EN

Case No IV/M.457 - LA ROCHE / SYNTEX

Only the English text is available and authentic.

REGULATION (EEC)No 4064/89
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 20.06.1994

Also available in the CELEX database
Document No 394M0457

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

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20th June 1994

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying parties

Dear Sirs,

Subject: Case n° IV/M.457 - La Roche/Syntex
Notification of 16th May 1994 pursuant to Article 4 of Council Regulation n° 4064/89

1. On 16th May 1994 Roche Capital Corporation, which is ultimately controlled by Roche Holding AG (ROCHE), notified an agreed public bid for the acquisition of Syntex Corporation (SYNTEX).

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

3. SYNTEX is a U.S. international health care company involved in the development and marketing of human and animal pharmaceutical products and medical diagnostic systems.

   ROCHE is a Swiss-based company involved in the development and marketing of pharmaceuticals, vitamins, diagnostics and other products.

II. THE OPERATION

4. The proposed operation consists in the acquisition (by way of an agreed public bid) of SYNTEX by ROCHE.

Rue de la Loi 200 - B-1049 Brussels - Belgium
Telephone: exchange (+32-2)299.11.11
Telex: COMEU B 21877 - Telegraphic address: COMEUR Brussels

III. COMMUNITY DIMENSION

5. The enterprises concerned have a combined aggregate world-wide turnover calculated in accordance with Article 5(3)(b) of the Merger Regulation in excess of 5,000 million Ecu. Both ROCHE and SYNTEX have a Community-wide turnover in excess of 250 million Ecu but do not achieve more than two-thirds of this turnover in one and the same Member State. Thus the operation has a Community dimension.

IV. THE RELEVANT MARKETS

A. Pharmaceuticals

1. Relevant product markets

6. The ATC classification gives guidance as to how to define product markets for pharmaceuticals. 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 medicines sales statistics, which are generally used by pharmaceutical firms for their market analysis.

   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 use other levels of ATC classification where appropriate in a particular context.

7. Within the pharmaceutical industry, it is generally considered that OTC and ethical products constitute two distinct markets, although this distinction may be blurred. However, these difficulties do not materially affect the analysis of these markets.

2. Relevant geographic markets

8. No medicine may yet be marketed in any Member State without the previous approval of the respective national administration, although procedures for mutual recognition of marketing authorisations exist. Notwithstanding the considerable harmonisation of the scientific criteria for the evaluation of a medicine achieved so far in the Community within pharmaceutical registration procedures, the decision to authorise its marketing remains at present with the competent authorities of the Member States.

9. In addition, prices of ethical medicines 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 medicines by the national health insurance systems (as in Germany). The differences in the pricing and reimbursement mechanisms result in wide disparities in medicine price levels among different Member States.

10. In view of these regulatory constraints, and given different medicine distribution systems, national brands, and different consumer preferences, pharmaceutical markets remain essentially national.

B. Diagnostics

1. Relevant product markets

11. In addition to the pharmaceutical categories mentioned above, the concentration concerns diagnostic systems and test kits for therapeutic medicine monitoring and drug abuse testing.

12. A diagnostic analysis is a procedure for monitoring the physiological condition of a subject. The analytical procedures differ, depending on whether they are designed for analysing the general health condition of a subject, a specific illness, a pre-birth pathology, or whether they concern the reaction of a subject to certain substances.

13. Diagnostics tests can be either in-vitro or in-vivo. While in-vitro tests are carried out outside the body, the in-vivo method concerns the use of diagnostic substances directly in or on the human body. The two methods are complementary for some applications.

14. Major overlaps between ROCHE and SYNTEX occur within the in-vitro area. In-vitro diagnostics can be used in a medical as well as in a non-medical context and they also serve for trials in research institutes.

15. A large part of the in-vitro diagnostics is sold in the form of multi-use diagnostics systems to hospitals, commercial laboratories, university laboratories or other institutions. In addition, a significant quantity of in-vitro diagnostics are marketed as single-use products to general practitioners, public authorities, employers or others, and in some instances they are even sold in the form of self-test kits over the counter (i.e. tests of pregnancy, sugar diabetes, cholesterol or in some states even HIV). Self-test kits probably are complementary to multi-use test kits for some applications.

16. The concentration between ROCHE and SYNTEX concerns primarily multi-use in-vitro diagnostics, which are used on-site. These diagnostics products typically form a system, that is basically a measuring instrument which is designed for the automated operation of several kinds of tests. The reagents for the different tests are supplied as part of a reagent kit which comprises among others a control substance and a test serum to verify the smooth functioning of the measuring instrument. A calibrator serves for regular - often weekly - adjustments of the measuring instruments.

    The main part of the multi-use products business is characterised by a series of test kits which are adapted to a system. Most of the major suppliers offer a package consisting of a measuring instrument, a series of test kits and a comprehensive after-sale service including quality control.

17. The concentration between ROCHE and SYNTEX leads to major overlaps in the field of immunochemistry diagnostics, and more precisely in the area of drug monitoring.

18. An immunochemical reagent effectively corresponds to a mechanism to identify a molecule in a test fluid. The reagent comprises a monoclonal antibody which is designed to lock on a specific target. Once the antibody has fixed its target, it is marked by a 'tag'. The 'tag' makes it possible to detect the existence of the targeted molecule in the test fluid.

The antibody of the reagent is made to fit to a certain target molecule. It is therefore the antibody which determines the scope of the reagent.

The 'tag' is not specific to the targeted molecule. Broadly speaking, a 'tag' can consist either of enzyme antigene, of a radio active antigene, it can be fluorescent, or two 'tag' antigenes can even be fixed onto a latex particle which is deformed by agglutination when hitting the target. Depending on the choice of the 'tag', a different technology is used for detecting the target molecule.

19. Drug monitoring forms an area of immunochemical diagnostics. The term describes the analysis of blood and urine samples to determine the existence and the level of certain specified chemicals in the body of a person. According to the classification proposed by the European Diagnostics Manufacturers Association (EDMA) one can further distinguish between therapeutic medicine monitoring (TDM) and drug abuse / toxicology tests (DAT). Whereas the first category concerns the monitoring of medicinal products in the body, the second category includes the detection of specific, often illegal drugs.

20. The two areas of therapeutic medicine monitoring (TDM) and drug abuse tests (DAT) are different in some respects.

21. The TDM area concerns all those products which are provided for testing patients receiving ethical pharmaceuticals. The TDM reagents measure the medicine level in patients whose results are used by physicians to adjust the medicine dose. Therefore, TDM is generally carried out for use in a medical environment, whereas DAT is used primarily for non-medical purposes, for instance in legal proceedings, for recruitment purposes etc.

22. It is true that depending on the make of the instrument, both TDM and DAT tests can be operated on the same systems. But TDM and DAT are in some ways different for the user.

23. TDM testing mostly requires quantification of analytes (one wants to know how many molecules are in the test fluid), whereas DAT testing is generally performed qualitatively or semi-qualitatively (one wants to know primarily whether somebody has consumed an illicit drug at all or not).

24. DAT often is carried out in two steps. In a first step the analyte is "screened", by using either an antibody with a broad scope of application or by conducting a panel of several tests; in a second step the consumed drug is determined more specifically. Legal requirements can also oblige the laboratory to carry out additional DAT tests to confirm the result of a first test.

25. TDM is in general carried out on sera, that is on blood samples. But it appears from the Commission's investigations that tests on urine samples are more common in the DAT area.

26. In spite of the differences, there are indications, at least technically, that some individual tests can be used both for TDM and DAT. It is also true that the basic technology for manufacturing TDM and DAT reagents is in principle the same and shows a certain communality with other immunochemical methods.

27. Some of the suppliers follow a strategy of extending the scope of application of their product lines. This fact gives an indication that product markets will probably widen in the future.

28. The facts available do not allow a definite conclusion as to whether TDM and DAT form separate markets. The question can be left open, since in any case no dominant position would be created or strengthened by the concentration.

Relevant geographic markets

29. The geographic reference markets for TDM and DAT remain essentially national.

30. The existence of national markets is illustrated by the fact that the suppliers organise their distribution nationally. SYNTEX for example has centralised its production in the US from where it ships the supplies to the different outlets in Western Europe. With the notable exception of Italy, SYNTEX has its own distributors in most of the Western European countries.

31. [Prices differ significantly from one country to the other][1].

These price differences would seem to reflect the diversity among national medical cultures and in particular the divergences in national health policies, social security regulations and the technology used in laboratories. Again, prices for reagents would systematically include the cost for leasing the analyser in some countries but not necessarily in others.

The fact that these price differences have not been significantly eroded over the past three to four years suggests, that the importance of parallel imports from one Member state of the European Union to the other is small. International tenders are relatively rare in the industry. One explantation is that users give great importance to after-sale services, and therefore closeness to the distributors.

32. National regulation plays a certain role, but it is less stringent than in the case of pharmaceuticals. The Commission is preparing a directive for the harmonisation of national regulations on in-vitro diagnostics. The directive, which is not likely to enter into force before 1997, will only apply to diagnostics products for use in a medical environment.

33. For these reasons and especially in view of the important price differences the markets for in-vitro diagnostics remain essentially national.

---

(1) In the published version of the decision, some information has been omitted or replaced pursuant to the provisions of Article 17(2) of Council Regulation (EEC) no 4064/89. Consequently, all [ ] replace information deleted as pertaining to business secrets.

V COMPATIBILITY WITH THE COMMON MARKET

A. Pharmaceuticals

34. No overlap will occur in the animal pharmaceutical market, as ROCHE has sold its animal health business within the last year. Nor will any overlap occur within the human non-prescription ('OTC') pharmaceutical market, since SYNTEX's only interest in this sector involves certain non prescription analgesic products in the U.S. market.

35. On the basis of the third-level ATC classification there will be overlaps between ROCHE and SYNTEX in the following ATC categories within the EEA:

- A1A Stomatologicals
- A7B Intestinal absorbants
- A8A Anti-Obesity preparations
- A11G Vitamin C including mineral combinations
- A13A Tonics
- C4A Cercbro vasotherapy
- C8A Calcium antagonists
- D3A Wound healing agents
- D7A Topical-Corticosteroid plain
- N11A Anti-rheumatic non-steroids
- N1A Anaesthetics
- N2B Non-narcotics analgesic
- R1A Topical nasal

As far as national markets are concerned, SYNTEX's and ROCHE's combined shares will exceed 10% in the following categories:

- A11G : Spain
- D3A : Belgium, Portugal, Greece
- D7A : Spain
- M1A : France, UK, Spain, Belgium, Sweden, Greece

According to IMS data, combined shares of more than 25% will occur in the following markets only:

Spain: A11G Vitamin C including mineral combinations: ROCHE 46.5% plus SYNTEX 1.7% = 48.2%

Greece: D3A wound-healing agents: ROCHE 39.4% plus SYNTEX 6.5% = 45.9%

36. Neither ROCHE nor SYNTEX own patents in the two markets where combined shares will be highest (ie A11G in Spain and D3A in Greece). Significant competitors are active in these markets, for example AKZO in wound-healing agents in Greece, E. Merck and Wellcome with about 27% and 12,6% respectively (IMS data) of the Vitamin C market in Spain (Vitamin C products are anyway generic in nature). Competition for branded medicines from generic medicines is very much an increasing feature of pharmaceutical markets, when a patent expires and a hitherto prescription-only medicine is licensed to be sold on an OTC basis (SYNTEX's own major product, an anti-inflammatory medicine sold under the brand name 'Naprosyn',

has experienced a drop of some 50% in sales since its patent expired at the end of 1993, because of substitution by generic medicines; moreover, it would seem that SYNTEX is not at the moment in a position to launch major new patented medicines on the market, nor is it likely to be in such a position for some time to come). The impact of a recent trend to switch i.e: change a medicinal product from a prescription only status to availability without a prescription has not yet been made fully apparent, although Syntex's anti-inflammaory product Naprosyn has been switched in some markets. Again, government agencies, health-care companies, and insurance companies are increasingly applying pressure on pharmaceutical companies to cut their prices in order to diminish the costs of public health-care regimes. In view of these factors the concentration will not lead to a position of dominance for ROCHE and SYNTEX.

B) Diagnostics

37. The parties estimate that the turnover of the total West European in-vitro diagnostics business was about 4.5 billion ECU in 1993. The total Western European turnover for drug monitoring was [over 160 Mio] ECU, of which [two thirds] were spent on TDM and [one third] on DAT.

38. As explained above, the business of multi-use TDM and DAT products is characterised by the supply of systems and product series. The development of a new system requires relatively large sums. The companies in the diagnostics industry spend between 10 and 20% of their total turnover on R&D according to the parties. The average life span of a system gives the supplier a five year period within which to recoup the development costs. [Less than 15%] of the turnover is achieved through the sale of instruments, while reagent kits account for most of the rest. This explains that the suppliers have a strong interest in obtaining long-term orders for a continuous supply of reagent kits.

39. Diagnostics manufacturers are following different strategies in the pursuit of this aim. Some companies, such as the US company Abbott, try to market their products as closed systems which are designed for the exclusive use of their reagents. The systems of other competitors are more open. It is also a common feature of the industry that delivery contracts with customers are concluded for one or more years. Often, the instruments are only leased under the condition that the customer purchases a certain number of reagent kits over a certain time period.

40. From a technical viewpoint the reagents of a certain supplier can be used on the instrument of another producer, provided that the technologies correspond to each other. This applies even for closed systems. Some reagent suppliers provide instructions to facilitate the adaptation of other suppliers' systems to their products. However, it appears that the switch from one supplier to the other requires a certain know-how on the side of the customer. It is nevertheless relatively frequent to switch supplier within the limits set by technical constraints. In addition, large customers follow a policy of multiple sourcing. Large laboratories use analysers of different suppliers depending on the application.

41. The major suppliers for TDM and DAT products are present in most Western European countries. The US company Abbott is the strongest player in the overall diagnostics business worldwide and it is also a strong competitor in the Western

European countries both for TDM and DAT. Other competitors in the TDM and DAT markets include among others DuPont and, especially for TDM, Merck.

42. SYNTEX traditionally is a strong niche player in the TDM and DAT market, where it is active through its subsidiary Syva. ROCHE entered the TDM and DAT business in 1989 and it has a significantly lower turnover for these markets than SYNTEX. Both companies offer systems. But whereas ROCHE supplies its own instruments, SYNTEX markets analysers manufactured by third companies. ROCHE analysers can be adapted for the use of SYNTEX reagent kits.

43. If the market shares of ROCHE and SYNTEX are aggregated, the two companies realise high market shares in several Member states of the European Union. The parties will achieve value-based market shares for DAT which [exceed 40%] in France, the UK, Spain and also in certain Scandinavian countries. For Western Europe the share of the DAT market would be [more than 40%]. As for TDM, the parties achieve a market share of between 20 and 30 % in France. They estimate their share of the Western European TDM market to be [less than 15%].

44. The US company Abbott is the strongest competitor for ROCHE and SYNTEX both in the TDM and the DAT markets. Although Abbott is a high-price supplier, it is considered as an aggressive competitor. Abbott distinguishes itself by offering closed systems which are easy to use and therefore imply low handling costs. As in the case of ROCHE and SYNTEX, Abbott has important stakes in most of the Western European countries. Therefore, the presence of Abbott seriously constrains the possibility of ROCHE and SYNTEX to act independently of their competitors.

45. It is reasonable to say that in principle any supplieractive in immunochemistry has the basic abilities to develop TDM or DAT products. It is expected that Boehringer-Mannheim, which has already a limited presence in the TDM area, will launch a new DAT product series at the end of 1994. The entry of Boehringer-Mannheim in the DAT field will further constrain the position of ROCHE and SYNTEX.

46. It should also be noted that the patent protection for SYNTEX's main diagnostic technology, ("EMIT") has recently expired. SYNTEX has therefore been obliged to modernise its product line by launching a new automated diagnostics system (VISTA automated system). The development of a new proprietary technology for drug abuse tests and therapeutic medicine monitoring (LOCI technology) is not expected to bear fruit before 1997.

47. For these reasons, the concentration will not lead to a position of dominance for ROCHE and SYNTEX.

VI. **CONCLUSION**

48. For the above reasons, the proposed concentration between ROCHE and SYNTEX does not raise serious doubts as to its compatibility with the common market and the functioning of the EEA Agreement.

*

* *

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,