EN

Case No IV/M.1325 - BAYER / CHIRON DIAGNOSTICS

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REGULATION (EEC) No 4064/89
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 17/11/1998

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.11.1998

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 Where possible the information omitted has been replaced by ranges of figures or a general description.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
Article 6(1)(b) Decision

To the notifying parties

Dear Sirs,

Subject: Case No IV/M.1325 Bayer/Chiron Diagnostics
Notification of 14.10.1998 pursuant to Article 4 of Council Regulation N/ 4064/89[1]

1. On 14.10.1998, the German company Bayer AG ("Bayer") notified the proposed acquisition of Chiron Diagnostics Corporation ("Chiron Diagnostics").

2. I THE PARTIES

3. Bayer is a diversified international chemical and pharmaceutical company offering its customers a wide variety of products and services ranging from health care and agriculture to plastics, speciality chemicals and imaging technologies.

4. Chiron Diagnostics belongs to Chiron Corporation ("Chiron") and is engaged in immunodiagnostics, clinical chemistry, critical care, nucleic and diagnostics (NAD) and blood screening business. Chiron Diagnostics is the "in vitro" diagnostics (IVD) subsidiary of Chiron Corporation, California, of which Novartis holds 46%.

II THE OPERATION

5. The notification concerns the acquisition by Bayer of the IVD business of Chiron. This business includes immunodiagnostics, clinical chemistry, critical care, NAD. Chiron will retain its joint business with the US company Ortho Clinical Diagnostics Systems Inc., a Johnson & Johnson company, in immunodiagnostics and blood

[1] OJ L 395, 30.12.89 p. 1; corrected version OJ L 257 of 21.9.1990, p. 13; as last amended by Regulation (EC) No 1310/97, OJ L 180, 9.7.1997, p. 1, corrigendum in OJ L 40, 13.2.1998, p. 17.

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screening for hepatitis and retrovirus such as HIV. Chiron will also retain its own blood screening business, as well as its informatic business. Finally, Chiron will retain all of its intellectual property rights, which primarily relate to fields other than IVD.

III THE CONCENTRATION

6. The proposed transaction will result in Bayer acquiring sole control over Chiron Diagnostics within the meaning of Article 3(1)(b) of Council Regulation (EEC) No 4064/89.

IV COMMUNITY DIMENSION

7. The combined aggregate world-wide turnover of the undertakings concerned exceeds 5.000 million ECU. The aggregate Community-wide turnover of each party exceeds ECU 100 million (Bayer ECU […] million; and Chiron Diagnostics […] million). In each of at least three Member States, namely France, Germany and the Italy, each of the parties has a turnover in excess of ECU 25 million, and in each of those Member States the parties' combined aggregate turnover exceeds ECU 100 million. The undertakings concerned do not achieve more than two thirds of their aggregate Community-wide turnover in one and the same Member State. Therefore, the operation has a Community dimension.

V THE RELEVANT PRODUCT MARKETS

8. The proposed operation concerns the economic sector of diagnostic analysis. Both parties offer products and services for IVD analysis. This sector has already to a larger extent been examined in previous cases dealt with under the Merger Regulation, in particular case IV/M.950 Hoffmann La Roche/Boehringer Mannheim. It can generally be subdivided into five main segments: clinical chemistry, immunochemistry, haematology/histology, microbiology and infectious immunology. This corresponds to the first level of the European Diagnostics Manufacturers Association (EDMA).

9. The product areas which are relevant in the context of the proposed operation are described in greater detail below. Some of them correspond to the EDMA second level classification. Some of them have already been considered as separate product markets in previous Commission decisions. For others, as indicated below, the question whether they can be considered as separate product markets can be left open to the extent that the proposed operation does not create or strengthen a dominant position even on the narrowest definition possible.

10.

11. *Laboratory Information Services*: these services relate to specially designed software support for the registration and evaluation of results. The question as to whether this area does constitute a separate product market is left open in the present decision.

12. *Blood Gas and Electrolytes Testing (Critical Care)*: Critical Blood Analyte (CBA) tests comprise blood gas analysis, blood electrolytes analysis and other metabolite tests, such as glucose and lactate. According to the parties, CBA tests differ significantly from all other central laboratory test for a number of reasons. Specimens for CBA analysis are whole blood, whereas the central laboratory routinely uses serum or other specimens. Samples are usually arterial blood and originate from emergency or rapid response sites within the hospital such as emergency rooms, intensive care units, surgical units and operating suites. The results are required in minutes to facilitate, monitor or modify a procedure or treatment for seriously injured or sick patients. In addition, CBA instruments are smaller, specialised instruments developed to meet the time critical requirements of urgent analysis. The question of the precise delimitation of the product market can, however, be left open in this case since there is no overlap between the activities of the parties.

13. *Rapid Tests:* rapid tests are mainly manual tests for glucose-monitoring, mostly carried out by patients themselves or by doctors. Small portable glucometer instruments are used to read the blood glucose reactive device (strips). The Commission has already indicated that rapid tests do constitute a separate product market (due to differences in customers, distribution channels and competitive conditions), the question whether separate product markets can be distinguished within rapid tests can be left open also in this case, as there is no overlap.

14. *Haematology Reagents:* haematology encompasses in vitro diagnostics concerning the blood itself, especially cellular elements and certain functions of proteins such as coagulation and fibrinolysis. Haematology tests are typically run before and during most surgeries or are performed to monitor patients on anti-coagulant therapy or to assess the anaemia status. The question whether different haematology reagents do constitute separate product markets will be left open in this case, as there is no overlap.

15. *Classical clinical chemistry reagents and instruments*: the reagents are primarily used to test for glucose, cholesterol, urea and other substances found in large concentrations in the human body. The Commission has already concluded in the Hoffmann/La Roche decision that all these reagents can be grouped together, since they have common characteristics, as customers regularly buy almost all of their requirements for such tests from one source and, on the supply side, all major suppliers offer the same range of instruments and reagents. The instruments are measuring instruments used to process the tests. There are different sizes ranging from small instruments to high end-high throughput instruments. All major reagent suppliers provide instruments.

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17. *Immunochemistry (Reagents and Instruments):* immunochemistry involves the use of targeted antibodies to identify and quantify levels of hormones, proteins, drugs and other biological substances found in relatively small concentrations in blood and urine. Depending on the condition monitored, a number of applications can be distinguished. If these were to be regarded as separate product markets, overlaps would exist, on the basis of the second level of the EDMA classification, for Tumour Markers (EDMA 12.03), Thyroid Function Hormones (EDMA 12.04), Fertility Function Hormones (EDMA 12.05), Anaemia Related/Vitamin Test (EDMA 12.07), Standard and Controls (EDMA 12.50). In immunochemistry, there seem to be significant differences for the users: customers do not regularly buy most of their requirements from one source, and on the supply side the major suppliers do not offer the same range of instruments and reagents. For the purpose of the present case however the question of the precise delimitation of the relevant markets may be left open, because in all alternative market definitions the proposed operation would not create or strengthen a dominant position in the common market.

18. *DNA Probes*: DNA probes are employed for the detection of infectious diseases, genetic disorders and cancer cells. The Commission has found that DNA probes did constitute a separate product market from other in vitro diagnostics methods in the Hoffmann/La Roche decision. DNA probes have four main fields of application: HIV, hepatitis C (HCV), mycobacterium tuberculosis (MTB) and sexually transmitted diseases (STD).

19. In order to detect any of these diseases the DNA probe has to be amplified. There are several competing amplification technologies such as Roche's Polymerase Chain Reaction (PCR), Gen-Probe's Transcription Mediated Amplification (TMA), Akzo-Nobel's Nucleic Acid Sequence-based Amplification (NASBA) and Chiron's branched DNA (b-DNA). The main DNA probe technology is Roche's PCR, which has become the industry standard. Bayer has recently acquired a licence from Roche.

20. In one of the four main fields of application, Hepatitis C (HCV), Chiron has historically held crucial patent rights because it discovered the virus in 1987. In order to market an HCV probe assay (the detection kit) the combination of both Chiron's HCV probe patents (the DNA-sequence of HCV, referred to as HCV probe) and an appropriate amplification technology is necessary. The major advantage of HCV probes over traditional immunochemical methods (HCV immunoassays) using antibodies is the significant reduction of the time period between the infection and the detection of the infectious virus. For blood testing this gain in time is crucial.

21. Within the field of blood testing for HCV there are two segments. The segment of mass testing in bloodbanks is usually referred to as blood screening. Instruments used for bloodscreening are designed for high throughputs. The other segment is referred to as clinical testing. Instruments used here are designed for small volumes, which are slower but more precise.

22. 19. A further distinction may be made between qualitative and quantitative tests. A qualitative test only tells whether the infection is present or not. A quantitative test reveals the actual amount of the virus present in the patient's body, referred to as the viral load. Immunoassays can only perform a qualitative test used mainly by blood banks for blood screening, whereas HCV probe assays can do both. HCV probe assays are currently mainly used in clinical diagnostics.

23. The quantitative segment is the smaller segment of the market for HCV probe products, amounting to only a third of total sales, which are around 38 Mio. USD in the EEA. Most market players expect that the sales volume will increase to up to 200 Mio. USD over the next 5 years.

24. The precise definition of the relevant market can, however, be left open since there will be no creation or strengthening of a dominant position irrespective of the market definition chosen.

VI THE RELEVANT GEOGRAPHIC MARKETS

25. On the basis of the Commission's practice in this sector[2] it is considered that the markets for *in vitro diagnostics* are essentially national for the following reasons.

26. The geographic extent of the market has to be determined primarily with regard to demand side considerations. In this sector customers tend to buy their reagents and instruments inside their Member State because of the need for rapid and reliable service to ensure continuous availability of the products. Moreover, there are considerable price differences between Member States, and national regulation plays a certain role.

27. VII ASSESSMENT

28. Bayer and Chiron Diagnostics have overlapping activities in reagents, classical clinical chemistry instruments and immunochemistry. In the market for nucleic acid diagnostics (DNA probes) Bayer has acquired a licence from HLR/BM and will enter the market thereby leading to an overlap in the near future.

29. According to the parties there are no overlaps in the markets for laboratory information services, blood gas and electrolytes testing, rapid tests and haematology reagents. All these markets are characterised by the presence of significant competitors. These markets are therefore not considered further.

A. Classical Clinical Chemistry (both reagents and instruments)

30. In the market for classical clinical chemistry reagents at EDMA second level (Enzymes, Substrates, Calibrators and Control) the parties' combined market share is highest in France [<10%]. For classical clinical chemistry instruments statistical information is only available for all IVD instruments combined. Therefore, the parties submitted figures based on a study undertaken by an independent expert. The parties have their highest market share in the UK [<20%]. Chiron Diagnostics' instrument is

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[2] See Case IV/M.950 Hoffmann –La Roche/Boehringer Mannheim, IV/M.954 –Bain/Hoechst – Dade Behring

based on an ageing technology and does not add much to Bayer's position in that market (Chiron Diagnostics' market share varies between close to 0% and [<10%].

31. In all of theses markets there are a number of important multinational competitors such as the market leader Roche, Johnson&Johnson, Beckman/Coulter and Dade Behring, the latter two being stronger than the parties in many important markets, who will continue to compete against the merged entity.

32. B. Immunochemistry

33. Using EDMA second level as the relevant product market there are 9 affected markets (5 product markets in three countries). However, there will be no competitive problem in the markets affected by the concentration, since the combined market share in all but one market is below 25% and since there are a number of strong international competitors such as Roche and Abbott.

34. In the market for Tumour Markers the parties will have a combined market share of [<20%] in the UK. This will rank Bayer/Chiron second behind Abbott (>30%). In the market for Thyroid Function Hormones the parties will become number three in Germany [<20%] behind Abbott (>20%) and Roche (>20%), number one jointly with Roche in Italy (around [< 25%] each) and the UK [<30%], where Abbott is number two (>15%). Concerning the market for Fertility Function Hormones Bayer/Chiron will rank second in Germany [<20%] behind Serono (>20%) and first in the UK [<30%] with Abbott being a close second (>15%). In the market for Anaemia Related/Vitamin Tests the combined entity will achieve a share of [<30%] in Germany, and [<20%] in Italy, a close second to Abbott (>30%) in both countries. Finally, in the market for standards and controls in the UK, Bayer is the current market leader. However, Chiron Diagnostics has sold its business to the number two in this market, Biorad, and acts as a non-exclusive distributor for Biorad only. Therefore there is no overlap anymore.

35. Consequently, the proposed concentration does not create or strengthen a dominant position in any of the markets for immunochemistry.

C. DNA Probes

36. Whereas Bayer has no activities in DNA probes yet Chiron Diagnostics has high market shares for Hepatitis B and C Viruses test as well as for HIV tests (EDMA fourth level). In some countries the market shares are in the region of [<40%]. Chiron Diagnostics' EEA-wide market share for HIV is [<30%]. Chiron has a broad patent portfolio relating to HIV and HCV. The investigation of the Commission has shown that patent rights relative to HIV probes and analytes other than HCV are generally available for licence on a non-exclusive basis and on commercially acceptable terms.

37. Patent rights for HCV probes remain with the seller, Chiron Corporation, and are cross-licensed to the new entity. At present, Bayer will be the only company with a license for HCV probes for use in clinical testing. For the moment, the new entity will be active in the field of quantitative HCV probe assays using the b-DNA technology. However, Bayer recently acquired a PCR-licence from Roche and will enter the market at a later stage with HCV probe assays using the PCR technology. In the course of the Commission's market investigation third parties have suggested

that Chiron Diagnostic's strong position in HCV in combination with Bayer's R&D and marketing capacities as well as the use of PCR technology could in the future be a cause for competitive concern.

38. The acquisition of Chiron Diagnostics by Bayer will lead to a situation where Bayer/Chiron Diagnostics (Bayer/Chiron) gets the HCV probe licence from Chiron on terms which are more favourable than those any other future licensee could obtain. While there is a high up front payment the cross licence agreement foresees that Bayer will only pay […%] of what the next licensee will have to pay as a royalty for each test.

39. Without prejudice to the possible application of Article 85(1) to this last clause, which is not addressed in this decision, its implementation will not enable Bayer to acquire a dominant position. Indeed, while it is true that any further licensee will have to pay a licence fee, which is higher than what Bayer/Chiron has to pay, the net advantage in total terms is not very significant. Indeed, under the current terms and conditions Bayer/Chiron's cost advantage will be [not exceed 10%] of net sales less than that paid by any future licensee.

40. Moreover, the royalty advantage granted to Bayer is approximately offset by the fact, that Bayer has to pay royalties for the use of the nucleic acid amplification technique for qualitative tests, be it PCR licensed from Roche or TMA under licence from GenProbe, the latter licence being transferred to the new entity as part of the transaction. This reasoning applies only vis-à-vis those competitors who have proprietary amplification technology suitable for qualitative tests. It has been suggested that competitors, who have proprietary amplification technology, are incurring amortisation costs which are comparable to a licence fee. However, it has not been shown that their amortisation costs, be they related to R&D or acquisition costs, when compared to the licence fee charged for the use of their technology, are higher than the cost advantage of [not exceeding 10%] Bayer will enjoy on its HCV probe licence.

41. According to the parties the b-DNA technology is not suitable for qualitative HCV probe products. Quantitative tests, for which the b-DNA technique is used, serve mainly the demand for clinical trials.

42. Furthermore, according to the parties, there is only one drug available for the treatment of the disease, Interferon. For this treatment the knowledge of the viral load produced by the quantitative test is unnecessary. According to the parties, there will be no new drug available for treatment of HCV within the next 5 years thereby making this segment relatively unattractive.

43. At present Roche is the only competitor marketing HCV probe assays using its proprietary PCR technique. However, in doing so it is disregarding the patent rights held by Chiron. Roche is currently the market leader for HCV probe assays for quantitative tests and the only provider for qualitative tests. This situation might change depending on the outcome of several pending patent litigation cases world-wide.

44. However, Chiron made it clear that the agreement with Bayer does not in any event affect its ability to grant further licences for HCV probes to third parties. In particular, Chiron is not legally prevented by the agreement from granting further

licences. Moreover, Chiron's post merger strategy will be to exploit its licences to the full, since the interest in that business will become purely financial. Should the market volume increase as predicted Chiron will have an even greater incentive to grant licences in order to increase its revenues. Therefore, Chiron's licence policy will become more open as a result of the planned transaction and will lead to increased competition from other players.

45. Roche is the owner of the PCR license. Licenses have already been granted to Abbott, Johnson & Johnson and more recently to Bayer. Generally, following the Commission's decision in the Hoffmann La Roche case, this technology is available on the market. Given the likely availability of the licence for HCV probes from Chiron, as indicated above, Roche will be best placed to operate effectively on the market.

46. For all the above reasons it is concluded that the proposed transaction will not create or strengthen a dominant position in the common market.

VIII ANCILLARY RESTRAINTS

47. Chiron has undertaken not to manufacture or sell IVD products for a period of three years from closing of the transaction, subject to certain permitted activities. These permitted activities include certain activities retained by Chiron and also licensing patents, patent applications and know-how owned or controlled by Chiron to third parties for use in any field. This last activity is permitted subject to provisions contained in the cross-license agreement concluded between Chiron and Bayer in the context of the proposed transaction.

48. As indicated in the relevant agreements and confirmed by Chiron in a written statement, these non-compete clauses allow Chiron to grant licenses for HCV probes under the following conditions:

    (1) Chiron has the right to grant up to two additional world-wide licenses;

    (2) Alternatively, if Chiron has granted […] world-wide license(s), instead of granting […] world-wide license(s) it may grant […] license(s) in each of the following four regions, for a total of […] world-wide license(s) and […] regional licenses: North America, the European Union, Japan, and all other countries of the world;

    (3) Again alternatively, if Chiron has not granted […] world-wide license(s), in lieu thereof, beginning […] years after closing and with Bayer's consent, Chiron may grant […] license(s) in each of the four regions described above, for a total of […] regional licenses.

    Chiron has the right to keep for itself […] of the additional licenses, subject to the non-competition clauses negotiated with Bayer. While these clauses prevent Chiron from manufacturing or selling HCV probes for a period of […] years from closing, it does not prevent Chiron from engaging in research and development relating to such products. If Chiron elects to retain a world-wide license, it has still the right to grant […] additional world-wide license(s); if Chiron elects to retain one or more regional

licenses for itself, it has still the right to grant […] additional license(s) in each such region.

49. This non-competition clause must be interpreted as

a) preventing Chiron from manufacturing or selling IVD products for a period of three years from closing of the transaction. However, it allows Chiron to engage in research and development for such products.

b) preventing Chiron from granting more than two licence(s) during the 3-year period provided for in the non-competition clauses. […]

c) preventing Chiron from granting […] regional licence(s) during the first […] years after closing.

d) preventing Chiron from granting […] regional licence(s) during the first […] years after closing unless it has already granted […] worldwide license(s) before.

e) preventing Chiron from granting […] regional license(s) without Bayer's prior consent during the […] year after closing.

50. Given the transfer of IVD assets to Bayer, the non-competition clause including the limitations indicated in para.46, points a) and b) can be considered as directly related and necessary to the proposed operation. The limitations described in par. 46, points c), d) and e), have not been duly motivated by the parties and cannot consequently be covered by the present decision.

51. IX CONCLUSION

52. For the above reasons, the Commission decides 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,