION

7. The proposed transaction is a concentration within the meaning of Article 3 of Regulation 4064/89. In arriving at this conclusion the Commission has taken into account the following elements :

- the parties merge, transfer, or otherwise lease or license on a permanent basis to operating entities established by the parties their existing production, distribution and marketing assets. All material contracts, government permits and licences (including manufacturing authorisations and product registrations) will be licensed, transferred or assigned. Employees will be transferred to the operating entities.

- product ranges will be marketed under common trade names ("Sanofi Winthrop" for the ethical business, the name for the OTC business as yet undecided),

- With regard to research and development, which is of crucial importance for the ethical business, the parties will continue to carry out their research activities ("discovery process") independently. However, they agree to enable each other to participate in the development of future products right from the initial stages of such development. Moreover, from the stage where new molecules might have a market potential, but before large scale clinical trials are started, all decisions as to further development are taken jointly by the parties.

To this effect a Development Committee is established, in which both parties are equally represented, which will monitor and coordinate all research efforts and which will decide whether or not development should be pursued jointly.

In the event that the committee decides against joint development the parties may not continue development individually, and instead may only assign or license such rights to third parties. With regard to the OTC business, the parties have the choice of carrying out research and development within the "Alliance" or availing themselves of Sterling Drug's facilities outside the territory.

- new acquisitions will be carried out jointly by the parties,

- the management structure will be fully integrated. Each venture provides for a management entity, which includes a strategic management committee responsible for all strategic management decisions, the appointment of financial and operating managers and the establishment of strategic plans including the rationalisation of production facilities, and for an operating committee responsible for the implementation of the strategic and policy decisions and the establishment of annual budgets.

With regard to the ethical business, it is intended that Sanofi has prime responsibility for day to day business in the territory of Prescription Venture A, while Sterling Drug performs the same role in Prescription Venture B. Membership of the strategic management committees reflects their respective equity interests in the two ventures, with Sanofi having five out of eight members on the board in Prescription Venture A, Sterling Drug having five out of eight members on the board of Prescription Venture B. However, qualified majority requirements (that is, an affirmative vote of the majority of the board, including two representatives of each of the parties) applies to certain matters, including, inter alia, the annual adoption of rolling five year strategic plans setting out major business initiatives, proposed financial performance and major synergy benefits targets where appropriate, plus the appointment of members of a nominating committee established to approve the appointment of managers of operations in the most important national markets of the parties. In effect, therefore, both ventures may be considered to be jointly controlled by both parties. In any event, the lead given to the parties in each venture is extremely narrow and the fact that the one exactly mirrors the other would be likely to ensure that the parties act jointly in both territories in all major respects.

With regard to the OTC business, control for day to day business will be with newly created companies in individual countries in accordance with the current interests of the parties in those countries. Sterling Drug, however, will have a 70% interest and five out of eight members on the board of the management company, to Sanofi's 30% and three members. Before taking any action with regard to matters, such as, inter alia, plant closures, acquisitions and divestitures, annual and multi year business plans, the parties shall consult each other at board level.

In the event of a failure to obtain a favourable vote of a majority of Sanofi members, extensive provisions are made in order to seek their agreement. These elements make it possible to consider that Sanofi shares joint control of this venture.

- with regard to the ethical business, while profits deriving from existing products will be divided between the parties in accordance with the value of that contribution, as determined by the parties, profits from new products developed jointly plus any commercial synergies resulting from the Alliance will be shared in virtually equal proportions, according to the equity interests of the parties. With regard to the OTC business the same principle applies, with profits from jointly developed products being shared in most cases in the same virtually equal proportions.

8. The Commission considers that these elements taken together bring about a lasting change in the structure of the undertakings concerned. The operation implies their effective withdrawal from the markets concerned, as they place all their interests in the various joint ventures.

9. This situation thus leaves no room for coordination of conduct as between the parents amongst themselves, or between them and the joint ventures. It is to be recalled that, the OTC venture covers the European market only, leaving Sterling Drug as an independent operator on the USA market. However, by transferring its assets and all its essential rights to the OTC venture, in particular trademarks and products registrations, Sterling Drug will not have any realistic possibility of acting as an independent operator on the European market. As a result there will be no room for coordination of its competitive conduct with that of the joint venture.

III. COMMUNITY DIMENSION

10. The combined aggregate worldwide turnover of the parties to the concentration was 39,009 million ECU in 1990. Both parties meet the requirement of Article 1(2) (b), Sanofi and Sterling Drug each having an aggregate Community-wide turnover of more than 250 million ECU in 1990, of which not more than two-thirds was achieved in one and the same Member State. Consequently, the proposed concentration has a Community dimension.

IV. COMPATIBILITY WITH THE COMMON MARKET

11. The new combined unit will rank among the first 20 largest pharmaceutical firms worldwide and the top 12 worldwide pharmaceutical R & D forces. With regard to the overall OTC market, the "Alliance" Sanofi-Sterling Drug will share with Rhône-Poulenc Rorer the leading position in Europe with about a 3.5 per cent share of a highly fragmented market.

Relevant product market

12. It is inevitable that any workable market definition in the pharmaceutical sector will involve a certain amount of arbitrariness, because in the final resort, substitutability among medicines may not only depend on the intrinsic characteristics of the drug itself, but also their intended use, taking into account the patient's overall condition.

13. The parties submit that the ATC classification of medicines is an appropriate tool for the purpose of defining product markets. This classification is recommended by the World Health Organisation, and most of the national administrations in the Community use it for the purposes of comparing different medicines. It is also the classification used by Intercontinental Medical Statistics (IMS) to establish its drugs sales statistics, which are generally used by pharmaceutical firms for their market analysis.

14. The third level classes of the ATC classification provide a grouping of medicines according to their therapeutic properties, that is, their intended use, and therefore may be accepted as an operational market definition. It may be necessary, however, to carry out analysis at other levels of ATC classification where it is appropriate to group particular 3rd level categories together or to descend to narrower classes at the 4th level.

15. Under this approach, well above 20 different product markets are affected by the proposed concentration. However, given the basic complementarity of Sanofi and Sterling Drug's activities, there is, no significant ovelapping of the parties' activities in the majority of these product markets. A significant reinforcement of market positions does arise, however, in the following markets:

- Bile therapy, cholalogues and choleretics (ATC class A5A).
- Centrally acting muscle relaxants (ATC class M3B).
- Cold preparations without anti-infectives (ATC class R5A).
- Antitussives and expectorants (ATC class R5F).
- Laxative fibres, not corresponding exactly to any ATC class.

16. Within the pharmaceutical industry, it is generally considered that OTC and ethical products constitute two distinct markets, although this distinction may be blurred (for instance ethical products may acquire OTC status after sufficient time has elapsed, conversely a doctor may prescribe an OTC product). However these difficulties do not materially affect the analysis of these markets.

Geographical reference market

17. Because the pharmaceutical industry operates within a very tight legal framework, pharmaceutical markets remain essentially national. No drug may yet be marketed in any Member State without the previous approval of the respective national administration, although procedures for mutual recognition of marketing authorizations exist. Notwithstanding the considerable harmonization achieved so far in the Community with regard to pharmaceutical registration procedures, the evaluation of a drug and the decision to authorize its marketing remains at present with the competent authorities of the Member States.

18. In addition, prices of ethical drugs are directly or indirectly regulated by national laws. The mechanisms used by each Member State to regulate pharmaceutical prices vary widely. They include direct price fixing (as in France, Italy or Spain), overall control of companies' profits (as in the UK), and special provisions affecting the reimbursement of the cost of drugs by the national health insurance systems (as in Germany). The differences in the pricing and reimbursement mechanisms result in wide disparities in drug price levels among different Member States.

19. Prices of OTC drugs are normally excluded from price or reimbursement regulation. However, the markets also remain national for these products because of the following factors: retail distribution is legally confined to pharmacies in certain Member States, whereas in others they are available in other consumer outlets (groceries or supermarkets); the decision to confer OTC status upon a medicine is a national one; the consumer's attitude to self-medication is to a large extent determined by cultural traditions and because of the importance of branding for these products. The existence of national markets is confirmed by the absence of Europe-wide brand names and the fact that there is little or no parallel trade in OTC products, the price of which may vary from country to country.

20. For the purposes of this decision, therefore, and taking into account the particular pharmaceutical markets affected by the proposed concentration, its impact has to be assessed in relation to national markets.

Affected markets

21. The markets affected by the proposed concentration are :

- bile therapy, cholalogues and choleretics in Italy
- centrally acting muscle relaxants in France
- centrally acting muscle relaxants in Germany
- cold preparations without anti-infectives in the Netherlands
- antitussives and expectorants in France
- laxative fibres in Italy.

22. Therefore, the analysis of the compatibility of the proposed concentration with the common market will focus on these product markets.

23. In respect of the bile therapy market (ATC Class A5A in Italy), the aggregation of Sanofi's and Sterling Drug's market shares is not meaningful since their respective products have different indications i.e. therapeutic properties (Deursil is a gall dissolving product whereas Varecolene is a stimulant laxative). In this particular case, therefore, the 3rd level of the ATC classification is not appropriate to define the relevant product market, and an analysis at the 4th level class is more suitable. At this level, no overlapping exists in Italy.

24. In respect of the other markets, which are all OTC markets except for muscle relaxants, the proposed combination of Sanofi and Sterling leads to relatively high market shares ranging between 45% in the laxative market in Italy to 74% in the cold preparations (without anti-infectives) markets in the Netherlands. However, in assessing the importance of these market shares the following elements must be taken into account :

- in all cases, there is some degree of substitution from alternative products not included in the operational market definition given above, because : they are not registered medicines (dietary products in respect of laxatives or sweets in respect of antitussives); or because market studies do not include homeopathic medicines, which may account for a high proportion of the market (as in the case of cold preparations without antiinfectives in the Netherlands); or because drugs classified in other 3rd level therapeutic groups are actually prescribed by doctors for the same indications (such as non steroidal anti-inflammatories or certain analgesics in the case of centrally acting muscle relaxants);

- large pharmaceutical firms, such as Merril Dow, Roussel-Uclaf, Boots, Ciba-Geigy are competitors of Sanofi and Sterling Drug in certain markets (centrally acting muscle relaxants, laxatives or cold preparations) and competition from generic products is well established in others (paracetamol);

- because of the relatively low technological content of the drugs in question and because they have been on the market for a long time, research and patents play a very limited role in these markets. As a result, barriers to entry are not significant, in particular for large pharmaceutical firms.

Conclusions

25. Taking into account:

- the basic complementarity of Sanofi's and Sterling Drug's activities, because of the limited number of product markets in which overlapping occurs,

- the different possibilities for substitution arising from generic products, non-medicines, homeopathic products, and drugs classified in other therapeutic groups in the affected markets,

- the relative ease with which major pharmaceutical firms may enter these markets,

the proposed concentration does not create or strengthen a dominant position in any of the reference markets as a result of which effective competition would be significantly impeded in the common market or in a substantial part of it.

V. ANCILLARY RESTRAINTS

The parties each agree not to enter into competing businesses for the duration of the agreements. These non-competition clauses are aimed at expressing the reality of the lasting withdrawal of the parents from the businesses in question. As such they are an integral part of the concentration and hence ancillary restraints covered by the present decision.

VI. FINAL ASSESSMENT

26. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market. This decision is adopted in application of article 6(1)(b) of Council Regulation No. 4064/89.

For the Commission