EN

Case No COMP/M.5661 - ABBOTT/ SOLVAY PHARMACEUTICALS

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REGULATION (EC) No 139/2004 MERGER PROCEDURE

Article 6(1)(b) in conjunction with Art 6(2)
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PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION IN CONJUNCTION WITH ARTICLE 6(2)

To the notifying party

Dear Sir/Madam,

Subject: Case No COMP/M.5661 - ABBOTT/ SOLVAY PHARMACEUTICALS Notification of 15 December 2009 pursuant to Article 4 of Council Regulation No 139/2004[1]

1. On 15/12/2009, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 (the "EC Merger Regulation") by which Abbott Laboratories ("Abbott"), US acquires, within the meaning of Article 3(1)(b) of the EC Merger Regulation, sole control of the pharmaceuticals business of Solvay S.A. ("Solvay Pharma"), Belgium by way of purchase of shares.

I. THE PARTIES AND THE OPERATION

2. Abbott is a global healthcare company headquartered in the US and listed on the New York, London and Swiss Stock Exchanges. Abbott has four main businesses: (1) pharmaceutical products, (2) nutritional products, (3) diagnostic products, and (4) medical devices.

[1] OJ L 24, 29.1.2004 p. 1.

3. Solvay Pharma is the pharmaceuticals division of Solvay S.A. ("Solvay"), headquartered in Belgium. Through the acquisition of the Belgian biotechnological company, Innogenetics, in 2008, Solvay Pharma also acquired activities in the diagnostics field.

4. On September 26, 2009, Abbott and Solvay entered into a Stock and Asset Purchase Agreement pursuant to which Abbott will acquire substantially all of Solvay Pharma, in exchange for all-cash consideration. As a result of the Transaction, Solvay Pharma will become part of Abbott's pharmaceutical products group.

5. The transaction therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation

II. COMMUNITY DIMENSION

6. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion[2] (Abbot EUR 20,000 million; Solvay EUR 2,700 million). Each of them has a Community-wide turnover in excess of EUR 250 million (Abbott EUR - […]*; Solvay […]*), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State.

7. The notified operation therefore has a Community dimension pursuant to Article 1(2) of the EC Merger Regulation.

III. ASSESSMENT

Relevant product and geographic markets

Finished dose pharmaceuticals

8. The Commission has analysed markets for existing pharmaceutical specialties in previous decisions.[3] According to the Commission, the market for existing pharmaceutical specialities can be classified into therapeutic classes by reference to the Anatomical Therapeutic Chemical Classification ("ATC") devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS").

9. The third level, referred to as ATC3, allows medicines to be grouped according to their therapeutic indications (i.e. their intended use) and is generally taken as the starting point for the product market definition in competition cases. However, it may be appropriate to carry out analyses also at other levels, for example at ATC4 or molecule (based on the same main active pharmaceutical ingredient or API) level[4], or across classes, if specific

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2 Turnover calculated in accordance with Article 5(1) of the Merger Regulation.

3 See e.g. Case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2009.

4 See e.g. Case COMP/M.5295 *Teva/Barr*, Decision of 19 December 2008.

circumstances indicate that the ATC3 level is not the most appropriate for the purposes of the market definition.

10. In some cardiovascular therapeutic areas, where the parties overlap, the Commission also previously considered some market definitions that do not correspond exactly to the ATC classification. Within the ATC3 category C7A (Beta Blocking Agents), the Commission previously considered a distinction between selective and non-selective drugs[5]. Within the ATC3 category C8A (Calcium Antagonists - Plain), the Commission considered a distinction between dyhidropyridine (DHP) and non-DHP drugs[6]. Finally, the Commission considered it possible that the relevant market for products falling into the ATC3 categories C9A (ACE inhibitors, Plain) and C9B (ACE inhibitors, Combination) may comprise both of these categories.

11. The Commission has in previous cases[7] tested the appropriateness of the distinction between pharmaceuticals available without prescription (over-the-counter "OTC") and pharmaceuticals only available on prescription in its assessment on a case-by-case basis. For the purpose of the present case, it can be left open whether a distinction should be drawn or not as the proposed transaction would not give rise to competition concerns irrespective of the market definition.

12. The exact delineation of the relevant product markets in finished dose pharmaceuticals is not necessary in the present case as the proposed transaction would not give rise to competition concerns irrespective of the market definition.

13. The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope as competition between pharmaceutical firms still predominantly takes place at a national level.[8]

Active pharmaceutical ingredients (APIs)

14. In previous decisions, the Commission concluded that active ingredients (APIs) form separate product markets which are upstream of the market of the finished pharmaceutical products. The Commission has looked at each individual API as potentially constituting a relevant market by itself. However, it cannot be excluded that certain APIs may be substitutable with each other for all, or for a range of, applications. The Commission has also found that active ingredients markets are, in

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5 See e.g. Case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2009.

6 The two types of drugs differ in their basic chemical structure and selectivity.

7 See e.g. Case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2009.

8 See e.g. Case COMP/M.5476 *Pfizer/Wyeth*, Decision of 17 July 2009.

terms of a geographic scope, wider than markets for finished pharmaceutical products and may be worldwide.[9]

15. In the present case, the precise product and geographic market definition can be left open as the proposed transaction would not give rise to competition concerns irrespective of the market definition.

Contract manufacturing

16. According to the Commission's previous decisions, contract manufacturing of finished dose pharmaceuticals ("contract manufacturing") consists of the manufacturing under contract, on behalf of third party pharmaceutical companies, of finished pharmaceutical products which may or may not include final packaging[10]. In previous decisions, the Commission has left open whether contract manufacturing should be delineated further by, for example, the technology and know-how needed to produce different forms of pharmaceuticals.[11] In these previous decisions, the geographic market was considered to be at least EEA-wide, and possibly wider.

17. The exact delineation of the relevant markets in contract manufacturing is not necessary in the present case as the proposed transaction would not give rise to competition concerns irrespective of the market definition.

In vitro diagnostics products

18. In 2008, Solvay acquired *Innogenetics*, a Belgian diagnostics company with a turnover of around EUR 50 million (<5% of Solvay Pharma's turnover). Given that Abbott has significant activities in *in vitro* diagnostics (IVD), the transaction leads to overlaps in this area. IVD diagnostics comprise the manufacture and sales of assays/reagents and related equipment/instruments (e.g. analysers) for the purpose of conducting tests outside the human body.

19. Previous Commission decisions relied on the classification of IVD products used by the European Diagnostics Manufacturers' Association ("EDMA")[12]. This is similar to the ATC classification for pharmaceuticals. EDMA classifies assays/reagents into 6 main 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

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9 Cases COMP/M.3751 – Novartis/Hexal, decision of 27 May 2005, COMP/M.3928 – Teva/Ivax, decision of 24 November 2005, paras 14 and 15.

10 See case COMP/M.5253 *Sanofi-Aventis/Zentiva*, Decision of 4 February 2009.

12 See Cases COMP/M.4865 Siemens/Dade Behring Decision of 21.10.07; COMP/M.4321 Siemens/Bayer Diagnostics; and COMP/M.950 Hoffmann La Roche/Boehringer Mannheim Decision of 4.2.1998

decisions,[13] the exact market definition was left open. The market investigation in the present case indicated that the EDMA classification in general could be applied for the market definition and that the narrower EDMA levels may be considered as the appropriate relevant market. This notwithstanding, as in pharmaceuticals, a case-by-case analysis is necessary. Except for cystic fibrosis testing, the product market definition can be left open as the proposed transaction would not give rise to competition concerns irrespective of the market definition.

20. 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 based on assays/reagents separately. In the case of immunochemistry and clinical chemistry, a systems approach was considered as plausible, especially in the case of "workhorse machines" (high capacity instruments used to carry out a large number of commonly performed tests). In the present case, the systems approach to market definition does not appear relevant. Innogenetics is a relatively small player and does not sell high capacity proprietary machines with wide assay menus. It does not even produce equipment. Its tests are performed on low capacity equipment procured from third parties, some of which is optimised for Innogenetics products. Innogenetics' sales of such equipment amounted to EUR – […]* in 2008. Furthermore, the main overlaps are not in the two categories where the systems approach was considered.

21. In *Hoffmann La Roche/Boehringer Ingelheim*[14] the Commission also previously considered a distinction based on the two principle testing methods/technologies used in IVD tests: protein based tests and DNA probes. It was concluded in that decision that the latter constitute a separate market due to different technological features and the unique ability of DNA probes to provide certain diagnostics results. According to the parties, DNA probes are equivalent to what are now called molecular products. While recognising their specific use outlined in *Hoffmann La Roche/Boehringer Ingelheim*[15], the parties do not consider molecular products to be distinct. In light of the clear Commission precedent and Innogenetics' focus on molecular products, however, a separate possible market definition for molecular products has been considered in the present case. The market investigation in the present case indicated that molecular products may constitute a separate market. However, for the purpose of this decision, the precise market definition can be left open as the proposed transaction would not give rise to competition concerns irrespective of the market definition.

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13 See e.g. *Siemens/Dade Behring*, *Siemens/Bayer Diagnostics* and *Hoffmann La Roche/Boehringer Mannheim op cit.*

14 *op cit.*

15 *op cit.*

22. The two main areas where the parties overlap are Genetic Testing and Infectious Immunology. There are further overlaps in Immunochemistry and Haematology/Histology.

23. **Genetic testing products** are classified into two main categories depending on whether the gene or chromosome alterations tested for are inborn (various disorders) or acquired (mainly cancer related). The former is classified into four groups of disorders (third level). Each of these comprises several specific diseases/disorders (fourth level). Innogenetics is active only with one product, a test for cystic fibrosis. This segment is also supplied by Abbott. Cystic fibrosis constitutes a fourth (and hence the narrowest) level within the wider (third level) group of "Monogenetic disorders". According to the parties, cystic fibrosis tests account for only about 10% of the workload of laboratories in Genetic Testing. Other fourth level segments in this group include other tests for other disorders.[16]

24. There are several different types of mutations within cystic fibrosis. Whereas some mutations are common to all ethnic groups, others may be found primarily within only one ethnic group.

25. The parties did not propose a wider market than cystic fibrosis tests. The market investigation confirmed cystic fibrosis products to be distinct due to the lack of substitutability with other Genetic Testing products. Only cystic fibrosis products (in the respective fourth level EDMA category) are capable of diagnosing mutations of the CTFR gene, which in turn is the underlying cause of cystic fibrosis.

26. In light of the above, cystic fibrosis diagnostic products are considered, for the purposes of this case, to constitute a separate product market.

27. **Infectious immunology tests** are performed in connection with certain types of diseases caused by bacterial or viral infections and are subdivided according to the type of disease. The parties overlap in Hepatitis viruses, Retroviruses, Bacteriology and an apparent "catch-all" category of "Other virology". Each of these categories is then subdivided into more specific types of diseases and assays/reagents (e.g. different hepatitis viruses or, in the case of Retroviruses, different types of HIV viruses and HTLV[17] viruses). The parties overlap in narrower categories (third and/or fourth level) in products used to test for the following diseases: Hepatitis B (HBV); Hepatitis C (HCV); two separate types of HIV viruses (HIV 1 and HIV 1/2 multiple); HTLV Multiple (tests for different types of HTLV) and Syphilis.

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16 All products within the wider category of "Genetic Tests" are molecular products. A further subdivision of this category according to molecular and non-molecular products is therefore not relevant.

17 Human T-lymphotropic virus (HTLV) is a human RNA retrovirus that causes T-cell leukemia and T-cell lymphoma in adults

28. As opposed to products used in genetic testing, infectious immunology products may be both molecular and traditional products. Molecular products, however, generally fall in distinct fourth level EDMA categories. Therefore, an analysis based on the EDMA classification would generally cover the molecular distinction as well.

29. In **Immunochemistry,** the parties only overlap in two second level categories, "Tumor markers" and "Auto-immune diseases". Within "Tumor markers", the parties overlap in the narrower, third level category of "Cancer Antigens", but there are no overlaps on any narrower fourth level category. In **Haematology/Histology**, Innogenetics has only one product used in determining tissue compatibility in transplants. Abbott has a product in the same fourth level category. The Immunochemistry and Haematology categories contain both molecular and traditional products.

30. Finally, the parties mention certain overlaps in molecular products that do not correspond to any one distinct EDMA category, in particular molecular products used in oncology and, within that, breast cancer. In the present case, however, it can be left open whether a distinction between molecular and non-molecular products should be made as the proposed transaction would not give rise to competition concerns even if the relevant product market would contain only molecular products.

31. The scope of the *geographic market* was consistently considered to be national in previous decisions. This has been confirmed in the market investigation. In the present case however, the exact market definition can be left open as the proposed transaction would either give or not give rise to competition concerns irrespective of the market definition

Competitive assessment

Finished dose pharmaceuticals

32. The parties overlap in 13 ATC3 categories at the national level. The Transaction gives rise to only two affected markets at the ATC3 level: C8A – Calcium Antoagnoists, Plain - Luxembourg (combined [20-30]*%, Abbott [5-10]*%, Solvay [10-20]*%); and C9A -ACE Inhibitors, Plain in the Slovak Republic (combined [20-30]*%, Abbott [20-30]*%, Solvay [5-10]*%). These market shares remain the same using possible further subdivisions based on the ATC4 level and on the Rx/OTC distinction.

33. In addition, there is only one market that is affected at the ATC4 level, which is not affected at the ATC3 level: N5A9 - Conventional Anti-psychotics in Italy (combined [30-40]*%, Abbott [5-10]*%, Solvay [20-30]*%).

34. In the ATC3 markets where they overlap at the national level, the parties do not overlap at the molecule level.

35. Assuming the various alternative market definitions considered in previous decisions (see paragraph 10) that do not correspond to the ATC classification, the transaction gives rise to only one affected market in the combined C9A-ACE Inhibitors, Plain /C9B - ACE Inhibitors, Combination category in the Slovak Republic. The combined market shares ([20-30]*%), however, are not materially different from the combined market shares in the C9A segment in the Slovak Republic ([20-30]*%).

36. In previous decisions concerning pharmaceutical markets, the Commission considered affected markets as so-called "Group 1" markets where the combined market share was 35% or more and the increment was 1% or above as a threshold to identify possible concerns. In the present case, the parties' market shares in each of the affected possible markets remain modest, i.e. no "Group 1" markets as the combined market shares remain below 35%. For each possible affected market, there remain at least four to five competitors with market shares of at least 5% each. Competition concerns could therefore be excluded without a market investigation.

37. Both Parties have pipeline products that reached the "Phase III" stage of development (broad clinical testing). This was considered by the Commission in previous decisions to be sufficiently advanced to compete with either existing or other pipeline products. In the present case, the parties' pipeline products do not overlap on the ATC3 level. There is only one ATC3 category (D5A – topical antipsoriasis products) where Abbott has a pipeline product in "Phase III" and Solvay has an existing product. Abbott is not yet active in D5A in the EEA. Abbott expects to enter the market with its product between […]*. There are no indications that Abbott would achieve a high market share in a very short time. Due to the modest market shares of Solvay in D5A – topical antipsoriasis products in the EEA ([10-20]* % in Sweden and [5-10]*% in Denmark), competition concerns could be excluded without a market investigation.

APIs

38. There is no horizontal overlap between the APIs of Abbott and Solvay at either the API level or the ATC3 level for finished dose pharmaceuticals in which the APIs sold by the parties are used. The proposed transaction gives rise to one vertically affected market.

39. When identifying vertically affected markets which may give rise to serious doubts, the Commission has previously focused on vertical relationships where (i) either party has a market share of more than 30% in an upstream API-market and the other party has a market share of more than 5% in an ATC3 class containing that particular API, or (ii) either party has a market share of more than 25% in a downstream ATC3 class and the other party has a market share of more than 5% of a corresponding upstream API-market.[18]

40. There is one downstream vertically affected market where Abbott's market share exceeds 30% in the upstream API market and Solvay has a market share of more than 5% in a

[18] See case COMP/M.5253 – Sanofi-Aventis/Zentiva, para 516.

corresponding downstream ATC3 class. This concerns the API biperiden hydrochloride, an anticholinergic API used in drugs that treat Parkinson's disease that is supplied by Abbott, while Solvay is active in the downstream ATC3 category N4A – Anti-Parkinson's drugs, that also contains products based on other APIs than biperiden hydrochloride. Abbott's market share on a worldwide market for APIs for biperiden hydrochloride is [50-60]*%, based on worldwide sales of approximately only EUR […]* in 2008. Abbott's worldwide competitors for biperiden hydrochloride are CE Pharma, Hungary, Hermes Chemical Company, India and Shiono Kyono Kaisha, Japan. The parties' combined downstream shares in N4A are below 15%.

41. The parties argue that biperiden hydrochloride is not protected by a patent and is not particularly important in the treatment of Parkinson's disease, because there are a number of anticholinergic agents available from other suppliers, e.g. procyclidine and benztropine, which can be used for similar drugs for the treatment of Parkinson's disease. Furthermore, Abbott has only […]* customers in the EEA who, according to the parties, could easily switch to other major worldwide suppliers to meet their needs should Abbott decide to raise prices or reduce availability.

42. In its previous decisions, the Commission found that moderate entry barriers for existing API suppliers, the frequent use of dual sourcing for APIs, the current spare capacity in the API-industry and increasing competition from producers in China and India makes any vertical foreclosure strategy unlikely to succeed. [19]

43. Taking this into account the transaction does not give rise to competition concerns due to input foreclosure.

Contract manufacturing

Finished dose pharmaceuticals

44. Both parties are active in the contract manufacturing of finished dose pharmaceuticals. There are no horizontal overlaps in the ATC3 classes and countries where the products manufactured on contract by the parties are sold. The parties estimate that their market shares on a worldwide market for contract manufacturing are below [0-5]*% respectively. There are no downstream markets where the parties have a contract manufacturing customer and a combined market share of 25% or over. Competition concerns can therefore be excluded.

Diagnostics

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19 See casees COMP/M.5253 – Sanofi-Aventis/Zentiva, para 521; COMP/M.5295 – Teva/Barr, Decision of 19 December 2008.

45. Both parties produce a Hepatitis C Genotyping test (fourth level EDMA category), but only Abbott markets such a test while Innogenetics' product is manufactured exclusively for Siemens Healthcare. The Innogenetics' product is a strip based HCV Genotyping product for which Siemens Healthcare holds the exclusive rights and sells it under its VERSANT trademark[20]. Innogenetics' revenues from this contract amounted to around EUR […]*in 2008. The parties argue that Siemens Healthcare's rights are protected under its agreement with Innogenetics. But even in the event that this agreement comes to an end, Siemens Healthcare is […]*. In the market investigation, Siemens Healthcare confirmed that it is ensured that it will be provided with the product after the transaction. Competition concerns can therefore be excluded.

In vitro diagnostics

46. Abbott is a leading global player in diagnostics products (both assays and equipment) with a wide a range of products. Solvay, via its subsidiary, Innogenetics, is a relatively small player, focusing on specific segments.

47. Given that Abbott has significant activities in *in vitro* diagnostics (IVD), the transaction leads to overlaps in this area. IVD diagnostics comprise the manufacture and sales of assays/reagents and related equipment/instruments (e.g. analysers) for the purpose of conducting tests outside the human body.

48. The EDMA data for the sales of diagnostics products (assays/reagents) are not as reliable as IMS statistics for finished dose pharmaceuticals. First of all, they cover only 10 EEA Member States.[21] According to the parties, these 10 EEA Member States account for 80% of total EEA demand. Furthermore, not all IVD suppliers report to EDMA. Where possible, the parties provided estimates of their own market shares or where these estimates were not possible, their own sales for each national market where they overlap. In order to get additional market data, competitors were requested in the market investigation to provide their own sales in some markets, in particular cystic fibrosis. The market investigation also examined whether there were any other possible markets where the parties may have high market shares besides those identified by them.

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[20] According to the parties, the two products are not close competitors. Abbott's product is a fully automated solution that, like Innogenetics' strip based product, is capable of identifying all six major genotypes. However, it can distinguish only two major subtypes while Innogenetics' product can identify all of the major subtypes. Abbott sells a RealTime PCR-based HCV Genotyping product which was re-launched in the EEA in 2008. The 2008 sales amounted to approximately EUR […]*.

[21] These are Austria, Belgium, the Czech Republic, France, Germany, Italy, the Netherlands, Portugal, Spain and the United Kingdom.

49. The two main areas where the parties overlap are Genetic Testing and Infectious Immunology. There are further overlaps in Immunochemistry and Haematology/Histology.

50. In previous Commission decisions in the field of human health[22], the Commission has as a starting point for the market investigation, applied a grouping according to certain thresholds of the market shares. So called "Group 1" markets are markets with a combined market share of 35% or more and an increment of at least 1%, "Group 2" markets are markets with a combined market share of 35% or more and an increment of below 1% and "Group 3" markets are markets with a combined market share of below 35%.

51. The parties have identified possible horizontally affected relevant markets where, based on any possible EDMA level, the transaction would lead to combined market shares of at least 35% with an increment of 1% or higher ("Group 1" markets).

52. There are in addition a number of possible markets where the combined market shares of the parties exceed 35% but the increment is below 1% ("Group 2" markets) or where the combined market share of the parties is between 15% and 35% ("Group 3" markets) based on any possible EDMA level. The market investigation confirmed that competition problems do not arise with respect to the possible "Group 2" and "Group 3" markets.

53. Based on the figures provided by the parties (using EDMA data and their own market intelligence), the parties would have a combined market share of 35% with an increment exceeding 1% in the EDMA categories assessed below. The transaction does not give rise to additional "Group 1" markets even if a molecular only segment of the respective EDMA categories is considered, except for molecular oncology tests for breast cancer in France and Germany as well as for molecular tuberculosis tests in Slovenia and Italy, where "Group 1" markets could not be excluded.

IVD products without serious doubts

54. In **Immunochemistry,** the parties only overlap in two second level categories, "Tumour markers" and "Auto-immune diseases". Within "Tumour markers", the parties overlap in the narrower, third level category of "Cancer Antigens", but there are no overlaps on any narrower fourth level category.

55. EEA wide, the parties' market shares in the two second level and the one third level categories are below 30%. On national markets in the EEA Austria is the only country where the combined market shares exceed 35% with an increment of more than 1%: in the second level EDMA category "Tumour markers", the combined market share amounts to [40-50]*% (Abbott [40-50]*%, Innogenetics [0-5]*%) and

22 Cases COMP/M.3354 *Sanofi-Synthelabo/Aventis*, Decision of 26 April 2004, para. 20; COMP/M.3751 *Novartis/Hexal*, Decision of 27 May 2005, para. 25; COMP/M.5295 *Teva/Barr*, Decision of 19 December 2008, para 23.

in the third level EDMA category "Cancer Antigens", the combined market share amounts to [50-60]*% (Abbott [40-50]*%, Innogenetics [0-5]*%).

56. The parties argue that their respective products have somewhat different specifications and functions, which would limit competition between them. Innogenetics only Cancer Antigen product is a protein-based product used to test for the presence of human placental alkaline phosphatise (hPLAP) protein while Abbott's various protein-based Cancer Antigen products are not uses to test hPLAP. Innogenetics' two molecular Tumour Markers screen for the presence or absence of certain RNA messengers in circulating tumour cells. One of Innogenetics' tests is used to detect breast cancer, and the other test to detect colon cancer while Abbott's molecular cancer tests fall in different fourth level EDMA classification and are mainly used for the prognosis of the response to therapy, or survival, of bladder, breast and other cancer patients.

57. The market investigation broadly confirmed that generally there are major differences between protein based tests (traditional) and molecular diagnostic tests. For the parties' products in Immunochemistry the majority of respondents confirmed the parties' view that they are not close competitors and that there are enough credible competitors remaining that are active in all or almost all EEA countries, including Austria. Competitors in the same second and third EDMA level category are Biomedica, Wragge, Siemens Healthcare, DiaSorin and bioMérieux with a number of products respectively.

58. Given the small increment on the part of Innogenetics, the fact that it was confirmed that the parties' products are not close competitors due to different applications, which is further confirmed by the fact that these products belong to different fourth level EDMA categories, and the sufficient number of credible competitors that remain (such as Roche, Siemens Healthcare, Biomedica and DiaSorin), it can be concluded that the proposed transaction does not raise serious doubts in any Immunochemistry segment in Austria, and hence that competition concerns could be excluded.

59. **Infectious immunology tests** are performed in connection with certain types of diseases caused by bacterial or viral infections and are subdivided according to the type of disease. Within this category the parties overlap in Hepatitis viruses, Retroviruses, Bacteriology and an apparent "catch-all" category of "Other virology". Each of these second level categories is then subdivided into more specific types of diseases and assays/reagents (e.g. different hepatitis viruses or, in the case of Retroviruses, different types of HIV viruses and HTLV[23] viruses). The parties overlap in narrower categories (third and/or fourth level) in products used to test for the following diseases: Hepatitis B (HBV); Hepatitis C (HCV); two separate types of

[23] Human T-lymphotropic virus (HTLV) is a human RNA retrovirus that causes T-cell leukemia and T-cell lymphoma in adults

HIV viruses (HIV 1 and HIV 1/2 multiple); HTLV Multiple (tests for different types of HTLV); and Syphilis.

60. As opposed to products used in genetic testing, infectious immunology products may be both molecular and traditional products. Molecular products, however, generally fall in distinct fourth level EDMA categories. Therefore, an analysis based on the EDMA classification would generally also cover the molecular distinction.

61. EEA wide, the parties' combined market shares would exceed 35% with an increment of 1% or more in the third level EDMA categories HCV and HIV 1/2 multiple.

Infectious Immunology - Hepatitis viruses

62. In the second level EDMA category "Hepatitis Viruses", the transaction leads to Group 1 markets at the EEA level (combined [40-50]*%, Abbott [40-50]*%, Innogenetics [0-5]*%) and in six Member States (Belgium, Germany, the Netherlands, Spain, Cyprus and Poland). The increment by Innogenetics in each of these Member States is [0-5]*% or less and parties list at least three other competitors in each market.

63. The situation is similar in the narrower categories within Hepatitis viruses. The transaction would give rise to three "Group 1" markets at the national level considering assays/reagents used to test for Hepatitis B – "HBV" (third level EDMA category). Although the combined market shares would be between [50 and 70]*%, the increment by Innogenetics would be small ([0-5]* – [0-5]*%) and the parties listed at least four other competitors in each of these markets (Austria, the Netherlands and Poland). These competitors include global health care companies such as Roche, Siemens Healthcare and Johnson & Johnson as well as the global diagnostics companies bioMérieux and Beckman Coulter. The parties also overlap in the narrower category of HBV NA reagents, which is a fourth level EDMA category containing all molecular tests used in the diagnosis of Hepatitis B. However, the parties did not identify any markets where they would reach a combined market share of 35% or more. In Austria and the Netherlands, the parties provided their own sales figures. Given these low sales figures (combined below EUR […]*with an increment of EUR […]* or less) and the situation in other Member States and the EEA, competition concerns can be excluded.

64. The parties also provided data for the third level EDMA category consisting of all products used to test for Hepatitis C – "HCV". At the EEA level, the parties would have a combined market share of [40-50]*% with an increment of [0-5]*% by Innogenetics. On the national level, there would be six "Group 1" markets (Austria, Belgium, Germany, Portugal, Spain and Poland) with combined market shares ranging from [30]*% to [70]*%. The increment by Innogenetics is [0-5]*% or less. In each of the six markets, the parties list Roche, Johnson&Johnson (Ortho Clinical Diagnostics), Siemens Healthcare and Bio-Rad (global supplier of IVD products) as competitors. The parties overlap in a narrower segment, a specific group of tests used for the diagnosis of Hepatitis C (Hepatitis C Antibody Tests – fourth level EDMA category). The parties

identified one "Group 1" market, Belgium, where they would have combined market shares of [70-80]*% with an increment of [0-5]*% by Innogenetics. Competitors listed in this market include Johnson&Johnson (Ortho Clinical Diagnostics), Bio-Rad (a global IVD player), Siemens Healthcare and Roche. The parties could not provide market share estimates for five Non-EDMA countries[24], where, with the exception of Poland, Innogenetics has only marginal sales.

65. On national markets in the EEA, on the basis of the data provided by the parties, the parties' combined market shares would result in "Group 1" markets in the second level EDMA category "Hepatitis viruses" in Belgium ([50-60]*%, increment [0-5]*%), Germany ([50-60]*%, increment [0-5]*%), the Netherlands ([40–50]*%, increment [0-5]*%), Spain ([40-50]*%, increment [0-5]*%) and Poland ([40-50]*%, increment [0-5]*%). In the third level EDMA category "Hepatitis B", this would be the case in Austria ([60-70]*%, increment [0-5]*%), the Netherlands ([60-70]*%, increment [0-5]*%) and Poland ([50-60]*%, increment [0-5]*%) and for the third level EDMA category "Hepatitis C" in Austria ([60-70]*%, increment [0-5]*%), Belgium ([50-60]*%, increment [0-5]*%), Germany [50-60]*%, increment [0-5]*%), Portugal([40-50]*%, increment [0-5]*%), Spain ([30-40]*%, increment [0-5]*%) and Poland ([40-50]*%, increment [0-5]*%). In the fourth level EDMA category "Hepatitis C Antibody", this would be the case in Belgium ([70-80]*%, increment [0-5]*%).

66. For the fourth level EDMA category "Hepatitis C antibody", the parties could not provide market share data for the countries not covered by EDMA. Therefore, the Commission sought to reconstruct the national markets where the parties overlap. According to the results, the parties' combined market shares on EEA level would result in a "Group 2" market with a combined market share of [50-60%] with an increment of below 1% and five competitors. For individual EEA countries, it was not possible to achieve a reliable market reconstruction. The main competitor of the parties, Ortho Clinical Diagnostics, a subsidiary of Johnson&Johnson, with an EEA wide market share of [20-30%] and activity in all EEA countries could not provide market data for the single countries as national sales for "Hepatitis C antibody" tests are not recorded. Despite this, "Group 1" markets could be excluded for all EEA countries except for Poland. In Poland, according to the data generated during the market investigation, the merged entity will likely only have an increment of [0-5%] due to Innogenetics. It has to be taken into account that the largest competitor at EEA level, Ortho Clinical Diagnostics, confirmed during the market investigation that it had sales in Poland, even though these could not be quantified. Other remaining competitors in Poland, (which did report sales there) are Roche, Biomedica and Bio-Rad with market shares of [0-10%] respectively.

67. In addition, the parties argue that even though their products fall into the same fourth level EDMA category "Hepatitis C antibody", there would be only little effective

[24] Finland, Greece, Hungary, Poland, Slovak Republic.

competition between them. While Abbott provides a high throughput automated system that provides a range of tests, Innogenetics offers a single manual test without automation. Innogenetics' Hepatitis C antibody test is supplied mainly to fill gaps in smaller Eastern European laboratories' portfolios, while Abbott is focused largely on supplying blood banks and large laboratories with a fully automated package that includes Hepatitis C antibody screening tests.

68. Most competitors confirmed the parties' view that their Hepatitis C antibody products are not close competitors. The respondents to the market investigation overwhelmingly confirmed that for all levels of Hepatitis testing, there are enough credible competitors remaining in the affected markets, such as Ortho Clinical Diagnostics, Siemens Healthcare, Roche, DiaSorin, Bio-Rad, bioMérieux, Biomedica. Furthermore, there are a number of competitors with pipeline products which expect to enter the market soon. The increment by Innogenetics at EEA level and in Poland is small and no concerns were raised by the market investigation for either of these markets.

69. As a result, competition concerns at all levels of the market for Hepatitis viruses can be excluded.

Infectious Immunology - Retroviruses

70. As mentioned above, the second level EDMA category "Retroviruses" comprises HIV and HTLV tests. The parties do not overlap if only molecular products in Retroviruses are considered as the relevant market.

71. Looking at all tests within the "Retroviruses" category (second level EDMA category including all HIV tests), the transaction would give rise to a "Group 1" market with combined shares of [40-50]*% with an increment of [0-5]*% at the EEA level. There would be seven "Group 1" national markets and the Baltic region would also be a "Group 1" market[25]. The apparently relatively high market shares are attributable to Abbott. Innogenetics generally has significantly smaller market shares. The market shares in question are as follows: Austria (combined [50-60]*%, increment [0-5]*%), Belgium (combined [40-50]*%, increment [0-5]*%), France (combined [30-40]*%, increment [0-5]*%), Germany (combined [40-50]%, increment [0-5]%), the Netherlands (combined [40-50]*%, increment [0-5]*%), United Kingdom(combined [40-50]*%, increment [0-5]*%), Denmark (combined [40-50]*%, increment [0-5]*%) and the Baltic countries (Estonia, Latvia, Lithuania) (combined [30-40]*%, increment [0-5]*%).

[25] The Parties provided data together for Estonia, Latvia and Lithuania under the category "Baltic".

72. The overlap in HIV-1 tests (third level EDMA category) does not give rise to any "Group 1" markets.[26]

73. The overlap in HIV 1/2 Multiple tests (third level EDMA category) gives rise to 13 "Group 1" markets on the national level. Innogenetics is significantly smaller than Abbott in all of these markets: Austria (combined [70-80]*%, increment [0-5]*%), Belgium combined [70-80]*%, increment [0-5]*%), France (combined [40-50]*%, increment [0-5]*%), Germany (combined [60-70]*%, increment [0-5]*%), Italy (combined [50-60]*%, increment [0-5]*%), the Netherlands(combined [80-90]*%, increment [0-5]*%), Portugal (combined [50-60]*%, increment [0-5]*%), Spain (combined [60-70]*%, increment [0-5]*%), Bulgaria (combined [30-40]*%, increment [5-10]*%), Cyprus (combined [50-60]*%, increment [0-5]*%), Denmark (combined [50-60]*%, increment [0-5]*%), Ireland (combined [60-70]%, increment [0-5]%) and Poland (combined [50-60]*%, increment [0-5]%). HIV 1/2 Multiple tests are combination products detecting both HIV 1 and HIV 2 type viruses. These tests are also sold separately. The parties do not have a market share of over 35% in the third level category of HIV 1 tests and do not overlap in HIV 2 tests.

74. For the fourth level EDMA category "HIV P24 Antigen", the parties could not provide market share data. Therefore, the Commission sought to reconstruct the national markets where the parties overlap. According to the results, the combined market shares at EEA level would result in a "Group 1" market with a combined market share of [50-60%] with an increment of [5-10%] with at least three competitors remaining. For individual EEA countries, it was not possible to achieve a reliable market reconstruction, except for Spain and Germany. Two competitors, Roche and Bio-Rad, with EEA market shares of [5-10%] and [0-5%] respectively and activity in all EEA countries could not provide market data for all individual countries, including Belgium, the Netherlands, the United Kingdom and Finland. Despite this, "Group 1" markets could be excluded for all EEA countries except for Belgium, the Netherlands, the UK[27], and Finland. The market reconstruction resulted in "Group 1" markets in Spain with a combined market share of [60-70%] and an increment by Innogenetics of [0-5%] and in Germany with a combined market share of [60-70%] and an increment by Innogenetics of [20-30%]. Competitors in all countries are bioMérieux, Bio-Rad and Roche with market shares between [0-40%] respectively.

75. Innogenetics' only HIV-1 product seeks to detect the HIV P24 Antigen. Innogenetics generated EEA wide revenues of around EUR […]* in 2008 for this product. Abbott

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[26] Within HIV-1 tests, the parties also overlap in the narrower segment of HIV P24 Antigen tests. In this segment, Abbott has very low sales ranging from EUR […]* to […]* in all five countries where there is an overlap, except in Germany, where it has sales of EUR […]* As specified below, Abbott sells an HIV p24 test that is manufactured by Innogenetics and sold by Abbott under its own trademark (contract manufacturing). […]*, Abbott has made the decision to discontinue its contract with Innogenetics and discontinue the sales of this product in 2010.

[27] According to the parties there is one further competitor which however, did not provide turnover figures.

sells an HIV P24 Antigen test that is manufactured by Innogenetics and sold by Abbott under its own trademark. The product generated EEA-wide revenues of only around EUR […]* in 2008.

76. Abbott recently advised Innogenetics that it was discontinuing this relationship due to low sales. Abbott and Innogenetics have subsequently mutually agreed to terminate the agreement and Abbott expects to stop purchasing products from Innogenetics in mid-2010.

77. The parties argue that their products are not close competitors in HIV 1/2 multiple testing. Abbott's main products accounting for the vast majority of their sales are used for an earlier stage of the diagnostic process (screening) than Innogenetics' only HIV multiple product (used for confirmation of the presence of the virus). Abbott also has a confirmatory product, but it constitutes less than [0-5]*% of its turnover of HIV multiple products (less than EUR […]* in the EEA). Innogenetics' turnover is almost […]* times the turnover of Abbott's confirmatory products. Other suppliers of HIV multiple confirmatory products in the EEA according to the parties are Johnson&Johnson (Ortho Clinical Diagnostics), Alfa Wasserman, Bio-Rad, Inverness Medical, DiaSorin and Mast Diagnostica. Furthermore, according to the parties, out of the two main HIV types (HIV-1 and HIV-2) the latter is a relatively rare virus accounting for less than 1% of all HIV infections. HIV 1/2 multiple tests, would therefore effectively compete with HIV-1 tests, where the parties' market shares are considerably lower, although EDMA nevertheless reports sales of each category separately.

78. The market investigation confirmed that for all levels of the market for HIV testing, there are enough credible competitors remaining in the affected countries, such as Roche, Biomedica, Wragge, Siemens, DiaSorin, Bio-Rad and bioMérieux. The only overlap occurs for confirmatory products. This overlap is limited as Abbott's presence in confirmatory products is very minor. Abbott's main products are screening products. Furthermore, even if it were assumed that HIV P24 Antigen tests would constitute a separate market, it has to be taken into account that all other HIV 1 tests and HIV 1/2 Multiple tests also test for HIV 1 as do HIV P24 Antigen tests. The market investigation indicated that these products compete with the parties' products to a significant extent. No concerns were raised by the market investigation either on EEA level or on any national level, including Spain and Germany.

79. Finally, with respect to fourth level EDMA category HIV P24 Antigen tests (screening), it should also be taken into account that Abbott expects to terminate sales of this product, which is provided by Innogenetics, in mid-2010. After this termination, Abbott will only have a HIV P24 Antigen test for confirmatory purposes that generated very low revenues in 2008.

80. In light of the above, competition concerns in the category of Retroviruses – and all levels of HIV can be excluded.

<u>Infectious Immunology – Bacteriology - Syphillis</u>

81. In the field of Bacteriology, the parties overlap only with regard to Syphilis tests. The transaction would give rise to "Group 1" markets in the second level EDMA category for Syphilis tests in Austria (combined [40-50]*% increment [0-5]*%), the Czech Republic (combined [60-70]*% increment [0-5]*%), Italy (combined [30-40]*% increment [0-5]*%) and the United Kingdom (combined [40-50]*% increment [0-5]*%). However, their products do not overlap in any fourth level EDMA category. The parties listed a number of competitors for each of these markets.

82. For the third level EDMA category "Syphilis tests", the parties could not provide market share data for the countries not covered by EDMA. Therefore, the Commission sought to reconstruct the national markets where the parties overlap. According to the results, the parties' combined market shares at EEA level would result in a "Group 1" market with a combined market share of [70-80%] and an increment by Innogenetics of [0-5%] with at least five competitors remaining, three of which have higher market shares than Innogenetics. For individual EEA countries, it was not possible to achieve a reliable market reconstruction. The main competitors of the parties at EEA level, Siemens Healthcare accounting for [10-20%] of the EEA wide market share, bioMérieux accounting for [10-20%] of the EEA wide market share and Ortho Clincal Diagnostics (Johnson&Johnson) accounting for [0-5%] of the EEA wide market share, with activity in all or almost all (bioMérieux) EEA countries, could not provide market data for all individual countries, including Cyprus, Finland, Hungary and Ireland. Despite this, "Group 1" markets could be excluded for all EEA countries except Cyprus, Finland, Hungary and Ireland. According to the market reconstruction, Innogenetics' increment would be between 1% up to a maximum of 10% in these countries. Taking into account that the sales figures of the main competitors at EEA level are missing in the market reconstruction for individual countries, the increment can be assumed to be even lower. In any case, it will be below 10% in all of these countries. Other competitors in addition to the ones mentioned above, that reported sales figures for national markets are Bio-Rad (Finland and Hungary), with market shares between [0-20%] and Human GmbH (Cyprus), with a market share of [5-10%].

83. The parties argue that their Syphilis testing products fall into different fourth level EDMA categories. Furthermore, Abbott will continue to face strong competition from Beckman Coulter, Roche, Becton Dickinson, Bio-Rad, Siemens Healthcare, bioMérieux and others.

84. Even though most respondents are of the view that the parties' products are close competitors, it has to be taken into account that the parties' products for Syphilis testing do not overlap on the fourth level EDMA category, which indicates that they are not close competitors. Moreover, the products of other significant competitors at the EEA level belong to the same fourth level EDMA category as Abbott's product, which indicates that they are closer competitors to Abbott. Furthermore, it was confirmed by the market investigation that Innogenetics' product is a niche product that serves smaller laboratories while Abbott's product is mainly provided to larger customers. A vast majority of respondents to the market investigation confirmed that for Syphilis testing, there are enough credible competitors remaining in the affected

countries. These include the major competitors at the EEA level, such as Siemens Healthcare, Roche, bioMérieux, Qiagen, Johnson&Johnson (Ortho Clinical Diagnostics) and others. The increment by Innogenetics would remain moderate. On the EEA level, it would be only [0-5%] and on national markets it would be below 10%. Finally, no concerns were raised by the market investigation either at EEA level or in Cyprus, Finland, Hungary and Ireland.

85. As a result, competition concerns in the category of Bacteriology - Syphillis can be excluded.

86. Finally, the parties also identified certain overlaps in **molecular products**, which do not correspond exactly to existing EDMA categories. These possible markets include molecular oncology diagnostics products, in particular products used for the diagnosis of breast cancer (overlaps in Germany and France), and molecular tests for mycobacteria (tuberculosis) (overlaps in Slovenia and Italy). Due to the difficulties of obtaining statistics, the parties only provided estimates on the EEA level. The transaction does not give rise to "Group 1" markets at the EEA level.

87. The majority of respondents in the market investigation are of the view that the parties do not have a combined market shares in molecular oncology tests in Germany and France that would exceed 35%. They state that enough credible competitors remain, such as Roche, Siemens Healthcare and Bio-Rad. According to the replies, the parties may have a combined market share of more than 35% in molecular oncology tests for breast cancer in Germany and France but it was indicated that enough credible competitors remain. There may also be combined market shares of more than 35% in bacteriology mycrobacreria-tuberculosis tests in Slovenia and Italy, but here also enough credible competitors remain, such as Roche, Becton Dickinson, Qiagen and bioMérieux.

88. As a result, competition concerns in the category of molecular products can be excluded.

89. The parties also overlap in **HTLV multiple tests**, in particular, in HTLV multiple confirmatory tests. Again, Abbott has a number of HTLV products, most of them used for the initial stages of testing (screening), mainly used by blood banks and big hospitals in connection with blood donations and purchases, whereas Innogenetics has only one product for the later, confirmation stage. Abbott also has a confirmatory product with EEA sales of around EUR […]*. Innogenetics' sales in 2008 amounted to EUR […]*. The parties estimate their shares to be modest. The results of the market investigation did not indicate that the parties' combined market shares would exceed 35% at the EEA-level or on any of the four national markets (Belgium, France, Germany and United Kingdom) where they overlap. Due to the lack of concerns raised by the market investigation, competition concerns can be excluded.

90. As a result, competition concerns in the category of HTLV multiple confirmatory tests can be excluded.

IVD markets with serious doubts

Market structure

91. Within the all-molecular category "Genetic Testing", Innogenetics is only active with tests for Cystic Fibrosis (hereinafter "CF"). According to the parties, their combined market shares would exceed 35% only on the fourth EDMA level category of CF tests. On this level, they estimate they would have combined market shares of [70-80]*% in the EEA (Abbott [20-30]*%; Innogenetics [50-60]*%). According to the parties, EDMA significantly underestimates the overall market size. The parties' estimates also include estimates of sales by some competitors that, according to the parties, do not report to EDMA.

92. The parties could not estimate their market shares at the national level. In 2008, the parties had overlapping sales in 12 Member States: Austria, the Czech Republic, France, Germany, Greece, Hungary, Italy, The Netherlands, Poland, Portugal, Spain and the UK. In 2009, Innogenetics had no sales in the UK (where Innogenetics' only had marginal sales in 2008 and Abbott had no sales in Poland (where Abbott only had marginal sales in 2008). Both parties, however, remain present in these markets, albeit only through distributors. In addition, the parties' activities overlapped in Lithuania, albeit both parties had only marginal sales.

93. In the notification the parties identified GenProbe, Luminex and NLM as current competitors in the EEA. All these competitors have been contacted in the market investigation and provided input on their sales revenue. Based on this input, the CF market was reconstructed at the EEA level and also in the national markets where the parties overlap. Based on the reconstruction, the parties would have combined market shares of [80-90]% in the EEA (Innogenetics [60-70]%, Abbott [20-30]%). Other competitors (GenProbe, NLM, Luminex) would have significantly lower market shares.

94. The parties would have very high combined market shares [75-100%] in most Member States where they overlap and also at the EEA level. The increment is also significant at the EEA level and in most Member States (approximately [10-50%]. These Member States account for a vast majority of the total EEA sales of each of the parties (more than 80% in 2009). Furthermore, based on the market reconstruction, this is also the case when comparing total sales of CF tests in these Member States to the total EEA sales.

95. It is only in the UK and in the Baltic Countries that the merged entity would have combined market shares of less than 50%. In addition, the increment by Innogenetics in the UK is insignificant. The market leader in the UK would be GenProbe and, based on the market reconstruction, Abbott would also hold significant market shares. In the Baltic Countries, the parties only overlap in 2009 (sales in Lithuania only) achieving a small combined sales revenue. Based on the market reconstruction, there is one other competitor identified in the Baltic Countries with significantly more sales than the parties.

96. In Austria, the parties would have a combined market share of [60-70%] in 2009. Only one other competitor could be identified in the market reconstruction.

97. In most countries, as at the EEA level, Innogenetics is the larger player (in some countries, including Italy, France, The Netherlands, Poland and the Czech Republic, by a significant margin). In Germany, Spain, and Austria, the parties have comparable market shares. In some countries (e.g. Austria, Hungary, Poland[28] and Portugal the parties achieve high to very high combined market shares with relatively small combined sales of less than […].*

98. Italy is by far the largest market in the EEA [over 50%] of the total EEA market, which is due to a specific genetic mutation and specific government regulation. Based on 2009 figures, the parties would have a combined market share of [>80]% in Italy with a significant increment of [20-30]%. Other competitors (GenProbe, Luminex, NLM) would have significantly lower market shares.

99. In a submission dated 3 February 2010, the parties state that CF markets are dynamic and that high shares of sales in any year and in any country are transient and unlikely to reflect market power. They also state that customers resort to "homebrew" testing (tests developed by customers) and outsource CF testing to larger laboratories.

100. Sales figures of the parties show that Abbott has lost around […]*% of their EEA sales since 2006. A significant part of this loss seems to be accounted for by a […]* drop in sales in […]* by around […]*% between […]* and […]*. This appears consistent with the forecasts of Abbott referred to in internal documents that […]* unless they solve a particular [issue]*, they may face an […]* loss of […]*% of its sales in the EEA. Innogenetics' sales, on the other hand, grew by around […]*.From 2008 to 2009, there are no significant decreases either i) in the parties' combined market shares or ii) the increment.

101. With respect to the importance of "homebrew testing", Abbott's own internal documents suggest that there is "little/no homebrew anymore"[29].

102. The parties also indicate that the market is dynamic and that significant growth ([…]*%) is expected. Abbott's internal documents, on the other hand, suggest that the CF market is a "mature market"[30]. A […]*% increase would be conditional on the implementation of carrier screening guidelines. An internal Abbott document from […]* also […]* shows that […]*[31]. The market investigation has also provided indications that the market is relatively stable and mature. There may be a potential for growth in some countries, but this is conditional on, in particular, certain national screening programs being implemented.

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28 In Poland, Abbott had low sales in 2008 and no sales in 2009, although they continue to have […]*.

29 [reference to internal document]*.

30 [reference to internal document]*

31 [reference to internal document]*

103. Finally, a number of customers raised concerns that Abbott would become dominant (even a monopoly) since the merger would combine the two major players.

Competitive assessment

104. The parties argue that the transaction would not raise competition concerns in the segment of cystic fibrosis IVD tests despite high combined market shares.

105. Firstly, they argue that their products are based on different technologies and have different capabilities in terms of capacity and scope (the number of mutations detected). Innogenetics has a cheaper, low capacity instrument. It can detect more mutations than Abbott's more expensive, higher capacity instrument (a sequencer). Due to these differences, the parties argue that their targeted customer base is different. Customers make purchasing decisions based on the capacity and scope of a machine. Once they buy the machine, they keep buying assays/reagents compatible with that machine. Since the parties' reagents are not compatible with each other's equipment, they do not compete with each other and target different customers.

106. This has not clearly been confirmed by the market investigation. Roughly half of the customers did not consider the parties products to be interchangeable, in particular, due to the different underlying technologies. However, a significant proportion of customers (over one third of the respondents) considered that the parties' products were interchangeable despite the difference in the underlying technology. Competitors' replies generally indicated the parties' products to be close competitors. Furthermore, Innogenetics is normally mentioned […]* with respect to the competitive situation in the EEA (and, in particular, in Italy) in the internal marketing documents which Abbott submitted.[32]

107. Secondly, the parties argue that the merged entity would face effective competition by GenProbe/Tepnel and next generation products developed by Luminex as well as by NLM in Italy.

108. In 2009, Luminex released two Cystic Fibrosis tests that, according to the parties, have […]* (more mutations detected) and […]*.

109. GenProbe is a global diagnostics supplier that, according to the parties, acquired a UK based company, Tepnel, in March 2009. According to the parties, Tepnel has recently (one or two years ago) developed a new CF product that the parties expect to intensify competition in CF testing. Tepnel has for a number of years been offering two country-specific products, which are tailored to the UK and French populations (Abbott's internal documents also refer to these two countries in connection with Tepnel[33]). Their

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[32] See e.g. [reference to internal document]

[33] [reference to internal document]

CF products are based on the same technology (running on the same third-party platform) as Abbott's. The parties estimate GenProbe's sales to amount to 5-10% of the EEA market for CF tests. The parties also estimate the acquisition of Tepnel by GenProbe to have a positive impact on GenProbe's market share in the future due to access to the former's sales and distribution network.

110. In Italy, the parties mention NLM as a new entrant that has the potential to constrain the merged entity with a product similar to that of Innogenetics.

111. The parties mention a number of other companies that recently entered or may shortly enter the cystic fibrosis segment.

112. Abbott also argues that in addition to competitors' strengthening positions, Abbott's own position may weaken […]* in the future. […]* In the EEA, Abbott distributes a CF test developed and manufactured by a US company, Celera. This test runs on a platform supplied by another US company, Life Technologies. An upgraded version of this platform has recently been launched. Abbott does not have a product compatible with the upgraded platform, but GenProbe does. Should Celera not invest in an upgraded product, Abbott states that it would face an expected annual loss of […]*% of its sales in the EEA as it expects customers to migrate to the new platform. Should Abbott be able to address the compatibility issue on the other hand, they expect to increase their sales by […]*%.[34] Abbott submits that the upgrading of their CF product would take […]* and would require an investment of around EUR […]*.

113. Abbott and Celera have a long-standing strategic relationship. In October 2008, they entered into an exclusive distribution agreement replacing the existing profit-sharing arrangement between the companies, which began in June 2002 and was restarted in January 2006. Under this distribution agreement, Abbott exclusively distributes certain molecular diagnostic products manufactured by Celera. Under a second agreement, Celera receives royalties on the sale of specific reagents, instruments, service and related consumables, and Abbott receives royalties on certain Celera genetic tests. The new distribution agreement has an initial term of five years with the possibility to renew for additional four years.

114. Abbott was requested to provide evidence (e.g. internal documents) to support their statements that they would not have, in the absence of the merger, an upgraded CF product in the EEA market. The internal documents subsequently provided do mention the upgrade to the new series of Life Technologies' sequencer as a […]* issue and confirm the forecast loss of sales. However, minutes of a […]* meeting […]* dating as late as October 2009[35] appear to launch a […]* to resolve this issue. This document does not suggest this to be unfeasible or particularly problematic. Abbott has stated that […]* in late 2009, but provided no further evidence to this

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34 [reference to internal document]*

35 [reference to internal document]*

effect. It should also be noted that this happened already during the present procedure to assess the transaction and hence could not be taken as a clear indication of what the situation would have been in the absence of the merger. On balance therefore, it is not possible to clearly conclude on the basis of the evidence provided that the […]* issue would not have been solved in the absence of the merger.

115. In addition to the upgrade of the current Abbott CF product, the Distribution and Royalty Agreements between Abbott and Celera also contain a […]* with a project start date of […]*. According to Abbott, this project has been discontinued. An internal document from […]* December 2008 mentions this project to be […]*"[36]. The same document, however, mentions under a slide entitled *[…]**. Again, based on this evidence, it is not possible to conclude that Abbott would not have […]* a […]* product […]* in the absence of the merger.

116. Luminex was confirmed by the market investigation to be a new entrant, which entered the market very recently. There is also evidence in certain selected internal documents provided by the parties that both parties consider Luminex as a threat. On the one hand, the market investigation also provided some indications that Luminex has the potential to constrain the merged entity's pricing behaviour in the future. The market investigation did not, on the other hand, confirm this clearly. Only a relatively small number of respondents considered this to be the case. The entry by Luminex could in any event be constrained due to the length of customer contracts and requirements for the installation of new equipment. On balance, it cannot therefore be established based on the information available to the Commission that the competitive pressure stemming from Luminex in the future would be stronger than the competitive constraint the parties presently exercise on each other, especially with respect to each national market where the parties have high combined market shares.

117. According to the parties, NLM is only active in Italy with a very similar product to that of Innogenetics. The parties argue than in Italy, the main competitive pressure on Innogenetics stems from NLM, which entered the market at the end of 2005. They argue that Innogenetics' […]* (they provided some internal documents which make reference to […]* and that they have lost -[…]* customers to NLM in the same period. On the other hand, the background data provided by the parties shows that this constitutes less than […]* of the number of Innogenetics' customers in Italy. Furthermore, Innogenetics gained several contracts from NLM in the same period. Overall, Innogenetics' sales revenues grew by […]* in Italy since 2006. […]* The market investigation revealed a similar picture. Notwithstanding that the market investigation provided some indications that the products of Innogenetics and NLM could be considered as closest competitors due to the underlying technology, Innogenetics' product seems to be significantly more known in the Italian market despite NLM being present for years and […]* . Furthermore, only one respondent indicated NLM as a recent entrant that would constrain the merged entity's pricing behaviour in the future.

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[36] [reference to internal document] *

118. As regards the competitive pressure exerted by NLM on Abbott in Italy, Abbott's general marketing documents submitted during the procedure make reference to Innogenetics with respect to competition in Italy, but not NLM.[37]

119. Overall, the market investigation did not clearly indicate that the current competitors listed by Abbott would be able to significantly constrain the merged entity in the near future. Of the competitors concerned, only one competitor stated that this would be the case. As for customers, less than one third considered that GenProbe and/or Luminex would be able to exert a significant constraint on the merged entity in the near future. A similar number considered GenProbe to be the closest competitor to Abbott. The market investigation did not reveal any additional potential entrants with the ability to significantly constrain the pricing behaviour of the merged entity in the near future. Finally, the market investigation indicated a reluctance to switch on the part of customers even in the case of a 10% price increase by the merged entity. Barriers to switching were also indicated, in particular the internal validation procedures of laboratories. Furthermore, a number of customers raised concerns that the merger would lead to price increases and/or risks to innovation.

120. In light of the i) high present combined market shares; ii) significantly smaller current competitors or even the apparent lack of current competitors in some national markets iii) the lack of clear indications that, in the absence of the merger, Abbott would have lost significant market shares in the future due to the lack of the ability to upgrade its product and iv) the lack of clear indications from the market investigation with respect to the potential competitive pressure stemming from recent entrants, serious doubts cannot be excluded in the EEA market for CF tests and with respect to the following national CF testing markets: Czech Republic, France, Germany, Greece, Italy, The Netherlands and Spain. Competition concerns could be excluded in the UK, where Innogenetics had only marginal sales in 2008 and no sales in 2009 and where GenProbe is the leading competitor of the market.

121. With respect to the national markets where parties would achieve high or very high combined market shares with relatively small combined sales revenues of less than [between EUR […]* to […]*] (Austria, Hungary, Portugal and Poland[38]), competition concerns could not be excluded. The Commitments offered to address serious doubts in the other markets would also solve any potential concern in these markets.

V. CONCLUSION – SERIOUS DOUBTS

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37 [reference to internal document]

38 2008 figures due to lack of sales by Abbott in 2009

122. For the reasons set out above, the Commission concludes that the notified operation gives rise to serious doubts as regards its compatibility with the common market and the EEA-Agreement for the EEA market for CF testing and the following national markets: the Czech Republic, France, Germany, Greece, Italy, The Netherlands, and Spain. Furthermore, serious doubts could not be excluded in Austria, Hungary, Portugal and Poland.

VI. MODIFICATION OF THE PROPOSED OPERATION

Description of the Commitments

123. In order to remove the serious doubts resulting from the proposed transaction, Abbott formally submitted commitments to the Commission on 21 January 2010. The Commitments were modified on 27 January 2010 and modified further on 10 February 2010.

124. The commitments consist in the divestiture of Innogenetics EEA CF Products business (the "Divestment Business") which includes at the option of the purchaser, all tangible and intangible assets (including IP rights) held by Innogenetics that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business. Further included are all licences, permits and authorisations issued by any governmental organisation held by Innogenetics for the benefit of the Divestment Business. The Divestment Business further provides access to raw materials necessary for the manufacturing of Innogenetics' EEA CF Products, the existing Innogenetics' EEA CF Product contracts with EEA customers and Innogenetics' CF customer lists in the EEA. The Commitments further include support to conclude agreements with the producers of the processing instruments as well as best efforts to encourage the transfer of certain types of Personnel (including Key Personnel) necessary to maintain the viability and competitiveness of the Innogenetics Divestment Business. The Divestment Business will include at the option of the purchaser a toll manufacturing agreement and technical assistance with a duration of three years.

Assessment of the Commitments

Suitability for removing the serious competition concerns

125. By offering to divest Innogenetics' EEA CF Products business (the "Divestment Business"), the Commitments would remove the entire overlap in the Parties' activities in the area of CF testing in the EEA. The Commitments would therefore be suitable to remove serious competition concerns.

126. The countries where serious doubts were confirmed represent most of the EEA market, both in terms of the parties' own CF sales and in terms of the overall EEA CF market. Furthermore, the assets included in the Divestment Business do not appear to be specific to any country, which calls into question the viability of a country-by-country divestment.

Viability and modification of the initial commitments in view of the market test

127. The market test of the commitments was positive overall but some potential issues concerning the assets required and the terms of transitional agreements have been indicated. The market test has also given more specific indications regarding the need for specific types of personnel. In addition, the market test indicated possible requirements for the purchaser in order to ensure the viability of the Divestment Business.

128. Following the initial market test, the Commitments clarified the assets and personnel included in the divestment. Special equipment dedicated to the production of strip tests has been specified as being included in the assets. The divestment of different types of intangible assets, in particular IP rights and the CE mark has been clarified. Commitments concerning specific types of personnel have been clarified with a best effort clause included to help the transfer of personnel if needed by the purchaser.

129. In addition, the duration of the transitional toll manufacturing agreement has been extended to three years. Additional guarantees have been included with respect to the conditions of supply (based on good industry practice) on the one hand, and technical assistance provided by the seller on the other.

130. Based on the indications from the market test, the Commission also concluded that the viability of the Divestment Business depends to a significant extent on the Purchaser. In addition to the basic requirement that the Purchaser should be an IVD company, the market investigation indicated experience with molecular testing and a presence in the EEA to be a key factor with respect to viability. These criteria were subsequently included in the Commitments.

Conclusion

131. The Commission therefore considers that the modified commitments are sufficient to eliminate all serious doubts as to the compatibility of the transaction with the common market.

Conditions and obligations

132. In order to ensure that Abbott complies with these commitments, the Commission attaches conditions and obligations to this decision. The commitments set out in Sections B and D of the Commitments annexed to the present Decision constitute conditions, since only by fulfilling them may the structural change on the relevant markets be

achieved so as to eliminate the serious doubts identified by the Commission. The other commitments constitute obligations, since they concern the implementing steps necessary to achieve the structural change intended to eliminate the serious doubts identified by the Commission.

VII. CONCLUSION

133. For the reasons set out above, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and the EEA Agreement, subject to full compliance with: (i.) the conditions in Sections B and D of the Commitments annexed to the present decision, and (ii.) the obligations in the other Sections of the Commitments. This decision is adopted in application of Articles 6(1)(b) and 6(2) of Council Regulation No 139/2004.

134. The full text of these commitments is annexed to this decision. These commitments form an integral part of the decision.

For the Commission
(signed)
Joaquin ALMUNIA
Vice-President of the Commission

By hand and by fax: 00 32 2 296 4301

European Commission

DG Competition

Rue Joseph II 70

B-1000 BRUSSELS

Case COMP/M.5661 – Abbott/Solvay Pharmaceuticals

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No. 139/2004 (the "***Merger Regulation***"), Abbott Laboratories ("***Abbott***") hereby provides the following Commitments (the "***Commitments***") in order to enable the European Commission (the "***Commission***") to declare the acquisition by Abbott of the pharmaceutical and diagnostic businesses of Solvay S.A. (the "***Transaction***") compatible with the Common Market and the EEA Agreement in a decision rendered pursuant to Article 6(1)(b) of the Merger Regulation (the "***Decision***").

The Commitments shall take effect upon the date of adoption of the Decision.

This text shall be interpreted in light of the Decision to the extent that the Commitments are attached as conditions and obligations, in the general framework of Community law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004.

In order to respond to Commission's concerns regarding the Transaction's impact in the EEA market for Cystic Fibrosis ("CF") testing, Abbott commits to divest the Innogenetics' EEA CF testing business (the "***Divestment Business***") to an independent and unconnected party that has the financial resources, expertise, and incentive to

maintain and develop the Divestment Business as a viable and active competitive force in the market (the "***Commitments***").

Section A. Definitions

For the purpose of the Commitments, the following terms shall have the following meaning:

Abbott: Abbott Laboratories, incorporated under the laws of State of Illinois, with its registered office at 100 Abbott Park Road Abbott Park, Illinois 60064-3500, USA.

Affiliated Undertakings: Undertakings controlled by Abbott, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation, Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings**.**

Closing: The transfer of the legal title of the Divestment Business to the Purchaser.

Divestment Business: The Innogenetics EEA CF Products business as defined in Section B and Schedule 1 or any wider business that includes the Innogenetics EEA CF Products business as defined in Section B and Schedule 1.

Divestiture Trustee: One or more natural or legal person(s), independent from Abbott, who is approved by the Commission and appointed by Abbott and who has received from Abbott the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Effective Date: The date of adoption of the Decision.

First Divestiture Period: The period of […]* from the Effective Date.

Hold Separate Manager: The person appointed by Abbott for Innogenetics to manage the day-to-day business under the supervision of the Monitoring Trustee.

Innogenetics: Innogenetics N.V., a corporation organized under the laws of Belgium, entered in the Belgium Companies Register under the number 0427550 660 (RPR Ghent) and having its registered office at Technologiepark 6, 9052 Zwijnaarde, Belgium. Innogenetics is the diagnostic business of Solvay S.A, and its subsidiaries.

Innogenetics EEA CF Products: The Innogenetics CF testing products described in **Annex 1.1**.

Key Personnel: The Personnel listed in **Annex 1.2**.

Monitoring Trustee: One or more natural or legal person(s), independent from Abbott, who is approved by the Commission and appointed by Abbott, and who has the duty to monitor Abbott's compliance with the conditions and obligations attached to the Decision.

Personnel: Personnel currently employed by the Divestment Business, including Key Personnel, staff seconded to the Divestment Business, and shared personnel considered necessary to maintain the viability and the competitiveness of the Divestment Business.

Purchaser: The entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Trustee(s): The Monitoring Trustee and the Divestiture Trustee.

Trustee Divestiture Period: The period of […]* from the end of the First Divestiture Period.

Trustee Mandate: The agreement that specifies the terms of the Trustee's mandate, including duties and obligations of the Trustee and Abbott with respect to the Divestment Business.

Section B. The Divestment Business

Commitment to Divest

1. In order to maintain effective competition in CF testing in the EEA, Abbott commits to divest the Divestment Business.

2. Abbott commits to divest the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a Purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 18. To carry out the divestiture, Abbott commits to find a Purchaser and to enter into a final binding sale and purchase agreement for the sale of the Divestment Business within the First Divestiture Period. If Abbott has not entered into such an agreement at the end of the First Divestiture Period, Abbott shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 27 in the Trustee Divestiture Period.

3. Abbott shall be deemed to have complied with this commitment if, by the end of the Trustee Divestiture Period, Abbott has entered into a final binding sale and purchase agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 18 and if the closing of the sale of the Divestment Business takes place within a period […]* after the approval of the Purchaser and the terms of sale by the Commission.

4. In order to maintain the structural effect of the Commitments, Abbott shall, for a period of 10 years after the Effective Date, not acquire direct or indirect influence over the whole or part of the Divestment Business, unless the Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the Common Market.

Structure and Definition of the Divestment Business

5. The Divestment Business comprises the Innogenetics EEA CF Products business as described in Schedule 1. The present legal and functional structure of the Divestment

Business as operated to date is described in **Annex 1.3**. The Divestment Business described in Schedule 1 includes, at the option of the Purchaser:

(a) All tangible assets (identified in **Annex 1.4)** and intangible assets (including intellectual property rights, including the Divestment Business trademarks and know-how, where applicable) held by Innogenetics that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business;

(b) All licenses, permits, and authorizations issued by any governmental organization held by Innogenetics for the benefit of the Divestment Business;

(c) All existing contracts between Innogenetics and its EEA customers to the extent they relate to Innogenetics EEA CF Products (as further described in **Annex 1.1**), all customer orders of the Divestment Business, and Innogenetics' EEA CF Products customer list, and customer records as they relate to the Innogenetics EEA CF Products (items referred to under (a)-(c) hereinafter collectively referred to as "***Assets***");

(d) Key Personnel; and

(e) Access to raw materials used to produce the Innogenetics EEA CF Products, instruments sold in connection with the Innogenetics EEA CF Products, toll manufacturing of CF Products, and technical assistance reasonably required to manufacture CF Products for a transitional period of up to three years after Closing (to be extended at the reasonable request of the Purchaser) on terms and conditions equivalent to those at present afforded to the Divestment Business, as specified in Schedule 1.

6. Subject to the Commission's approval, the Purchaser shall be free to select such combination of assets and rights identified in Schedule 1 as it considers necessary in light of its expertise and current activities.

Section C. Related Commitments

Preservation of Viability, Marketability, and Competitiveness

7. From the Effective Date until Closing, Abbott shall preserve the economic viability, marketability, and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimize as far as possible any risk of loss of competitive potential of the Divestment Business. In particular Abbott undertakes:

(a) Not to carry out any act upon its own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) To make available sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans; and

(c) To take all reasonable steps, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Divestment Business.

8. Abbott shall use reasonable best efforts to the extent permitted by law, to facilitate the transfer of Key Personnel and any other Personnel who are desired by the Purchaser. Abbott shall provide relevant contact details for the Personnel, or otherwise make such Personnel available to the Purchaser subject to compliance with applicable laws. Prior to Closing, Abbott shall facilitate interviews between such Personnel and the Purchaser, shall not discourage such employee from participating in such interviews, and shall not interfere in employment negotiations between such Personnel and the Purchaser.

9. With respect to such Personnel who receive an offer of employment from the Purchaser (conditional on or following the Closing), Abbott shall do the following: (i) not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Personnel from being employed by the Purchaser, and not offer any incentive to the Personnel to decline employment with the Purchaser; (ii) if the Personnel accepts such offer of employment from the Purchaser, Abbott shall cooperate with the Purchaser in effecting transfer of the Personnel to the employ of the Purchaser and Abbott shall amend or waive the relevant provisions of employment agreements, stock options and other employee benefit

arrangements of Personnel so that they do not suffer adverse consequences as a result of their negotiations with, or acceptance of an offer from, the Purchaser.

Hold-Separate Obligations

10. Abbott commits, from the Effective Date until Closing, to keep Innogenetics separate from Abbott (and thereby to ensure that Key Personnel, including the Hold Separate Manager, have no involvement in any of Abbott's businesses, and no Abbott personnel has any involvement in the Divestment Business), except to the extent provided for in paragraph 11 below, and/or permitted by the Monitoring Trustee.

11. Until Closing, Abbott shall assist the Monitoring Trustee in ensuring that Innogenetics is managed as a distinct entity separate from Abbott. Abbott shall appoint a Hold Separate Manager who shall be responsible for the management of Innogenetics, under the supervision of the Monitoring Trustee. The Hold Separate Manager shall manage Innogenetics independently and in the best interest of the business with a view to ensuring its continued economic viability, marketability, and competitiveness and its independence from Abbott.

Ring-fencing

12. Abbott shall implement all necessary measures to ensure that it does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Business. Abbott may obtain information that is reasonably necessary for the divestiture of the Divestment Business or whose disclosure to Abbott is required by law.

Non-Solicitation Clause

13. Abbott undertakes, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Personnel hired by (as opposed to seconded to) the Purchaser for a period of two years after Closing or after the date of termination of employment of such Personnel by Innogenetics.

Due Diligence

14. In order to enable potential Purchasers to carry out a reasonable due diligence of the Divestment Business, Abbott shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

(a) Provide to potential Purchasers sufficient information as regards the Divestment Business; and

(b) Provide to potential Purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

Reporting

15. Abbott shall submit written reports in English on potential Purchasers of the Divestment Business and developments in the negotiations with such potential Purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request).

16. Abbott shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of an information memorandum for the Divestment Business to the Commission and the Monitoring Trustee before sending the memorandum out to potential Purchasers.

Section D. The Purchaser

17. In order to ensure the immediate restoration of effective competition, the Purchaser, in order to be approved by the Commission, must:

(a) Be independent of and unconnected to Abbott;

(b) Have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with Abbott and other competitors;

(c) Have experience in developing, manufacturing, and/or selling molecular IVD products in the EEA, it being understood that this requirement need not be satisfied in the event that Abbott divests any wider business that includes the Innogenetics EEA CF Products business as defined in Section B and Schedule 1 to a Commission-approved Purchaser that otherwise meets the criteria identified in 17(a)-(b) and 17(d); and

(d) Neither be likely to create, in the light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business (the before-mentioned criteria for the Purchaser hereafter the "***Purchaser Requirements***").

18. The final binding sale and purchase agreement shall be conditional on the Commission's approval. When Abbott has reached an agreement with a Purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), to the Commission and the Monitoring Trustee. Abbott must be able to demonstrate to the Commission that the Purchaser meets the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Commitments. For the approval, the Commission shall verify that the Purchaser fulfills the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Commitments. The Commission may approve the sale of the Divestment Business without one or more Assets, Key Personnel, or other parts of the Divestment Business as listed in the Schedules if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed Purchaser.

Section E. Trustee

I. Appointment Procedure

19. Abbott shall appoint a Monitoring Trustee to carry out the functions specified in the Commitments for a Monitoring Trustee. If Abbott has not entered into a binding sales and purchase agreement one month before the end of the First Divestiture Period or if the Commission has rejected a Purchaser proposed by Abbott at that time or thereafter, Abbott shall appoint a Divestiture Trustee to carry out the functions specified in the Commitments for a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

20. The Trustee shall be independent of Abbott, possess the necessary qualifications to carry out its mandate, for example as an investment bank or consultant or auditor, and shall neither have nor become exposed to a conflict of interest. The Trustee shall be remunerated by Abbott in a way that does not impede the independent and effective fulfillment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, the fee shall also be linked to a divestiture within the Trustee Divestiture Period. There shall be only one single Monitoring and Divestiture Trustee, regardless of

the number divestiture options or commitment texts entered into by Abbott relating to the Transaction.

Proposal by Abbott

21. No later than one week after the Effective Date, Abbott shall submit a list of one or more persons whom Abbott proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period, Abbott shall submit a list of one or more persons whom Abbott proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the proposed Trustee fulfills the requirements set out in paragraph 19 and shall include:

(a) The full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfill its duties under these Commitments;

(b) The outline of a work plan which describes how the Trustee intends to carry out its assigned tasks; and

(c) An indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or rejection by the Commission

22. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfill its obligations. If only one name is approved, Abbott shall appoint or cause to be appointed, the individual or institution concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Abbott shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by Abbott

23. If all the proposed Trustees are rejected, Abbott shall submit the names of at least two more individuals or institutions within one week of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 19 and 22.

Trustee nominated by the Commission

24. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Abbott shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

25. The Trustee shall assume its specified duties in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Abbott, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and Obligations of the Monitoring Trustee

26. The Monitoring Trustee shall:

(a) Propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision;

(b) Oversee the on-going management of Innogenetics with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by Abbott with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(i) Monitor the preservation of the economic viability, marketability and competitiveness of Innogenetics, and the keeping separate of Innogenetics from Abbott, in accordance with paragraphs 7 and 10 of the Commitments;

(ii) Supervise the management of Innogenetics as a distinct entity, in accordance with paragraph 11 of the Commitments;

(iii) (A) In consultation with Abbott, determine all necessary measures to ensure that Abbott does not after the Effective Date obtain any business secrets, know how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Business, in particular strive for the severing of Innogenetics' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business, and (B) Decide whether such information may be disclosed to Abbott as the disclosure is reasonably necessary to allow Abbott to carry out the divestiture, or information not related to the Divestment Business, or as the disclosure is required by law; and

(iv) Monitor the splitting of Assets and the allocation of Personnel between Abbott, Innogenetics, and the Divestment Business;

(c) Assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision;

(d) Propose to Abbott such measures as the Monitoring Trustee considers necessary to ensure Abbott's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, the holding separate of Innogenetics and the non-disclosure of competitively sensitive information;

(e) Review and assess potential Purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, (i) potential Purchasers receive sufficient information relating to the Divestment Business and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and (ii) potential Purchasers are granted reasonable access to the Personnel;

(f) Provide to the Commission, sending Abbott a non-confidential copy at the same time, a written report within 15 days after the end of every month. The report shall cover the operation and management of the Divestment Business so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential Purchasers. In addition to these reports, the Monitoring Trustee shall promptly report in writing to the Commission,

sending Abbott a non-confidential copy at the same time, if it concludes on reasonable grounds that Abbott is failing to comply with these Commitments; and

(g) Within one week after receipt of the documented proposal referred to in paragraph 18, submit to the Commission a reasoned opinion as to the suitability and independence of the proposed Purchaser and the viability of the Divestment Business after the sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of the Divestment Business without one or more Assets or not all of the Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed Purchaser.

Duties and obligations of the Divestiture Trustee

27. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a Purchaser, provided that the Commission has approved both the Purchaser and the final binding sale and purchase agreement in accordance with the procedure laid down in paragraph 18. The Divestiture Trustee shall include in the sale and purchase agreement such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of Abbott, subject to Abbott's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

28. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to Abbott.

III. <u>Duties and Obligations</u>

29. Abbott shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance, and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access (as permitted by applicable privacy laws) to any of Innogenetics' books, records, documents, management or other personnel, facilities, sites, and technical information necessary for fulfilling its

duties under the Commitments. Abbott shall provide the Trustee upon request with copies of any Innogenetics document. Abbott shall make available to the Trustee one or more offices on Innogenetics' premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

30. Abbott shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of Innogenetics. This shall include all administrative support functions relating to Innogenetics that are currently carried out at headquarters level. Abbott shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential Purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential Purchasers in the due diligence procedure. Abbott shall inform the Monitoring Trustee on possible Purchasers of the Divestment Business, submit a list of potential Purchasers, and keep the Monitoring Trustee informed of all developments in the divestiture process.

31. Abbott shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, Abbott shall cause the documents required for effecting the sale and the Closing to be duly executed.

32. Abbott shall indemnify the Trustee and its employees and agents (each an "***Indemnified Party***") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Abbott for any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the willful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

33. At the expense of Abbott, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Abbott's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Abbott refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Abbott. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 32 shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Abbott during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

IV. Replacement, Discharge, and Reappointment

34. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a conflict of interest:

(a) The Commission may, after hearing the Trustee, require Abbott to replace the Trustee; or

(b) Abbott, with the prior approval of the Commission, may replace the Trustee.

35. If the Trustee is removed according to paragraph 34, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 19-24.

36. Beside the removal according to paragraph 34, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The Review Clause

37. The Commission may, where appropriate, in response to a request from Abbott showing good cause and accompanied by a report from the Monitoring Trustee:

(a) Grant an extension of the time periods foreseen in the Commitments; or

(b) Waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments.

Where Abbott seeks an extension of a time period, it shall submit a request to the Commission no later than one month before the expiry of that period, showing good cause. Only in exceptional circumstances shall Abbott be entitled to request an extension within the last month of any period.

Duly authorized for and on behalf of

Abbott Laboratories

……

[…]*February 9, 2010

SCHEDULE 1

1. The Divestment Business is operated by Innogenetics, which is in turn operated separately from the pharmaceutical business of Solvay S.A. An organizational chart is provided in **Annex 1.3**.

2. Following paragraph 5 of these Commitments, the Divestment Business will comprise, at the option of the Purchaser:

(a) All tangible assets listed in **Annex 1.4** […]* that are owned by Innogenetics and that are necessary for the Purchaser to manufacture the Innogenetics EEA CF Products described in **Annex 1.1**.

(b) All IP rights that are held by Innogenetics and used exclusively in the development, manufacture, and/or sale of the Innogenetics EEA CF Products, including:

- […]*

(c) An irrevocable, royalty-free, and perpetual license to all IP rights held by Innogenetics that are exclusive with respect to the development, manufacture, and/or sale of CF Products in the EEA, including:

- IP rights to […]*
- IP rights to […]*.

(d) An irrevocable, royalty-free, perpetual, and non-exclusive license (on terms comparable to those in the licenses held by Innogenetics) to […]* to the extent necessary to develop, manufacture, and/or sell the Innogenetics EEA CF Products.

(e) An irrevocable, royalty-free, perpetual, and non-exclusive license (on terms comparable to those in the licenses held by Innogenetics) to the following IP rights held by Innogenetics to the extent necessary to develop, manufacture, and/or sell the Innogenetics EEA CF Products:

- Non-exclusive license from […]* to Innogenetics to use […]* technology.

In the event that such rights may not be transferred or granted to the Purchaser under the existing arrangements between Innogenetics and its contractual partners, Abbott commits to use its best efforts to negotiate with Innogenetics' contractual partners either the partial transfer of such licenses as far as they relate to the Innogenetics EEA CF Products to the Purchaser, or the conclusion of new licensing contracts between Innogenetics' contractual partners and the Purchaser on terms comparable to those in the licenses held by Innogenetics.

(f) An irrevocable, royalty-free, perpetual, and non-exclusive license (on terms comparable to those in the licenses held by Innogenetics) to the following IP rights that are held by Innogenetics and used exclusively by Innogenetics in the Innogenetics EEA CF Products:

- Non-exclusive license from […]* to Innogenetics for use and marketing of technology developed by the licensors as encompassed by the claims of […]*.

- Non-exclusive license from […]* to Innogenetics for use and marketing of technology as encompassed by the claims of […]*."

In the event that such rights may not be transferred or granted to the Purchaser under the existing arrangements between Innogenetics and its contractual partners, Abbott commits to use its best efforts to negotiate with Innogenetics' contractual partners either the partial transfer of such licenses as far as they relate to the Innogenetics EEA CF Products to the Purchaser, or the conclusion of new licensing contracts between Innogenetics' contractual partners and the Purchaser on terms comparable to those in the licenses held by Innogenetics.

(g) Transfer of, or, if not legally possible, access to, as appropriate, all licenses, permits, and authorizations issued by any governmental organization and held by Innogenetics that are necessary to manufacture and/or sell the Innogenetics EEA CF Products, including any relevant dossiers relating to current or pending authorizations available to Innogenetics and, where necessary, reasonable assistance related to the transfer to the Purchaser of such licenses, permits, and authorizations concerning the Innogenetics EEA CF Products, and providing reasonable assistance to the Purchaser to make any necessary regulatory filings and obtain any necessary authorizations.

(h) Transfer of, or, if not legally possible, access to, as appropriate, all current and pending CE marks relating to the Innogenetics EEA CF Products or a part thereof held by Innogenetics, including all relevant dossiers relating to the current and or pending CE marks relating to the Innogenetics EEA CF Products available to Innogenetics, and, where necessary, reasonable assistance to the Purchaser to make any necessary regulatory filings and obtain any necessary authorizations

(i) Access to raw materials necessary for the manufacturing of the Innogenetics EEA CF Products. Abbott will use its best efforts (i) to (partially) transfer the agreements to the Purchaser, or (ii) to enable the Purchaser to conclude agreements with Innogenetics' contractual partners on terms comparable to those offered to Innogenetics, or (iii) to conclude back-to-back supply agreements with the Purchaser to make such raw materials available to the Purchaser on a reasonable cost-plus basis.

(j) Innogenetics' existing contracts with EEA customers relating to the Innogenetics EEA CF Products, and the Innogenetics EEA CF Products' customer list, and customer records as they relate to the Innogenetics EEA CF Products.

(k) Key Personnel listed in **Annex 1.2**. The Purchaser will be given an option to hire one or more Personnel (including, if reasonably necessary, research and development, production and supply chain, technical assistance, customer support, and/or sales and marketing

personnel), as described in paragraphs 8 and 9. Abbott shall, at the option of the Purchaser, provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sales and marketing, research and development, and customer support of the Innogenetics EEA CF Products for a period of three years (to be extended at the reasonable request of the Purchaser) on a reasonable cost-plus basis to be agreed with the Purchaser, and in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

(l) For at least an interim period of three years (to be extended as reasonably necessary) after Closing, Abbott commits to toll manufacture the Innogenetics EEA CF Products for the Purchaser on a reasonable cost-plus basis to be agreed with the Purchaser, and in accordance with good industry practice.

(m) Abbott will use its best efforts to enable the Purchaser to (i) conclude agreements with […]* to purchase from […]* processing instruments (and ancillary products (*e.g.*, trays)) comparable to […]*, and (ii) customize these instruments and validate them for the Innogenetics' EEA CF Products. In the event that such arrangements cannot be made, Abbott is prepared to conclude back-to-back supply agreements with the Purchaser to make such instruments available to the Purchaser on a reasonable cost-plus basis.

(n) Abbott will use its best efforts to enable the Purchaser to (i) conclude agreements with […]* to purchase from […]* processing instruments (and spare parts for such instruments) comparable to […]*, and (ii) customize these instruments and validate them for the Innogenetics EEA CF Products. In the event that such arrangements cannot be made, Abbott is prepared to conclude back-to-back supply agreements with the Purchaser to make such instruments available to the Purchaser on a reasonable cost-plus basis.

3. The Divestment Business shall not (and does not need to) include any tangible assets, intangible assets, personnel, contracts, agreements, or authorizations not identified in the Commitments.

ANNEX 1.1

ANNEX 1.1

Innogenetics EEA Cystic Fibrosis Products

Annex 1.1

Innogenetics produces and sells the following three CF testing assays (strips) in the EEA:

- INNO-LiPA CFTR Italian Regional <20T,CE>
- INNO-LiPA CFTR 17+Tn Update <20T,CE>
- INNO-LiPA CFTR 19 <20T, CE>

In addition to the strips, CF testing kits sold by Innogenetics in the EEA may include the following ancillary components:

- Amplification CFTR <2x20OT,CE>
- Hybridization pack 40x5SSC <GLR>
- Color Development Pack 40 <GLR>
- Amplification CFTR <GLR>
- Probe Arrays CFTR 36 <2x20T, RUO>
- Primers CFTR36<2x20T, RUO>

The Innogenetics EEA CF Products also include the following Innogenetics pipeline product:

- […]*

ANNEX 1.2

ANNEX 1.2

Innogenetics Key Personnel

Annex 1.2

The Key Personnel for the Innogenetics Divestment Business are:

[…]*

ANNEX 1.3

ANNEX 1.3

Innogenetics Organizational Chart

[Confidential Annex]*

ANNEX 1.4

ANNEX 1.4

Innogenetics LiPA Production Equipment

[Confidential Annex]*

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