EN

Case No COMP/M.6175 - DANAHER/ BECKMAN COULTER

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 16/06/2011

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EUROPEAN COMMISSION

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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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 Sir/Madam,

Subject: Case No COMP/M.6175 - Danaher/ Beckman Coulter
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1]

1. On 6 May 2011, the European Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which the undertaking Djanet Acquisition Corp. (USA) controlled by Danaher Corporation (USA) ("Danaher") acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of the undertaking Beckman Coulter, Inc. (USA) ("Beckman") by way of public bid announced on 15 February 2011. Danaher and Beckman are designated hereinafter as the "parties (to the proposed transaction)"[2].

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1 OJ L 24, 29.1.2004, p. 1 ("the Merger Regulation"). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ("TFEU") has introduced certain changes, such as the replacement of "Community" by "Union" and "common market" by "internal market". The terminology of the TFEU will be used throughout this decision.

2 Publication in the Official Journal of the European Union No C 149, 20.05.2011, p.25.

I. THE PARTIES

2. Djanet Acquisition Corp. (USA) is the acquisition vehicle of Danaher, which is the ultimate holding company of a corporate group that designs, manufactures and markets professional, medical, industrial, commercial and consumer products in the following segments: Test & Measurement, Environmental, Life Sciences & Diagnostics, and Dental and Industrial Technologies. In the clinical diagnostics field, Danaher is primarily active through its Radiometer subsidiary and, to some extent, through its subsidiary Leica Microsystems, specifically its Leica Biosystems division. Both Leica and Radiometer are active in product markets (point of care clinical chemistry/immunochemistry and histology, respectively) in which Beckman is not present. In the analytical instruments field, Danaher is active primarily through its subsidiaries Leica Microsystems, Molecular Devices and AB SCIEX. Danaher's Hach subsidiary, although focusing on water testing applications, also has some operations in this area, particularly through its Lachat Instruments division.

3. Beckman, Inc. (USA) is a manufacturer and marketer of biomedical testing instrument systems that simplify and automate complex laboratory processes in the clinical diagnostics and life sciences categories. Beckman's operations can be broadly categorized into (i) clinical in vitro diagnostics products, including instruments and consumables, which account for 87% of Beckman's overall revenue, and (ii) analytical instruments and associated consumables for biomedical research (life sciences) and other applications, which account for the remaining 13%.

II. THE OPERATION

4. On February 6, 2011, Danaher entered into an agreement with Beckman pursuant to which Danaher will acquire Beckman by (i) making a cash tender offer for all of the outstanding shares of common stock of Beckman and (ii) acquiring any such shares not acquired upon consummation of the tender offer through a subsequent merger of an indirect-wholly-owned subsidiary of Danaher into Beckman, with Beckman becoming an indirect wholly-owned subsidiary of Danaher post-merger.

III. CONCENTRATION

5. As a result of the operation, Danaher will, for the purposes of the Merger Regulation, gain sole control over Beckman. The proposed transaction therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

IV. EU DIMENSION

6. The aggregate worldwide turnover of all the undertakings concerned in 2010 is more than EUR 5000 million (Danaher: EUR 9959 million; Beckman: EUR 2763 million).[3] Each of them has a EU-wide turnover in excess of EUR 250 million (Danaher […]; Beckman: […]). The parties do not achieve more than 2/3 of their EU wide turnover in one and the same Member State. The notified operation therefore has an EU dimension within the meaning of Article 1(2) of the Merger Regulation.

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[3] Turnover calculated in accordance with Article 5 of the Merger Regulation.

V. ASSESSMENT

V.1 RELEVANT MARKETS

7. The proposed transaction concerns the markets for (i) clinical in vitro diagnostics ("IVD") products including instruments and assays/reagents, and (ii) analytical instruments for scientific laboratories.

1.1 IVD – clinical diagnostics

8. IVD comprises the manufacture and sales of assays/reagents and related equipment/instruments (e.g. analysers) for the purpose of conducting tests outside the human body.

9. Previous Commission decisions in this sector relied on the classification of IVD assays/reagents used by the European Diagnostics Manufacturers' Association ("EDMA")[4]. EDMA classifies assays/reagents into 6 main (1st level) categories: Clinical Chemistry, Immunochemistry, Haematology/Histology, Microbiology, Infectious Immunology and Genetic Testing. Within each of these broad ("first level") categories, EDMA classifies IVD products into a further three levels that constitute progressively narrower segments. In previous Commission decisions, the relevance of the different levels was assessed on a case-by-case basis[5]. In addition, EDMA also offers a classification of instruments, software and services.

10. The parties overlap in three main reagent/assay categories: Clinical Chemistry, Immunochemistry and Haematology/Histology.

i) Clinical Chemistry (EDMA category 11) diagnostics are primarily used to test for glucose, cholesterol, sodium, and other substances found in large concentrations in the blood stream. These tests are typically run for both routine and emergency patients to help doctors understand the performance of basic bodily functions.

ii) Immunochemistry (EDMA category 12) involves the use of targeted antibodies to identify and test enzymes, drugs, hormones, and other substances found in relatively small concentrations in the body. Depending on the condition monitored, a number of separate applications can be distinguished within the immunochemistry segment (e.g., proteins, tumor markers, hormones, anemia-related/vitamin tests, therapeutic drug monitoring, rheumatoid and autoimmune diseases, and standards and controls).

iii) Haematology/Histology/Cytology (EDMA category 13) 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 anemia status. Histology is the study of the microscopic anatomy of tissues; it is typically performed by analyzing thin slices

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4 See Cases M.5661 – *Abbott/Solvay*; M.4865 – *Siemens/Dade Behring*; M.4321 – *Siemens/Bayer Diagnostics*; and M.950 – *Hoffmann La Roche/Boehringer Mannheim* Decision of 4.2.1998.

5 See e.g. Cases M.4865 – *Siemens/Dade Behring*, *Siemens/Bayer Diagnostics* and M.950 – *Hoffmann La Roche/Boehringer Mannheim op cit.*

(sections) of tissue under a microscope. Cytology refers to the study of cells in terms of structure, function, and chemistry. In clinical diagnostics, cytology typically involves the study of disease and the use of cellular changes for the diagnosis of a disease.

11. In only one of these three categories (Haematology/Histology/Cytology) did the Commission explicitly exclude such a wide market definition[6] (although competition has consistently been assessed on the basis of narrower categories in the other categories as well). In particular, it was found that competition within this category takes place at the level of hemostasis, core haematology and histology – i.e. each of these represents the widest possible product market definition in this category.

12. EDMA classifies instruments somewhat differently from reagents, insofar as it groups together in category 21 instruments for clinical chemistry, immunochemistry, and infectious immunology. Haematology/histology/cytology instruments are included in category 23.

13. In previous decisions, the Commission considered whether competition takes place at the level of systems (including both analysers and reagents) or whether competition needs to be assessed separately for assays and reagents[7]. In the case of immunochemistry and clinical chemistry, a systems approach was considered as plausible[8], especially in the case of "workhorse machines" (high capacity instruments used to carry out a large number of commonly performed tests)[9].

14. The parties note to this effect that nearly all of Danaher's and Beckman's customers in the clinical diagnostics field acquire instruments in combination with reagents under arrangements that combine the lease of instruments with an ongoing contract for the proprietary reagents to be used with the equipment (Operating Type Leases or "OTL"). In addition, the parties submit that both Danaher's and Beckman's instruments are specifically designed for the respective party's reagents, and accuracy of test results is only guaranteed if the party's own reagents are used.

15. Regarding ancillary products such as software and after-sales services, the parties only offer these for their own products. Their market positions in these segments are therefore unlikely to be stronger than their positions in e.g. complete systems (especially if there are independent suppliers of such services)

16. The Commission has traditionally made a distinction between clinical chemistry tests performed in laboratories and tests performed at the point-of–care (POC), also called rapid tests. The parties argue that this distinction also holds for immunochemistry.

17. In the present case, each aspect of the market definition can be left open as no concerns arise on any basis.

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6 Case M.4865 *Siemens/Dade Behring*.

7 Case M.4321 *Siemens/Bayer Diagnostics* para 23

8 Case M.4321 *Siemens/Bayer Diagnostics* para 23 and Case M.4865 *Siemens/Dade Behring* para 27

9 Case M.4321 *Siemens/Bayer Diagnostics* paras 19 and 23

18. The Commission has previously considered IVD markets to be national.[10] This is not disputed by the parties in the present case.

1.2 Analytical instruments (life sciences)

19. The analytical products field encompasses the development, manufacture, and sale of laboratory instrumentation and related equipment (e.g., consumables such as reagents, parts, and software) for biomedical research and other laboratory applications (e.g., life science, pharmaceuticals and other industries). These applications are distinct from applications in clinical settings such as hospitals and reference laboratories that service medical professionals, clinics, and other care-giving institutions. The analytical products field also includes certain instruments, such as laboratory robotics, which as such do not have the capability to make analytical determinations, but which are ancillary to the underlying laboratory processes leading up to and following the actual determination.

20. Consumables, services and software do not seem to be a relevant consideration from a competition perspective since the parties offer them essentially exclusively for their own instruments, and they likewise provide after-sales repair and maintenance services only for their own products. The parties state that, as a rule, the same is true for their competitors. Consumables, services and software do not therefore seem to be relevant from a competition perspective. Even if this were not the case, the parties' market position regarding consumables, services and software would not be stronger than in the respective instrument markets which are in any case not affected markets. Distribution markets are not affected by the transaction as the parties do not essentially distribute other products than their own.[11]

21. In previous decisions[12], the Commission considered that it is possible to identify different categories within the analytical instrumentation field according to the following nine techniques used for analysis: (i) Separations, (ii) Life Sciences Instruments, (iii) Mass Spectrometry, (iv) Molecular Spectroscopy, (v) Atomic Spectroscopy, (vi) Surface Science Techniques, (vii) Materials Characterisation, (viii) Laboratory Automation, and (ix) General Analytical. This is in line with the approach of Strategic Directions International (SDI), a business intelligence firm that monitors the life science equipment sector.

22. Separations techniques are designed to transform a mixture of substances, which may be in liquid or gaseous form, into two or more distinct products, which can then be analyzed using a variety of instruments. The broader separations space includes several different chromatography techniques (such as high performance liquid chromatography, low pressure liquid chromatography, gas chromatography, ion chromatography, thin-layer chromatography, and flash chromatography), as well as capillary electrophoresis, and chemical sensors.

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10 See Case M.5661 – *Abbott/Solvay Pharmaceuticals* and cases cited therein.

11 Beckman has the non exclusive right to sell some of CompuCyte's high content screening instruments and related products to certain customers. In 2010, it had minor sales […] to customers outside the EEA, which represents less than [0-5%] of the worldwide market size. As no vertically affected markets arise in relation to the distribution of any analytical life sciences instruments, vertical links are therefore not further considered in the present Decision.

12 See Cases M.5611 – *Agilent/Varian* and M.6128 – *Thermo Fischer/Dionex*.

23. The life science instrumentation segment encompasses a range of instruments for DNA and genetics research, including DNA sequencers and synthesizers, flow cytometry, high content screening/cell imaging, electrophysiology/patch clamp, nucleic acid amplification, in vivo animal imaging, microarrays, molecular biology purification, (gel) electrophoresis, biosensors, and related informatics products.

24. Mass spectrometers are instruments that convert a chemical compound from a molecule into ions, which are then separated according to their mass-to-charge ratio, which permits the abundance of each ion to be measured. Depending on the specific technology, mass spectrometers can be further segmented into different categories (e.g., single quadrupole, triple quadrupole, ion traps, matrix-associated laser desportion ionization Time-of-Flight (MALDI TOF), liquid chromatography mass spectrometer systems, and gas chromatography mass spectrometer systems).

25. Molecular spectroscopy is the analysis of molecular species by measuring a sample's absorption, emission and/or reflection of ultraviolet, visible, and/or infrared light. Depending on wavelength and type of radiation used for a device, molecular spectroscopy can be further segmented into visible and ultraviolet-visible (Vis and UV-Vis), near-infrared (NIR), infrared (IR), fluorescence & luminescence, color measurement, nuclear magnetic resonance (NMR), raman, polarimetry & refractometry, and ellipsometry.

26. Atomic spectroscopy is used to determine the elemental/atomic composition of a sample, typically using optical spectroscopy. Distinct light spectra made by the different elements in a sample can be used to identify particular elements. The atomic spectroscopy field can be segmented further depending on the relevant technology (e.g., atomic absorbance spectroscopy, optical emission spectroscopy, X-ray diffraction, and others).

27. Surface science techniques are primarily devoted to the microscopic analysis of material surfaces. These instruments investigate surfaces and subsurface volumes with a variety of probes, including physical probes, electron beams, and electromagnetic radiation of different frequencies. These instruments can range from modest optical microscopes to multimillion Euro systems of extreme sophistication.

28. The materials characterization segment encompasses a range of techniques that measure the physical characteristics of solid and liquid samples. These instruments investigate the physical response of a sample to changes in temperature or the application of different physical forces or stresses. Instruments that characterize the shape, size, or other properties of the particles within a sample also belong to this segment. The broader materials characterization space can be further segmented into calorimetry, particle characterization, petroleum analyzers, physical testing, thermal analysis, and viscometry & rheometry.

29. The laboratory automation segment encompasses systems designed to automate repetitive laboratory procedures, and consequently to increase the efficiency, accuracy, and pace of work done in the laboratory. The main systems within this broader segment include microplate readers, liquid handling systems, robotics systems, and management informatics.

30. The general analytical techniques field encompasses basic laboratory instruments, which are typically technologies at the lower end of the spectrum. The main technologies within this field include electrochemistry, laboratory balances, radioactivity applications, continuous flow/discrete analyzers, and dissolution testing.

31. Each of these nine categories may in turn be segmented into different product groups by reference to the specific analytical technique identified above. For example, within the

separations sector, it is possible to identify sub-segments for instruments based on the gas chromatography technique, on the (high or low pressure) liquid chromatography technique or on the basis of capillary electrophoresis (among others). Similarly, it is possible to identify a number of sub-segments within the mass spectrometry category. The exact market definitions can, however, be left open, as no concerns arise on any basis.

32. As to the geographic scope, the Commission previously concluded that certain markets within the separations and mass spectrometry category and hypothetical markets for certain consumables were EEA-wide in scope. However, given the small overlaps which resulted from the transactions in these previous cases, the question whether the markets or possible submarkets were EEA-wide or global was left open.[13] The same approach is followed in this case and is not disputed by the parties.

V.2 COMPETITIVE ASSESSMENT

2.1 IVD – clinical diagnostics

33. As also specified by a recent Commission decision,[14] there does not appear to be reliable third party data on the overall size of IVD markets, especially on narrower product categories and at the national level.

34. One source of market data is EDMA, which compiles sales data submitted by its members and makes it available in an aggregated format under the label European Diagnostic Market Statistics (EMDS). However, there are inherent limitations to EDMA data as outlined already in a previous Commission decision[15]. In particular EDMA does not cover all EEA Member States and all competitors. In addition to this, the parties also submit that due to the prevalence of OTL-style purchasing, delineating the sales of assays/reagents from the sales of instruments is not a straightforward exercise. In the parties' view, EMDS in particular overestimates the size of reagents sales and underestimates the size of corresponding instrument sales.

35. Another source of market data […] is a report published by Boston Biomedical Consultants (BBC)[16]. This report includes market data worldwide as well as for Europe, which includes the 27 EU Member States and Switzerland[17]. The BBC report does not provide, however, separate market data for individual EU Member States.

36. The parties therefore used their own market intelligence as well as EMDS and BBC to estimate their market positions for each EEA Member State and for each possible product market (including narrower EDMA categories).

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13 M.5611 – *Agilent/Varian*; M.6128 – *Thermo Fischer/Dionex*.

14 Case M.5661 – *Abbott/Solvay*.

15 Case M.5661 – *Abbott/Solvay*.

16 BBC is a consulting company focused on the IVD sector. The most recent BBC report, "*The Worldwide In Vitro Diagnostic Test Product Market - Segment Discussions 2008, 2009 and 2014 Estimate*" was published in 2010.

17 According to the parties the overall market size would not materially change if calculated on the basis of the EEA as the EFTA states account only for a minimal share of the market.

37. In previous human health cases[18] and the most recent IVD decision[19], the Commission has generally focused its market investigation to examine in more detail markets where the Parties achieved a combined share of over 35% and the increment in the share was over 1%. Based on their estimates, the parties could exclude affected markets for most markets where they overlap and excluded that their combined market share would be 35% or over with an increment of 1% or over for all markets.

38. Due to potential uncertainties pertaining to the market data, the Commission nevertheless carried out a market investigation to verify if there are any IVD market segments where both parties are strong suppliers and have combined market shares of 35% or over and/or where a sufficient number of credible alternative suppliers would not be present following the merger. The market investigation covered the main competitors (for the whole of the EEA) and leading medical professionals in the IVD field (i.e. Key Opinion Leaders).

Clinical chemistry

39. The parties argue that they are not close competitors. Whereas Beckman offers core laboratory instruments with a wide range of tests and high output, Danaher offers only one specific type of instrument/reagent (critical blood analyte tests), which the parties submit is primarily a POC instrument. The fact that the parties do not overlap in any possible narrower category within clinical chemistry (EDMA 21) and the corresponding instrument category including instruments for clinical chemistry, immunochemistry and infectious immunology) (EDMA 21) supports their argument that they are not close competitors.

40. When estimating their market positions the parties provided estimates based on the possible following market definitions: (i) clinical chemistry systems; (ii) clinical chemistry instruments; (iii) clinical chemistry reagents (EDMA 11); and (iv) instruments for clinical chemistry, immunochemistry, and infectious immunology (EDMA 21).

41. Having considered all these possible market definitions, the parties could not exclude that they would have a combined market share of over 15% in some EEA Member States. However, they could exclude that the transaction would lead to market shares of 35% or over with an increment of 1% or over even for these markets.

42. In addition, the parties identified a number of significant competitors which would remain in clinical chemistry, including Roche, Siemens, Johnson and Johnson and Abbott.

43. The market investigation clearly confirmed that the parties do not achieve market shares of 35% or over in any segment. Furthermore, the market investigation did not indicate any segments where it would be difficult for medical professionals to find credible alternatives besides the parties.

44. Due to the moderate combined market positions of the parties, the presence of credible suppliers and the fact that the parties are not appear close competitors, competition concerns can be excluded in clinical chemistry.

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18 See e.g the most recent Case M.5865 – *Teva/Ratiopharm* and Case M.5778 – *Novartis/Alcon*.

19 Case M.5661 – *Abbott/Solvay*.

Immunochemistry

45. While Danaher and Beckman are both present in the overall immunochemistry category, the parties submit that their offerings are fundamentally different in terms of characteristics, field of application, pricing, and other parameters. Danaher's immunoassay product is a POC instrument for time-sensitive tests and a limited test menu, while Beckman offers high-throughput machines for core laboratory applications with a very broad test menu.

46. The parties overlap in the following wider categories: (i) immunochemistry systems; (ii) immunochemistry instruments; (iii) immunochemistry reagents (EDMA 12); and (iv) instruments for clinical chemistry, immunochemistry, and infectious immunology (EDMA 21). Furthermore, the parties overlap in the supply of reagents within the second and third level categories "Cardiac markers" (EDMA 12.13 and EDMA 12.13.01 – the two categories are identical). Furthermore, the parties overlap within four EDMA 4 level Cardiac Marker categories[20].

47. The parties could exclude affected markets in immunochemistry based on any possible market definition. Furthermore, the market investigation did not indicate any segments which may be of concern due to high combined market shares and/or due to the lack of sufficient number of credible competitors remaining. Competition concerns can therefore be excluded for immunochemistry.

Haematology/Histology/Cytology

48. Based on the relevant market definition considered by the Commission previously (see paragraph 11 above), the transaction does not lead to overlaps in the EEA[21]. In particular, according to the parties, Beckman is active in haematology, whilst Danaher is active in histology.

Conclusion IVD – clinical diagnostics

49. Based on the analysis outlined above, competition concerns can be excluded in the area of IVD.

2.2 Analytical instruments life sciences

50. Danaher and Beckman's activities overlap in six categories defined in the SDI report[22], namely separations, life science instrumentation, molecular spectroscopy, materials characterisation, laboratory automation and general analytical techniques. The parties claim that with a few exceptions, their products are typically not substitutable from a supply or demand side perspective. This is plausible in view of their products' different uses and the price differences. However, the SDI categories where the parties' activities overlap would

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20 BNP/ProBNP (12.13.01.01); Creatine Kinase (12.13.01.02); Myoglobin (12.13.01.05) and Troponin I/T (12.13.01.07).

21 Whilst both parties supply hemastasis-related products (though Beckman only distributes the products of another company), Beckman does not sell these products in the EEA.

22 Strategic Directions International, Inc.: "Global Assessment Report 11th Edition: The Laboratory Analytical and Life Science Instrumentation Industry, 2010-2014".

not constitute affected markets as the parties' combined market share is in any of the abovementioned SDI categories well below 5% in four of these categories and below 10 % in the remaining two[23] (at both EEA or worldwide level). The source for the market data is the SDI 2010 report, on which the Commission has in the past relied.

51. Should product groups within the six SDI categories where the parties' activities overlap be regarded as separate markets, there would be no overlaps in the separations category as the parties are not present in the same product group (subsegment).

52. In the other five categories, there are six product groups where the activities of the parties overlap, namely (i) DNA Sequencing (Category Life Science Instrumentation), (ii) Ultraviolet Visible Spectoscopy Instruments (Category Molecular Spectroscopy), (iii) Particle Characterization (Category Materials Characterization), (iv) Liquid Handling, (v) Laboratory Robotics (both Laboratory Automation), and (vi) Electrochemistry (Category General Analytical Techniques).

53. None of these product groups constitutes an affected market, because in none of them do the parties' combined market share exceed 15%, either at an EEA or at a worldwide level[24] (with one exception, their combined market shares are even less than 10%).

54. Competitors in the analytical products field include numerous large broad-based companies that manufacture and sell instruments across many categories of analytical instruments, even more multi-product companies with more narrowly focused activities, as well as hundreds of single product and niche players that typically focus on only one instrument category. The overall number of competitors within the field of analytical products is estimated at more than 1,000.[25]

55. In all the product groups where the parties overlap, there are at least six other competitors active in the market. Neither Danaher nor Beckman are currently in the group of major broad-based analytical products companies as identified by SDI, which is led by Life Technologies (Applied Biosystems), Thermo Scientific, Agilent Technologies, Waters Corporation, Shimadzu, Perkin Elmers, and others. Indeed, SDI ranks Danaher only at number 12 and Beckman at number 13 of the relevant players in the markets for analytical products.[26]

56. Based on the analysis outlined above, competition concerns can be excluded in the area of analytical instruments life sciences.

VI. CONCLUSION

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23 Below 10% in the categories of laboratory automation and of select laboratory equipment.

24 Only if within the molecular spectroscopy category, and there within the group of Ultraviolet Visible Spectroscopy Instruments, a distinction would be made between different subsegments such as Single Beam or Dual Beam Ultraviolet Visible Spectroscopy Instruments, would there be market shares of slightly over 15%([15-20%]) on a worldwide market but not on an EEA wide market.

25 See SDI Report 2010, pp. 23-29.

26 See SDI Report 2010, p. 26.

57. For the above reasons, the European Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation.

For the Commission
(Signed)
Neelie Kroes
Vice-President