# Case No COMP/M.4865 -SIEMENS / DADE BEHRING

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# REGULATION (EC) No 139/2004 MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION Date: 25/10/2007

In electronic form on the EUR-Lex website under document number 32007M4865

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



# COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.10.2007

SG-Greffe(2007) D/206646

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 party

Dear Sirs,

#### <u>Subject</u>: Case No COMP/M.4865 – Siemens / Dade Behring Notification of 20.09.2007 pursuant to Article 4 of Council Regulation No 139/2004<sup>1</sup>

1. On 20.09.2007, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ("the Merger Regulation") by which the German undertaking Siemens AG ("Siemens", Germany) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of Dade Behring Inc. ("Dade Behring", USA) by way of purchase of shares.

#### **1.** THE PARTIES

- 2. Siemens (also referred to as "the notifying party") is active in various manufacturing, technology and services business activities, including medical systems. Within the latter, Siemens is notably active in the in-vitro diagnostic ("IVD") sector pursuant to the acquisitions in 2006 of Diagnostic Products Corporation ("DPC") and of Bayer Diagnostics ("BD")<sup>2</sup>.
- 3. Dade Behring develops, manufactures and markets IVD systems and reagents for hospitals and clinical laboratories (Siemens and Dade Behring are collectively referred to as "the parties").

<sup>&</sup>lt;sup>1</sup> OJ L 24, 29.1.2004 p. 1.

<sup>&</sup>lt;sup>2</sup> Case M. 4321 Siemens/Bayer Diagnostics

#### 2. THE CONCENTRATION

- 4. On 25 July 2007, Siemens, the acquisition vehicle Belfast Merger Co. and Dade Behring concluded an "Agreement and Plan of Merger" ("the Agreement"). Pursuant to the Agreement, Siemens will acquire all the shares in Dade Behring, via Belfast Merger Co.
- The proposed transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation, since it provides Siemens with sole control over Dade Behring.

# **3.** COMMUNITY DIMENSION.

6. The proposed transaction has a Community dimension pursuant to Article 1(2) of the Merger Regulation: the parties have a combined aggregate worldwide turnover in excess of € 5 billion (Siemens: € 87 billion, Dade Behring: € 1.4 billion), and each has a Community-wide turnover in excess of € 250 million (Siemens: € [...], Dade Behring: € [...]). The parties do not achieve more than two thirds of their Community-wide turnover in one and the same Member State.

#### 4. RELEVANT PRODUCT AND GEOGRAPHIC MARKETS

- 7. The proposed transaction concerns the manufacture and sale of IVD diagnostics analysers and reagents<sup>3</sup>. All IVD tests have in common that they involve medical tests conducted outside the human body. The European Diagnostic Manufacturers Association ("EDMA") currently classifies IVD tests into six main categories: clinical chemistry, immunochemistry, haematology/histology, microbiology culture, infectious immunology and genetic testing. The only EDMA categories in which there is no overlap between the activities of Siemens and Dade Behring concern genetic testing and microbiology culture.
- 8. Both parties to the transaction offer products and services for IVD analysis.<sup>4</sup> In order to carry out IVD analyses, laboratories need dedicated equipment as well as specific reagents to diagnose a variety of medical problems (cancer, HIV, thyroid problems, etc...).

<sup>3</sup> Reagents are consumable substances used in conjunction with the analysers to perform IVD tests.

<sup>4</sup> This sector was examined in previous cases (IV/M.950 Hoffmann La Roche/Boehringer Mannheim, IV/M.954 Bain/Hoechst – Dade Behring, IV/M.1325 Bayer/Chiron and most recently in COMP/M. 4321 Siemens / Bayer Diagnostics), without however reaching a definite conclusion regarding product market definitions.

## Relevant product market

#### Immunochemistry

- 9. The main overlap in the respective IVD activities of the parties concerns the EDMA category of immunochemistry (also referred to as "immunoassay"). This EDMA category includes biochemical tests for the analysis of body fluids using the reaction of an antibody or antibodies to its antigen to identify and test enzymes, drugs, hormones and other substances found in relatively small concentrations in the body.
- 10. According to the notifying party, to define the relevant product market as the market of immunochemistry systems, along the lines of the EDMA qualification, may for two reasons result in a too narrow product market definition.
- 11. The notifying party first refers to the strong links that exist between the EDMA categories of immunochemistry and clinical chemistry. Clinical chemistry covers biochemical tests that measure the level of constituents of body fluids (e.g. serum/plasma and urine) and compare them to reference values.
- 12. Although the notifying party recognises that clinical chemistry and immunochemistry analyses are mostly performed by different testing methods and have traditionally required separate testing instruments, the recent introduction and subsequent successful spread of so-called integrated analysers, which perform both clinical chemistry and immunochemistry tests on the same analyser, would, according to the notifying party, prove that the EDMA categories of clinical chemistry and immunochemistry testing are integrating. The use of integrated analysers significantly reduces the need to split testing samples (i.e. one part for clinical chemistry and a separate part for immunochemistry testing)<sup>5</sup>. Currently, Dade Behring and Hoffmann La Roche ("Roche") offer integrated analysers; Ortho Clinical Diagnostics will introduce its integrated analyser in 2008, while other competitors are developing such analysers.
- 13. In previous decisions, the Commission recognised the existence of a trend towards integration between clinical chemistry and immunochemistry, however it left open if the product market should be broader than immunochemistry<sup>6</sup>.
- 14. The market investigation confirmed the strong interest of customers in integrated testing systems. Many of them currently have such a system in use, as both laboratories and hospitals are under increasing pressure by national health care systems to reduce their costs. The use of integrated analysers rationalises their testing procedures, increases efficiency and reduces their costs. Therefore, tender specifications often explicitly refer to integrated analysers.
- 15. According to the notifying party, the links between clinical chemistry and immunochemistry also follow from the fact that certain immunoassays, i.e. homogeneous immunoassays, can be run on clinical chemistry analysers. Thus clinical chemistry analysers are in many instances used to perform homogeneous immunoassay testing. This is not possible with the other type of immunoassays, i.e. heterogeneous immunoassays. The latter can only be run on dedicated immunoassay analysers (or

<sup>&</sup>lt;sup>5</sup> The splitting of testing samples is generally considered as a (costly) labour intensive activity.

<sup>&</sup>lt;sup>6</sup> Case M. 4321 *Siemens/Bayer Diagnostics*.

integrated analysers) as they require a washing step to separate a bound antibodyantigen complex from the free antigen for delivering their test result. The market investigation confirmed that it is common practice for laboratories to run at least part of their homogeneous immunoassays on their clinical chemistry analysers.

- 16. Apart from the trend towards integration between clinical chemistry and immunochemistry on the one hand, the notifying party, on the other hand, also points at the links between immunochemistry and, at least part of, the EDMA category of infectious immunology. EDMA includes in its category of infectious immunology all tests performed in connection with certain types of diseases caused by viral or bacterial infection. A significant part of the tests falling in this category are immunochemistry tests based on the anti-body testing method, which can be run on immunochemistry equipment. The other type of infectious immunochemistry tests is based on a genetic testing method (i.e. molecular/nucleic acid testing), which, according to the notifying party, requires different analysers and reagents and therefore cannot be considered to be part of the immunochemistry market.
- 17. In previous Commission decisions, the precise delimitation of the immunochemistry and infectious immunology markets was left open<sup>7</sup>. The majority of respondents to the market investigation confirmed the use of (anti-body based) infectious immunology tests on immunochemistry analysers and considered both to be part of the same product market. The minority of the respondents to the market investigation referred to the fact that traditionally infectious and non-infectious immunochemistry tests were performed in separate laboratory departments and to regulatory barriers in a number of EEA countries which prevent laboratories from running infectious immunology tests in an immunochemistry environment. Nonetheless, the majority of the respondents to the market investigation did not perceive any obstacles in running (anti-body based) infectious immunochemistry analysers in an immunochemistry environment.
- 18. In the present case, it can however be left open if the market for immunochemistry should include clinical chemistry or the part of infectious immunology, since the transaction will not raise competition concerns under any alternative product market definition.

## Immunochemistry thematic panel level /assay level

- 19. Within immunochemistry, several hundreds different immunoassays are marketed. However, according to the notifying party, up to 90% of all immunochemistry testing is accounted for by only 40 out of roughly 450 individual immunoassays. For reasons of exactness and comparability these tests are typically run on the same analyser. The remaining less common immunoassays are referred to as "esoteric" tests. These esoteric tests are normally not included in the standard assay menu of an immunochemistry system.
- 20. The notifying party argues that the purchasing decision of a laboratory or hospital is driven by a demand for a complete (immunochemistry) system, including both analyser and assays, often in combination with after-sales service and training. There is hardly any demand, according to the notifying party, for immunochemistry assays that is

<sup>&</sup>lt;sup>7</sup> Case M. 4321 Siemens/ Bayer Diagnostics.

unrelated to the provision of the analyser. As example, the notifying party refers to the trend to conclude supply contracts whereby the costs of the analyser is included in the cost of the individual assays which the customer will purchase over a number of years. This system reduces the upfront costs for the customers and leads to successive amortisation of the system (analyser + assays).

- 21. Relevant product markets could however be defined at a narrower level than the system level. EDMA proposes a classification of immunochemistry tests based on a number of thematic panels of tests, which include: (i) cardiac, (ii) cancer, (iii) therapeutic drug monitoring ("TDM"), (iv) drugs of abuse ("DOA"), (v) thyroid, (vi) fertility, (vii) anaemia, (viii) specific proteins, (ix) allergy, and (x) individual and specific hormones. This classification is widely used at European level and the firms active on the immunochemistry market report their sales under this classification.
- 22. Within each thematic panel, a number of different assay tests can be conducted in order to detect different pathogens. According to the notifying party, the grouping of assays into thematic panels does not reflect economic and competitive reality. Customers are seeking to automate testing and to concentrate their standard immunochemistry testing to preferably a few analysers on which they run all or most immunoassays. Even if customers have more than one supplier (as larger laboratories do) this is, according to the notifying party, often because the customer wants to cover certain esoteric tests with a dedicated system from a specialised supplier for perceived quality reasons. In any case, the customer will sign two or more package contracts, providing him with two entire systems (each including its own analyser, assays, service and training) and the customer may then split its test volume between the two systems. Thus if the customer uses two suppliers, according to the notifying party, it makes two purchasing decisions for a system rather than purchasing decisions for individual thematic panels of one or the other supplier. The notifying party therefore argues that the grouping of assays by EDMA into thematic panels merely serves scientific/statistical purposes and does not reflect any particular competitive relationship among the assays of a certain thematic panel.
- 23. In previous Commission decisions, the question of the precise delimitation of the product market (total immunochemistry system vs. panels vs. specific assays) was left open<sup>8</sup>. The Commission noted that the competitive assessment should be based at the level of systems and at the level of thematic panels or even at the level of specific assays, if these prove to be crucial in the purchasing decisions of the laboratories. Nonetheless, it was recognised that the purchasing decision of most laboratories concerns the package, i.e. analyser, assays and after-sales service.
- 24. In the present case, the large majority of the respondents to the market investigation confirmed that the purchasing decision of a laboratory or hospital is primarily driven by a demand for a complete (immunochemistry) system. In particular, the throughput, cost-effectiveness of the system and the breadth of the assay menu of the system were considered more important purchasing criteria than the presence of complete panels of assays, or of specific individual assays. As to the assay menu of the system, customers tend to have a preference for those systems which have a broad and representative menu covering the most used assay areas. Customers generally do not aim at purchasing complete assay panels. This may be different only for laboratories which specialise in

<sup>&</sup>lt;sup>8</sup> See e.g. Case COMP/M. 4321 *Siemens / Bayer Diagnostics*.

particular specific fields of immunochemistry testing. However, the market investigation confirmed that such specialised laboratories represent only a small part of total demand. The market investigation therefore confirmed that competition in immunochemistry primarily takes place at the level of the systems, and not at the level of panels and individual assays.

25. However for the purpose of this case, the definition of the relevant product market can be left open, since the transaction will not lead to competition concerns under any alternative product market definition

#### **Clinical Chemistry**

- 26. Both parties are also active in the EDMA category of clinical chemistry. The parties hold that, if one would distinguish between immunochemistry and clinical chemistry, the relevant product market should be the overall market for clinical chemistry systems (equipment and reagents).
- 27. In previous decisions, the Commission held that all clinical chemistry reagents and analysers belong to the same market for clinical chemistry systems 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<sup>9</sup>.
- 28. Relevant product markets could however be defined at a lower level than the system level. In this respect a distinction could be made between i) clinical chemistry tests performed in laboratories and ii) those which are used at the point-of-care, which are also referred to as "rapid tests". Rapid tests are primarily manual tests for several applications (e.g. glucose monitoring, pregnancy, and drug monitoring), carried out by patients themselves or by doctors. In previous decisions concerning the clinical chemistry market, the Commission considered rapid tests to be part of a separate product market from laboratory test in view of the differences in customers, distribution channels and competitive conditions<sup>10</sup>. It left open however whether within the market for rapid tests separate product markets should be established for, e.g. urine-strip tests and blood-strip tests. The market investigation confirmed the distinction of rapid tests as a separate product market.
- 29. For the purposes of the present case, the definition of the relevant product market can be left open, since the transaction will not lead to competition concerns under any alternative product market definition.

#### Haematology/ Histology

30. EDMA groups all IVD reagents for haematology and histology together into one category haematology/histology. The parties submit that the haematology/histology category does not necessarily represent one single product market because of its

<sup>&</sup>lt;sup>9</sup> Cases IV/M. 1325 Bayer/Chiron Diagnostics and IV/M. 950 Hoffmann La Roche/ Boehringer Mannheim.

<sup>&</sup>lt;sup>10</sup> Case IV/M. 950 Hoffmann La Roche/ Boehringer Mannheim.

heterogeneity. Haematology/histology essentially comprises three testing areas, i.e. haemostasis, core haematology and histology.

- 31. Haemostasis tests (coagulation) involve the study of clotting of blood. These tests are normally run before and during a patient's surgery or are performed to monitor patients on anti-coagulant therapy. Core haematology concerns the measurement and counting of the number of white and red blood cells, platelets and haemoglobin within the blood. Core haematology tests are performed to monitor patients for common haematology abnormalities, including leukaemia. Histology is closely related to pathology as it studies the dying of cell elements. It involves testing on cells, usually collected through biopsies by light microscopy, electron microscopy and immunochemistry. According to the parties, all three sub-categories of haematology/histology pursue different objectives, use different analysers and reagents and require different procedures.
- 32. In previous decisions, the Commission left the market definition open<sup>11</sup>. The market investigation, however, overwhelmingly confirmed that competition takes place at the level of haemostasis, core haematology and histology rather than at the level of the EDMA category haematology/histology. The respondents to the market investigation confirmed that these three areas are essentially unrelated economic activities with no substitutability from either the supply or demand side. In view of these differences, there are insufficient grounds to consider the EDMA category haematology/histology as a single product market.
- 33. In the present case, this implies that the transaction does not result in any affected markets in this area, as there are no overlaps in the activities of the parties in the sub-segments.

## Relevant geographic markets

- 34. In previous decisions, the Commission concluded that the relevant geographic markets for the individual IVD instruments and reagents markets were essentially national<sup>12</sup>. The Commission based its conclusion on the reasoning that the geographic extent of the market must be determined primarily with regard to the demand side considerations. It was found in relation to most EEA countries that 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, considerable price differences between Member States were observed, and national regulation played a certain role.
- 35. The notifying party takes the view that this situation has considerably changed, notably thanks to the application of Directive 98/79/EC on in-vitro diagnostic medical devices which provides harmonised European standards, and because customers increasingly purchase by way of tenders, reducing further the importance of national borders.

<sup>&</sup>lt;sup>11</sup> Case IV/M. 1325 Bayer /Chiron Diagnostics.

<sup>&</sup>lt;sup>12</sup> See e.g. Case COMP/M. 4321 *Siemens / Bayer Diagnostics*.

- 36. The market investigation confirmed that most respondents still consider the relevant geographic market to be based on a national delineation, in view of price differences, the existence of national reimbursement schemes and the preference for local service. It also appeared however, that, in particular in smaller EEA countries where total sales for immunochemistry products are limited and fewer producers of IVD systems are directly represented, customers are more inclined, than in other EEA countries, to directly purchase the products concerned abroad.
- 37. As most indicators point towards national markets, in the present case, the relevant geographic markets are defined as national.

#### **5.** COMPETITIVE ASSESSMENT

The proposed transaction results in possible affected markets for laboratory clinical chemistry, immunochemistry and a number of sub-markets thereof.

#### Laboratory clinical chemistry

- 38. The Parties' combined market share on the EEA market for laboratory clinical chemistry<sup>13</sup> was below 15% in 2006 (Siemens [0-10]%, Dade Behring [0-5]%).
- 39. At a national level, the Parties' combined market share in 2006 leads to affected markets in Sweden ([10-20]%), the United Kingdom ([20-30]%), Portugal ([20-30]%), Finland ([10-20]%) and Estonia ([30-40]%). In all affected markets, Dade Behring has only a limited presence [0-5]%. In Estonia, the only market where the Parties' combined market share [20-30]%, Dade Behring's share is far below [0-5]% and there are other strong competitors in the (laboratory) clinical chemistry market.
- 40. Therefore, the proposed concentration does not raise serious doubts as to its compatibility in the common market or in a substantial part of it in relation to laboratory clinical chemistry.

#### Immunochemistry

41. As a result of this transaction, the merged entity will become a market leader in the EEA for immunochemistry with [20-30]% market share, followed by Roche and Abbott and a number of smaller competitors. If, however, one includes non-genetic infectious immunology into the immunochemistry market, as suggested by the notifying party and the majority of the respondents to the Commission's market investigation, the combined market shares of the parties would be lower ([20-30]%). Based on the EDMA data and the parties' estimates<sup>14</sup>, the market position of the main players in the EEA is shown in Table 1.

<sup>&</sup>lt;sup>13</sup> The proposed transaction does not result in affected markets for either clinical chemistry as such, or for rapid test clinical chemistry.

<sup>&</sup>lt;sup>14</sup> The market shares provided by the parties are reported in this decision. However, some discrepancies between the parties' estimates and the results of the market investigation occurred for countries which are not EDMA members or in which the parties are not active or have a very small presence. To the extent

Company	Immunochemistry	Immunochemistry + non-genetic infectious immunology
Siemens + Dade Behring	[20-30]% (S[10-20]% +DB [10-20]%)	[20-30]% (S[10-20]% +DB[0-10]%)
Roche	[20-30]%	[20-30]%
Abbott	[10-20]%	[20-30] %

Source: EDMA data and parties' estimates

42. When considering the immunochemistry market at national level, 23 markets out of 30 EEA countries are affected (i.e. all EEA countries except Bulgaria, Finland, Luxembourg, Malta, Romania, Slovakia and Liechtenstein). The merged entity will be market leader in 13 countries (10 countries if non-genetic infectious immunology is added) with a share [20-30]% (see Table 2), usually closely followed by its main competitors Abbott and Roche.

that these discrepancies have no bearing on the competitive assessment of the proposed concentration, they will not be mentioned in the decision.

Country	Immunochemistry: Total (Siemens(S) + Dade Behring(DB))	Immunochemistry + non-genetic infectious immunology: Total (Siemens(S) + Dade Behring(DB))
Estonia	[50-60]% (S[50-60]%, DB [0-5]%)	[50-60]% (S [40-50]%, DB [0-5]%)
Cyprus	[50-60]% (S [40-50]%, DB [0-5]%)	[40-50]% (S [30-40]%, DB [10-20]%)
Denmark <sup>15</sup>	[50-60]% (S [40-50]%, DB [0-10]%)	[40-50]% (S [30-40]%, DB [0-10]%)
Norway	[40-50]% (S [30-40]%, DB [10-20]%)	[30-40]% (S [20-30]%, DB [0-10]%)
Portugal	[40-50]% (S [20-30]%, DB [10-20]%)	[20-30]% (S [10-20]%, DB [0-10]%)
Czech Republic	[30-40]% (S [30-40]%, DB [0-5]%)	[20-30]% (S [20-30]%, DB[0-5]%)
Italy	[30-40]% (S [20-30]%, DB [10-20]%)	[20-30]% (S [10-20]%, DB [0-10]%)
Lithuania	[30-40]% (S [30-40]%, DB [0-5]%)	[40-50]% (S [20-30]%, DB [10-20]%)
The Netherlands	[30-40]% (S [20-30]%, DB [0-5]%)	[20-30]% (S [20-30]%, DB [0-5]%)
Belgium	[20-30]% (S [20-30]%, DB [0-10]%)	[20-30]% (S [10-20]%, DB [0-10]%)
Greece	[20-30]% (S [10-20]%, DB [10-20]%)	[20-30]% (S [10-20]%, DB [10-20]%)
Latvia	[20-30]% (S [20-30]%, DB [0-5]%)	[30-40]% (S [10-20]%, DB [20-30]%)
Ireland	[20-30]% (S [10-20]%, DB [0-10]%)	[20-30]% (S [10-20]%, DB [0-10]%)

 Table 2 Market share on national level, sales in 2006

Source: EDMA data and parties' estimates

- 43. In all countries listed in Table 2, the merged entity will face strong competition from other full-range immunochemistry suppliers (Abbott, Roche, Ortho Clinical Diagnostics, Olympus, Beckman Coulter) and many specialist suppliers (e.g. Phadia, bioMérieux, Brahms, Perkin Elmer, DiaSorin, BioSite, etc). During the Commission's investigation customers from these countries confirmed that after the merger they would have a choice from a sufficient number of effective competitors, both small and big ones, as most of them are present via direct own sales representatives or independent distributors in all EEA countries. In addition, entry into new geographic markets of established immunochemistry providers is relatively easy due to the regulatory harmonisation at the EU level.
- 44. It should also be noted that the size of the national immunochemistry markets in those EEA countries where the joint market shares of the parties are highest is

<sup>&</sup>lt;sup>15</sup> It should be noted that competitors estimate the total volume of the Danish immunochemistry market significantly higher than the notifying party. On the basis of these alternative estimates, the parties would have a significantly lower joint market share on the Danish immunochemistry market of [30-40]%. See also footnote 17.

relatively small<sup>16</sup> and is composed of sales to a small number of customers only. In addition, Dade Behring's presence on these markets is rather modest and the increment in market shares resulting from the transaction is [0-5]% for Lithuania, The Netherlands, the Czech Republic, Cyprus, and Estonia. Moreover, the market investigation indicated that sales of competitors in specific countries are higher than estimated by the parties<sup>17</sup>. While the adjusted market figures do not change the competitive assessment, they confirm that competitors have significant foothold also in the markets where the parties enjoy a significant presence.

- 45. Further, competition between suppliers of immunochemistry systems is strong in all EEA countries. The market investigation confirmed the existence of strong price competition and pressure on prices both for equipment and reagents. In the last five years prices for reagents were reported to have decreased. The immunochemistry suppliers compete also on different pricing schemes and capital deals, for example equipment is offered for free or leased in order to minimise the capital expenditure. These developments can, amongst others, be explained by the fact that immunochemistry customers are exposed to strong cost pressure by their respective national health insurance systems. This pressure to cut medical costs is directly passed on to the system suppliers, which need to adjust their reagent prices to stay competitive.
- 46. In addition, in the last few years there has been a trend towards consolidation on the customers' side. The customer consolidation can be observed both at the level of public hospital labs<sup>18</sup> and at the level of private labs hospitals<sup>19</sup>. This consolidation trend leads to an increase in countervailing purchaser power and also increases the level of customer sophistication in making their purchasing decisions.
- 47. This increased power of customers is further enhanced by their use of particular purchasing procedures. Publicly-owned hospital laboratories and private customers increasingly launch formal tendering procedures or at least request offers from various suppliers while purchasing new equipment. A significant part of IVD purchases is done by way of tenders in the context of which customers clearly specify their requirements and are regularly able to compare various suppliers against each other. Thus, tender procedures ensure competitive pricing. Laboratories confirm that the use of tender procedures has increased in most EEA countries, with tenders accounting for 20-90% of all IVD purchases.
- 48. Further, the market investigation confirmed that switching by customers between immunochemistry suppliers is not just a theoretical possibility, but rather an

<sup>&</sup>lt;sup>16</sup> In Cyprus, Estonia, Latvia and Lithuania the immunochemistry market volume does not exceed EUR 1.5 million in 2006.

<sup>&</sup>lt;sup>17</sup> For example in Denmark Dade Behring also lost [...] of its [...] customers [...] in 2006, so the combined parties' market share is expected to drop even further

<sup>&</sup>lt;sup>18</sup> In the public sector, examples include the mergers of the public hospitals in the German cities of Berlin, Hamburg, Munich and Hanover.

<sup>&</sup>lt;sup>19</sup> Regarding the formation of large hospital groups see, e.g., case no. COMP/M. 4010 – Fresenius / Helios. In Germany, see decisions of the Bundeskartellamt in cases B10-123/04 – Rhön-Klinikum / Rhön-Grabfeld, B10-109/04 – Rhön-Klinikum / Eisenhüttenstadt, and B10-161/04 Asklepios Kliniken / Hamburg. For the entry of private equity investors into the sector see COMP/M. 3723 – EQT / ISS / Healthcare / Carepartner JV; and Case M. 4367 - APW/APSA/Nordic Capital/Capio.

accepted market reality. As equipment accounts for approximately only 10% and reagents for 90% of total system costs, an increase in price of specific reagents or technological advances in analysers would likely lead to switching. Most laboratories have more than one immunochemistry equipment and supplier. Switching to another provider is therefore relatively easy, especially if price increases. Moreover, competing suppliers can offer to bear switching costs; for example, costs in training staff on a new system.

- 49. A large proportion of laboratories use instruments from different manufacturers to avoid dependency on one single supplier and to address different testing needs with different suppliers' instruments. This practice of multiple sourcing allows them to optimise quality, throughput and costs. It also means that the customers will be in regular contact with more than one supplier and familiar with how different suppliers' instruments are laid out and work. In such a laboratory environment the change of a supplier for particular instruments will have only limited disruptive effects.
- 50. According to the immunochemistry suppliers, significant shifts in demand can be easily accommodated as they produce their instruments and reagents according to existing demand, without being subject to particular restrictions on capacity. In particular, reagents are produced in large tanks that can be used for a production of all kinds of different reagents.
- 51. While looking at the joint market position of the parties on the immunochemistry market, the progressing convergence between the clinical chemistry and the immunochemistry systems should also be taken into account. Most laboratories have much higher throughput in clinical chemistry than in immunochemistry (85-95% of tests (in volume) are done in clinical chemistry systems) and run homogenous immunoassays on clinical chemistry analysers. As Siemens and Dade Behring are relatively weak in the clinical chemistry systems many competitors alongside the merged entity are very well positioned to offer complete solutions for both, clinical and immunochemistry solutions.
- 52. Finally, it needs to be underlined that a large and consistent majority of customers and competitors consider that the proposed concentration will not give the power to the merged entity to raise prices for immunochemistry systems or in any other way will lead to a significant impediment to effective competition in the common market or in a substantial part of it. On the contrary, a significant number of customers expect positive effects from the proposed concentration in terms of increased competition, lower prices and the availability of more advanced integrated analysers with broad assay menus.

#### *Immunochemistry – thematic panel level/assay level*

53. When considering the EDMA classification at the EEA panel level, the merged entity would enjoy its highest market shares on six out of 12 thematic panels.

# Table 3 Market shares at panel level in the EEA, sales in 2006

Thematic Panel	Total (Siemens + Dade Behring)
Cardiac	[30-40]% (S [10-20]%, DB [10-20]%)
Specific Proteins	[30-40]% (S [0-5]%, DB [20-30]%)
Therapeutic Drug Monitoring	[20-30]% (S [0-5]%, DB [20-30]%)
Drugs of Abuse	[20-30]% (S [0-5]%, DB [20-30]%)
Fertility	[30-40]% (S [30-40]%, DB [0-5]%)
Anaemia	[20-30]% (S [20-30]%, DB [0-5]%).

EEA market shares – Immunochemistry panels

54. As

# depicted

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Table 3, except for the cardiac panel, the increments in the EEA market shares resulting from the proposed transaction are minor and represent less than [0-5]%.

- 55. At a national level, the combined market shares of the parties generally show a similar picture as at EEA level. Only in relation to, generally, smaller EEA countries with limited market sizes combined market shares exceed [40-50]% for certain panels: i.e. cardiac (Portugal), cancer (Cyprus, Ireland and Lithuania), fertility (Cyprus, Portugal and Denmark), anaemia (Cyprus, Denmark, Latvia and Lithuania) and allergy (Czech Republic). However, the market share increments tend to be small: in case of the cancer, fertility, anaemia and allergy panels they amount to a maximum of [0-5]%<sup>20</sup>. For other panels, the national market shares are lower.
- 56. In addition, the market investigation strongly confirmed that the panel level may not be the level at which competition takes place. Customers make decisions concerning complete systems. They seldom purchase all assays within a specific panel. It is not uncommon for laboratories to purchase assays within one thematic panel from different suppliers. For cost efficiency reasons they tend to make a selection of assays available in a specific panel depending on their particular needs.
- 57. Looking at the level of assays, the concentration will combine two producers with a relatively broad menu of assays. Except for the cardiac and special proteins assays, overlaps of the parties' activities only exist in respect of particular assays in single countries. Accordingly, there are significant overlaps in seven cardiac assays, and 14 overlapping assays in the specific/plasma proteins segment. For most of the other assays the overlap of the Parties' activities does not exceed [0-5] % or the combined market share is less than [20-30]%.
- 58. The market investigation confirmed that most laboratories do not expect to face problems of assay availability once the concentration is effective. The transaction will not limit their choice of assays, considering that similar assays are available from many competitors in all EEA countries. Any attempts to raise prices could result in a demand shift to alternative providers. For example, in relation to allergy assays, the parties may have relatively high market shares in certain countries<sup>21</sup>, however specialised suppliers of allergy assays such as Phadia, which are stronger in the allergy assay market on an overall EEA market provide sufficient countervailing power to take away a potential incentive for price increases<sup>22</sup>. For all overlapping cardiac assays, there are several alternative suppliers (at least four suppliers post-concentration for each assay) active on the market. Due to the feeble position of Siemens in specific proteins, only a minimal increment in the position of Dade Behring will result from the concentration. Moreover, the merging parties provide very few unique assays, which are essential for the laboratories.

<sup>&</sup>lt;sup>20</sup> With the exception of the Cypriot, Latvian and Lithuanian anaemia markets. However, on these markets the joint turnover of the merged entity is very small with turnovers of respectively € [...], € [...] and € [...] in 2006.

<sup>&</sup>lt;sup>21</sup> In the Czech Republic the parties have a joint market share of approximately [80-90]% in 2006. Customers in the Czech Republic however did not express any concerns for price increases or other anticompetitive behaviour.

<sup>&</sup>lt;sup>22</sup> See also case M 4321 Siemens/ Bayer Diagnostics.

- 59. In addition, at the level of individual assays, there is broad supply side substitutability as suppliers can easily switch to the production of additional assays. As capacity constraints do not seem to be an issue in the IVD industry, most of the suppliers are able to offer and sell the various immunochemistry assays immediately and without significant increases in costs.
- 60. In- and out-licensing of technology used for the development and production of reagents is not unusual in the immunochemistry market. While it is true that, once a supplier has access to the intellectual property for a certain assay, it still needs to adapt it to its specific proprietary system, licensing does allow suppliers to react to market opportunities in respect of individual assays of the immunochemistry market within a reasonable time frame (usually between 12-24 months).
- 61. Finally, the market investigation shows that customers do not expect the merged entity to gain market power for one or several specific assays and do not identify a risk of shortening assay supply or price increases. Some customers point out positive aspects of this transaction like increased competition for prices and new products.
- 62. Therefore, the proposed concentration does not raise serious doubts as to its compatibility in the common market or in a substantial part of it in relation to immunochemistry.

#### **6.CONCLUSION**

63. 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 Articles 6(1)(b) of Council Regulation (EC) No 139/2004.

For the Commission signed Vladimir ŠPIDLA Member of the Commission