# Case No COMP/M.6293 - THERMO FISHER/ PHADIA

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# REGULATION (EC) No 139/2004 MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION

Date: 18/08/2011

In electronic form on the EUR-Lex website under document number 32011M6293

### **EUROPEAN COMMISSION**



Brussels, 18.8.2011

C(2011) 6057 final

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus [...]. Where possible the information omitted has been replaced by ranges of figures or a general description.

**PUBLIC VERSION** 

MERGER PROCEDURE

# To the notifying party:

Dear Sir/Madam.

**Subject:** Case No COMP/M.6293- THERMO FISHER/ PHADIA

Commission decision pursuant to Article 6(1)(b) of Council Regulation

No 139/2004<sup>1</sup>

1. On 12 July 2011, the European Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which the undertaking Thermo Fisher Scientific, Inc. ("Thermo Fisher", USA) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of CB Diagnostics Holding AB, the holding company and sole owner of Phadia Holding AB ("Phadia", Sweden) by way of purchase of shares.

### I. THE PARTIES

- 2. Thermo Fisher is a US-based company offering a wide range of laboratory and life science instruments and related products and services, including in vitro diagnostics systems.
- 3. Phadia supplies immunodiagnostic blood test systems for the clinical (in vitro) diagnosis and monitoring of allergy and autoimmune diseases.

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

### II. THE OPERATION

4. Thermo Fisher is to acquire through the transaction the entire issued share capital of CB Diagnostics Holding AB, which is the holding company of the Phadia Group<sup>2</sup>.

### III. CONCENTRATION

5. The proposed transaction constitutes a concentration within the meaning of Article 3(1)(b) of Regulation 139/2004.

### IV. EU DIMENSION

6. The combined aggregate worldwide turnover of all the undertakings concerned is more than EUR 2 500 million (2010, Thermo Fisher: EUR 8 138 million; Phadia: EUR [...]million). Only Thermo Fisher has a EU-wide turnover in excess of EUR 250 million (EUR 1710 million), but Phadia also has a Community-wide turnover of over EUR 100 million (EUR [...] million). The parties have a combined turnover of over EUR 100 million in each of the following six Member States: [...]. In three of these Member States ([...]) each of the parties achieves a turnover of over 25 million. Neither Thermo Fisher nor Phadia achieved more than two thirds of their turnover in any single Member State. The notified operation therefore has an EU dimension within the meaning of Article 1(3) of the Merger Regulation.

#### V. **COMPETITIVE ASSESSMENT**

#### 1. HORIZONTAL EFFECTS

#### 1.1. **Relevant market - In vitro diagnostics (IVD)**

#### 1.1.1. Product market

7. IVD comprise the manufacture and sales of tests (also called reagents or assays) and related equipment/instruments (also called analysers) for the purpose of conducting tests outside the human body. Instruments can generally run several types of tests that are not substitutable with each other as they test for different things. Ancillary products and services include related software and after-sales services.

8. Previous Commission decisions relied on the classification of IVD tests used by the European Diagnostics Manufacturers' Association ("EDMA")<sup>3</sup>. In addition, EDMA also offers a classification of IVD instruments, software and services. EDMA classifies IVD tests into 6 main (first level) categories: Clinical Chemistry, Immunochemistry, Haematology/Histology, Microbiology, Infectious Immunology and Genetic Testing. Within each of these broad categories, EDMA classifies IVD tests into a further three levels that constitute progressively narrower segments.

CB Diagnostics Holding AB is currently owned by funds managed by private equity firm Cinven Ltd and Phadia management (together accounting for less than [10-20]%).

See Cases COMP/M.5661 Abbott/Solvay, decision of 11.2.2010; COMP/M.4865 Siemens/Dade Behring, decision of 21.10.2007; COMP/M.4321 Siemens/Bayer Diagnostics, decision of 26.9.2006;; and COMP/M.950 Hoffmann La Roche/Boehringer Mannheim, decision of 4.2.1998.

- 9. Whilst Thermo Fisher is active in the Immunochemistry, Clinical Chemistry and Haematology/Histology segments, Phadia is only active in the Immunochemistry segment. EDMA classifies hundreds of assays in the Immunochemistry segment under several EDMA 2<sup>nd</sup> level categories. Allergy and Autoimmune Diseases (where Phadia is active) are two of these 2<sup>nd</sup> level categories. Within each 2<sup>nd</sup> level category, a number of different tests can be performed in order to detect different pathogens. Within each second level category assays are therefore often further sub-divided into different categories (EDMA 3<sup>rd</sup> level). The narrowest EDMA category (EDMA 4<sup>th</sup> level) most often corresponds to one specific type of assay.
- 10. Within Immunochemistry, the parties overlap in "Autoimmune disease tests" (EDMA 2<sup>nd</sup> level category 12.10).<sup>4</sup> This category is sub-divided into several narrower categories (EDMA 3<sup>rd</sup> level) according to the types of autoimmune-diseases to be tested for with the assays classified in this thematic panel. These include Autoimmune Connective Tissues Diseases (EDMA 3<sup>rd</sup> level category 12.10.01), Neuro-Auto-Immune Diseases (EDMA 3<sup>rd</sup> level category 12.10.02) and Thyroid Autoimmune Disease (EDMA 3<sup>rd</sup> level category 12.10.03). There is also a "catch-all" category including assays used for other types of autoimmune diseases (EDMA 3<sup>rd</sup> level category 12.10.90).
- 11. Both Parties supply tests for diagnosing thyroid autoimmune diseases (3<sup>rd</sup> level category 12.10.03). Based on the figures provided by the parties, thyroid autoimmune disease assays account for [...] of the sales of all assays grouped in the Autoimmune Disease category. Phadia in addition supplies several other assays for other categories of autoimmune diseases within the Autoimmune Disease category. The market investigation confirmed the parties' views that thyroid autoimmune tests are not substitutable with assays used to test for other autoimmune diseases.
- 12. There are three main assays that are grouped by EDMA under thyroid autoimmune diseases. Each of these assays is assigned their own EDMA 4<sup>th</sup> level category. These assays are Thyroid Peroxidase Antibodies or "anti-TPOs" (classified in the EDMA 4<sup>th</sup> level category 12.10.03.01); TSH Receptor antibodies (classified in the EDMA 4<sup>th</sup> level category 12.10.03.03); and Thyroglobulin Antibodies or "anti-TGs" (classified in the EDMA 4<sup>th</sup> level category 12.10.03.04).<sup>5</sup> Whilst both parties supply anti-TPOs and anti-TGs, only Thermo Fisher supplies TSH receptor antibodies.
- 13. According to the parties TSH receptor antibodies are used to test for the more serious thyroid autoimmune disease (Grave's disease), whilst the other two mainly test for another type of thyroid autoimmune disease (Hashimoto thyroditis). The market investigation indicated a somewhat more complex and varied use of these assays. However, it was confirmed that TSH receptors are not frequently and effectively substitutable by either anti-TPOs or anti-TGs. Also, whilst thyroid peroxidase and thyroglobulin antibodies are generally fully automated tests, TSH receptors are still sold to a significant extent as manual tests. Manual tests are not run on any instruments. An instrument is only used to measure the results. Such instruments are, according to the parties, relatively commoditised and offered by third parties. Thermo Fisher's own TSH

The remaining 4th level Thyroid Autoimmune Disease category is the catch-all category "Other thyroid autoimmune disease" (EDMA 4th level category 12.10.03.90)

3

The parties also overlap in rheumatoid – inflammatory disease markers (EDMA second level 12.11), but the transaction does not lead to affected markets on any possible level, i.e. on the basis of any respective EDMA category. This overlap will therefore not be considered further.

receptor antibody test is validated for an instrument offered by a third party (Berthold), but could also be measured on others' instruments. In any event, Thermo Fisher's TSH receptor test cannot be run on Phadia's proprietary system.

- 14. In the parties' view the product market should be defined along the EDMA 1<sup>st</sup> level category, Immunochemistry, and based on complete systems, not based on the components of the system (assays, instruments etc). The parties submit that customers purchase complete systems, including tests, instruments, software and after-sales services. In particular, it is common practice not to charge the customers separately for the instruments. The costs/lease of the instrument is therefore included in the price of tests. Prices are typically negotiated based on the quantity of reagents/assays the customer proposes to purchase. Customers can choose what type of tests they wish to purchase from the parties to reach this quantity (i.e. the parties do not require the customer to purchase any specific range of tests within the quantity agreed). The parties further argue that the commercial and hospital labs that purchase IVD products require a wide range of tests and the main suppliers (e.g. Abbott, Roche, Siemens) offer a wide range of immunoassays across the whole immunochemistry segment (including instruments with a wide test menu). These elements, in their view, justify the inclusion of all immunochemistry products (including assays and instruments) in the relevant product market.
- 15. In previous decisions<sup>6</sup>, the Commission considered whether competition takes place at the level of immunochemistry systems (including both analysers and reagents) or whether competition needs to be assessed based on narrower categories of assays separately. In the case of immunochemistry, a systems approach was considered as plausible<sup>7</sup>, but a market definition based on assays/reagents was not excluded. In one precedent, in particular, the Commission pointed out that "laboratories (which often utilise in parallel immunochemistry systems from different suppliers) have the possibility to select the best assays (in terms of price, quality, specific needs) to perform with each proprietary piece of equipment they have available."<sup>8</sup>
- 16. The market investigation confirmed that customers in general purchase a package of immunochemistry diagnostic products and services, including instrument rental, reagents/assays and services. Also, the market investigation confirmed that customers would not typically have an instrument installed specifically to have thyroid autoimmune diseases tested, but would tend to use the spare capacity available on other instruments. These elements appear to support the parties' argument for a wider systems approach to market definition.
- 17. At the same time, there are indications that competition may take place at the level of 2<sup>nd</sup> or 3<sup>rd</sup> level categories or even at the level of individual assays. For example more specialised suppliers (including Phadia itself) exist, which suggests that there is distinct demand also for more specific type of tests. The parties also acknowledge the existence of demand for instruments with relatively narrow test menus within Immunochemistry. This is firstly because even instruments with the widest range of tests may not offer certain tests. The market investigation has shown, for example, that some major suppliers active across Immunochemistry do not have as wide a range of autoimmune

<sup>6</sup> See e.g. Siemens/Dade Behring and Siemens/Bayer Diagnostics op cit.

<sup>&</sup>lt;sup>7</sup> Siemens/Dade Behring and Siemens/Bayer Diagnostics op cit.

<sup>8</sup> Siemens/Bayer Diagnostics op cit.

tests that Phadia and some smaller suppliers have. Furthermore, certain providers of systems have a strong reputation for certain types of tests and this may persuade labs to acquire these systems even if they can already perform the same kind of tests on their existing systems.

- 18. In addition, based on the market investigation it seems to be common for customers to have more than one instrument on which thyroid autoimmune disease tests (i.e. the products that both parties supply) can be run. Furthermore, it is also relatively common to purchase the different thyroid autoimmune assays (TSH receptors, anti-TPOs, anti-TGs) from different suppliers and the market investigation suggests that this would in any event be possible for most customers who currently purchase all these assays from one supplier. In particular, it appears relatively common to purchase the core assay of Thermo Fisher (TSH receptors) from a different supplier than the supplier of anti-TPOs and anti-TGOs (which are often purchased together). Customers therefore appear to have certain flexibility to source thyroid autoimmune disease assays from different suppliers. This suggests that, at least in the case of thyroid autoimmune products, there may be some competition between different types of assays in addition to competition at the systems level. There are therefore good arguments to consider a possible market definition based on thyroid autoimmune tests or even individual thyroid autoimmune assays in addition to the wider market definition proposed by the parties.
- 19. Finally, the parties submit that their main systems are proprietary<sup>9</sup>. In other words, their tests can only run on their own instruments and they only offer ancillary products (such as software and after-sales services) for their own systems. This was broadly confirmed in the market investigation.
- 20. The market definition can be left open in the present case as the transaction does not raise competition concerns in any segment and at any EDMA level where the parties overlap irrespective of whether it is the sales of complete systems or individual assays that are considered. The possible segments where the parties overlap and where the transaction leads to affected markets are:
  - i) EDMA 1<sup>st</sup> level: Immunochemistry (12);

  - ii) EDMA 2<sup>nd</sup> level: Autoimmune Diseases (12.10); iii) EDMA 3<sup>rd</sup> level: Thyroid Autoimmune Diseases (12.10.03); and
  - iv) EDMA 4<sup>th</sup> level: individual thyroid autoimmune assays (anti-TPO, anti-TG and TSH receptor antibodies).

# 1.1.2. Geographic market

- 21. The Commission has previously considered IVD markets to be national as customers (laboratories and hospitals) source products and after-sales services from within the country where they are located. The parties do not dispute this market definition.
- 22. The market investigation in the present case also indicates that customers tend to source the relevant products from subsidiaries/distributors within the country where they are located. Whilst most competitors do not disagree with considering the geographic scope

Phadia has one open system, including tests which can be used with other suppliers' analysers. However, theses tests cannot run on either Thermo Fisher's analysers or the main competitors' analysers in the relevant markets, according to the information by the parties. In any event, this open system product line is of minor importance in terms of sales and no longer actively marketed and the key new systems to be launched shortly (high capacity instruments with a wide range of assays) are all closed systems.

as national, some consider the markets to be EEA-wide from a supply side point of view. This is due for example to a common European regulatory background for the approval of diagnostics products and to the pan-European sales and distribution networks that main competitors already have.

23. In any event, the exact scope of the geographic market can be left open in the present case as the transaction would not raise competition concerns at either the national or the EEA level.

# 1.2. Competitive assessment – IVD

# 1.2.1. Introductory remarks

- 24. As specified by recent Commission decisions,<sup>10</sup> there do not appear to be reliable third party data on the overall size of IVD markets, especially on narrower product categories and at the national level. The parties therefore used their own market intelligence to estimate market shares for each possible market.
- 25. The parties provided market shares based on reagent sales. They argue that this broadly reflects the market positions based on complete systems as well as installed base of instruments. This was confirmed by competitors in the market investigation. As the parties offer software and ancillary services for their own systems only, their market positions for software and ancillary services would be reflective of their market positions based on complete systems.
- 26. In previous human health cases<sup>11</sup> and the most recent IVD decisions<sup>12</sup>, the Commission has generally focused its market investigation on examining in more detail markets where the Parties achieved a combined share of 35% or more and where the increment in the share was over 1%.
- 27. The transaction would lead to combined market shares of 35% or more with an increment of at least 1% only in a relatively small number of national markets in the following possible markets: i) all autoimmune disease assays (EDMA 2<sup>nd</sup> level category 12.10); ii) all thyroid autoimmune assays (EDMA 3<sup>rd</sup> level category 12.10.03) and iii) certain individual thyroid autoimmune assays. The parties do not achieve a combined market share of 35% with an increment of 1% or more at the EEA level in any other segment.
- 28. The market investigation did not uncover any other product and/or geographic areas of overlap where the transaction may raise competition concerns due to high combined market shares.

#### 1.2.2. Immunochemistry (EDMA 12)

29. The parties' activities in Immunochemistry are largely complementary. Phadia is mostly active in allergy tests within the EDMA 2<sup>nd</sup> level category 12.02 ("Allergy"), where Thermo Fisher is not active. Thermo Fisher in turn is active in various other

6

<sup>10</sup> Case COMP/M.6175 Danaher/Beckman Coulter, decision of 16.6.2011 and Abbott/Solvay op cit.

See e.g the most recent cases COMP/M.5865 Case COMP/d.5865 *Teva/Ratiopharm*, Decision of 3.8.2010 and COMP/M.5778 *Novartis/Alcon*, decision of 9.8.2010.

<sup>12</sup> Danaher/Beckman Coulter and Abbott/Solvay op cit.

- Immunochemistry segments where Phadia is not active. As stated above, the only overlap that leads to affected markets within Immunochemistry is in Autoimmune Diseases (EDMA 12.10)
- 30. If all sales of immunochemistry assays were to be considered, the transaction would only lead to one affected market in the Netherlands, where the parties would have a combined market share of [10-20]%. The main competitors of the parties in the overall Immunochemistry segment are large, diversified IVD players such as Abbott, Roche, and Siemens. All these competitors have a wide portfolio of products in Immunochemistry and in other major IVD segments. In the Netherlands, each of these competitors has a significant market share in the range of 20-25%.
- 31. Due to the moderate combined market shares and the existence of a number of strong, credible competitors, the transaction would not raise competition concerns for the overall market of Immunochemistry IVD products.

# 1.2.3. Assays for autoimmune diseases (EDMA 12.10)

32. This section assesses the potential competitive impact of the transaction in the area where the parties significantly overlap, i.e. autoimmune disease diagnostics, and, in particular, thyroid autoimmune disease diagnostics. There are certain characteristics of these markets and the products supplied that are common to the countries investigated. These characteristics are therefore described in sections 1.2.3.1. and 1.2.3.2. before a country-by-country assessment in section 1.2.3.3.

### 1.2.3.1. Scope and characteristics of the parties' and competitors' products

- 33. In a wider hypothetical market comprising all assays for different types of autoimmune diseases (EDMA 12.10) Phadia has generally a significantly stronger position than Thermo Fisher in the EEA and in the EEA Member States. Whilst Phadia supplies a wide range of assays for different types of autoimmune diseases, Thermo Fisher only supplies assays to test for autoimmune diseases specifically related to the thyroid. Thyroid autoimmune assays on the other hand are not the focus of Phadia's activities in these markets. Such assays account for less than [0-5]% of Phadia's sales of autoimmune assays in the EEA. This shows that in terms of product offering, the parties are not close competitors.
- 34. Given that Thermo Fisher does not offer any autoimmune disease tests besides thyroid autoimmune tests, there does not appear to be any merger-specific incentive to attempt a price increase for Phadia's other autoimmune disease assays or for their overall systems. This is because Thermo Fisher is not an alternative supplier for the overwhelming majority of Phadia's products. If, prior to the merger, Phadia attempted a price increase for any of their products (except for thyroid autoimmune disease tests) it would not therefore have lost a significant part of its sales to Thermo Fisher. It would have been competitors with a similar product offering who would have been most likely to benefit from any such price increase. This is also true if Phadia attempted a price increase for their entire systems (instruments and all assays included), because thyroid autoimmune disease assays make up only a minute part of the sales of the overall Phadia systems. The results of the market investigation are in line with these considerations and support the parties' argument that Thermo Fisher is not currently a significant competitive constraint on Phadia in the overall segment of autoimmune disease diagnostics. In particular, the market investigation indicated competitors with wider autoimmune

product portfolios as close competitors to Phadia in the overall autoimmune disease segment. These competitors include for example Euroimmun, Bio-rad, Inova, Orgentec and Diasorin.

- 35. It is therefore only for thyroid autoimmune disease assays that an incentive for the merged entity to raise prices following the merger cannot be excluded per se. This is because both parties supply such tests, and, as explained in recital 18 above, it cannot be excluded that there is competition at the level of such tests (i.e. not only at a higher level involving systems with a wider assay offering).
- 36. Considering only thyroid autoimmune disease tests, Thermo Fisher is generally significantly stronger than Phadia in the EEA Member States. It appears that the closest competitors to Thermo Fisher are companies that also focus on thyroid autoimmune tests in the autoimmune disease category and like Thermo Fisher have no other significant product offering in this segment. These competitors are Roche, Abbott and Siemens. As sales of thyroid autoimmune disease account for a significant part of the overall autoimmune assay market (around[...] in the EEA) competitors only supplying thyroid autoimmune disease products may also achieve significant market shares in the overall autoimmune disease diagnostics segment despite their limited product offering (e.g. Roche, Abbott, Siemens).
- 37. Thermo Fisher already offers the two tests offered by Phadia (anti-TPOs and anti TGs) as well as TSH receptor tests (which Phadia does not have). The TSH receptor assay is Thermo Fisher's core product in thyroid autoimmune disease diagnostics, accounting for EUR [...] million of their EUR [...] million EEA-wide thyroid autoimmune disease diagnostics sales. In addition, the market investigation did not indicate Phadia's anti-TPO and anti-TG assays to be superior to other assays on the market (including Thermo Fisher's). The transaction would therefore not seem to extend the scope or improve significantly the quality of the Thermo Fisher thyroid autoimmune disease product offering.
- 38. As explained in recital 13 above Thermo Fisher's TSH receptor assay is a manual test, which is not part of their system. [...]. Based on the market investigation there are at least three current suppliers who, like Thermo Fisher, can offer all three types of thyroid autoimmune disease tests. Two of these competitors (Roche and Euroimmun) already offer automated tests also for TSH receptors. They therefore appear [...] in the thyroid autoimmune disease diagnostics segment.
- 39. In summary, the parties do not appear to be close competitors in autoimmune disease diagnostics due to their complementary product focus, as also confirmed by the market investigation. Phadia is already a strong player in overall autoimmune disease diagnostics and Thermo Fisher only adds one single assay to their autoimmune disease testing portfolio (which in any event is not compatible with the Phadia system). This was generally not considered by respondents as a significant advantage that Phadia would gain from the transaction in the area of autoimmune disease testing. In particular, according to the majority view of the market investigation, Phadia would not acquire, through the transaction, any significant advantages it does not already have and which would be difficult to emulate by its competitors<sup>13</sup>. Similarly, Phadia does not appear to

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Whilst a minority of respondents did indicate such advantages, these indications did not point consistently to any single specific advantage (i.e. each of these respondents indicated a different advantage).

- add significantly to Thermo Fisher's activities in thyroid autoimmune disease testing either by way of additional products or significant additional sales.
- 40. The combined entity will have a wider portfolio of products due to Thermo Fisher's activities outside autoimmune disease testing. However, Phadia already appears to have a competitive advantage in autoimmune disease testing due to their strong product offering in allergy testing (EDMA 2<sup>nd</sup> level category 12.02), as indicated by the market investigation. Synergies between allergy and autoimmune disease testing seem to be more pronounced than between autoimmune disease testing and the areas where Thermo Fisher is active (e.g. cancer testing, fertility). The fact that the parties' products run on two separate systems which are not compatible also seems to work against such synergies, at least in the short term. In any event, a clear majority of respondents accounting for over 80% of the sales of autoimmune disease tests in the EEA confirmed that they already have a comparable or wider portfolio of products than the merged entity would have and/or could continue to compete effectively in autoimmune disease testing despite having a narrower portfolio of products.
- 41. It can therefore be concluded that the only area where the parties seem to be in direct competition is thyroid autoimmune disease testing. The other activities of the parties seem to be complementary. The combination of such complementary activities does not, on the other hand, appear to have a significant negative impact on competition in autoimmune disease testing products.

### 1.2.3.2. Barriers to expansion and barriers to entry

- 42. The market investigation indicated that developing a new assay may take a significant amount of time (generally 1-2 years or even longer). This notwithstanding there are already several existing suppliers of thyroid autoimmune disease tests in the EEA, including Roche, Abbott, Siemens, Beckman Coulter, DiaSorin, Euroimmun, Bio-Rad, Inova and Medipan. Competitors did not indicate any significant barriers to expansion for existing suppliers in any EEA country.
- 43. Notwithstanding that switching by labs from one thyroid autoimmune test to another involves an evaluation of the quality/price performance of new tests, switching seems to be facilitated by a number of factors. As explained in recital 18 it is common for customers to purchase different kind of thyroid autoimmune assays from different suppliers and the market investigation suggests that this would in any event be possible for most customers who currently purchase all kinds of thyroid autoimmune assays from one single supplier. The market investigation also indicated that customers typically have instruments from more than one supplier on which thyroid autoimmune diseases can be run and that they generally use the spare capacity of instruments with wider test menus for thyroid autoimmune disease testing. This suggests that they would not have to switch to a whole new system to change suppliers for this particular product.
- 44. Based on the market investigation it can therefore be concluded that expansion by current competitors in thyroid autoimmune disease assays would be possible in case of an attempted price increase by the merged entity.

# 1.2.3.3. Country-specific assessment

45. In the EEA, the transaction does not lead to particularly high combined market shares in either the overall autoimmune or the thyroid autoimmune disease diagnostic segment.

The parties would achieve a combined market share of [30-40]% of autoimmune disease tests with a relatively small increment of [5-10]% added by Thermo Fisher. In thyroid autoimmune disease diagnostics the parties would achieve a combined market share of [10-20]% with a small increment of only [0-5]% by Phadia. Considering the presence of a number of other significant competitors<sup>14</sup> and the general considerations in sections 1.2.3.1. and 1.2.3.2. above the transaction does not raise competition concerns at the EEA level.

- 46. The transaction would lead to combined market shares of 35% or more with an increment of 1% or more in the following EEA countries within autoimmune disease testing considering either i) the overall category of autoimmune disease testing; and/or ii) thyroid autoimmune disease testing; and/or individual thyroid autoimmune assays: Denmark, Finland, Germany, Ireland, the Netherlands, Norway, Portugal, Spain, Slovenia and Sweden. The competitive situation in these countries is considered below. Where the market structure and parameters of competition are similar in certain Member States, a joint assessment is provided for these countries.
- 47. The market investigation did not indicate any other countries where the transaction may raise competition concerns based on high combined market shares of the parties. Consequently, and in accordance with previous Commission precedents in the pharmaceutical and IVD sectors<sup>15</sup>, it is only the countries listed in recital 46 that are assessed in detail.

#### Denmark

48. In Denmark Thermo Fisher achieves significantly higher market shares in the overall autoimmune disease diagnostics segment than in the EEA in general or in most other EEA countries. The transaction would lead to combined market shares of [60-70]% (Thermo Fisher [10-20]%, Phadia [40-50]%). Based on market shares alone the other three significant competitors remaining would be Abbott ([5-10]%); Roche ([10-20]%) and Siemens ([10-20]%). However, the market investigation confirmed that the parties are not close competitors as they focus on different autoimmune diseases: whilst Thermo Fisher supplies only assays to test thyroid autoimmune diseases, these assays account for a minute share (<[0-5]%) of Phadia's overall sales of assays for autoimmune diseases in Denmark. Phadia in turn accounts for only [0-5]% of the sales of thyroid autoimmune disease assays, where the significant competitors are Thermo Fisher ([70-80]%), Siemens ([10-20]%) and Roche ([10-20]%) The vast majority of market investigation respondents also confirmed that the parties do not currently exercise significant competitive pressure on each other as they do not appear to be close competitors. There were other competitors that were indicated as the main/closest competitor to Phadia on autoimmune disease on the one hand (i.e. mostly Euroimmun, Inova, Bio-Rad) and to Thermo Fisher in thyroid autoimmune disease on the other (i.e. mostly Siemens, Roche, Abbot).

10

Market shares of competitors in the autoimmune disease category: Roche, Abbott, Inova with [10-20]% each and Siemens, Orgentec, Euroimmun and Diasorin with 5-10% each. Market shares of competitors in the thyroid autoimmune disease category: Roche [20-30]%, Siemens and Abbott [10-20]% each, Diasorin [5-10]%, Beckman Coulter [5-10]%.

<sup>15</sup> See for example Abbott/Solvay Pharmaceuticals and Teva/Ratiopharm op cit.

- 49. In Denmark the parties also achieve a market share of over 35% with an increment of over 1% at the individual assay (EDMA 4<sup>th</sup>) level, for the supply of the anti-TPO assay (combined [50-60]%, Phadia [0-5]%). Other suppliers include Roche ([20-30]%), Siemens ([10-20]%) and Abbott ([0-5]%). The market investigation confirmed that these competitors would be sufficient to constrain the merged entity for the supply of this assay.
- 50. Based on the above and taking into account the general considerations in sections 1.2.3.1. and 1.2.3.2. above, which also apply to Denmark, the transaction would not raise competition concerns in any segment where the parties overlap. In particular the parties are not close competitors and are presently primarily constrained by third party competitors.

# Germany and Sweden

- 51. In Sweden and Germany, Thermo Fisher again has a relatively stronger position, as compared to most other countries, with [5-10]% and [10-20]% respectively of the sales of all autoimmune disease assays, but the combined market share would be only [30-40]% and [30-40]% respectively. In both countries there would remain at least five significant competitors. In Sweden this would include Roche ([20-30]%), Abbott ([10-20]%, Siemens ([10-20]%) and BioRad and Inova (5-10%). In Germany the remaining competitors would be Euroimmun ([10-20]%), Siemens ([10-20]%), Roche ([10-20]%), Orgentec ([5-10]%) and Abbott ([5-10]%). Based on the market investigation, the parties are not close competitors.
- 52. The parties would have a combined market share of [30-40]% in thyroid autoimmune tests with a small increment of only [0-5]% added by Phadia in Germany (in Sweden they would have a combined market share of only [10-20]%). Other competitors include Siemens ([20-30]%), Roche ([10-20]%), Abbott ([10-20]%) and Beckman Coulter ([0-5]%). The remaining competitors were confirmed as credible and sufficient by the market investigation.
- 53. Based on the absence of high combined market shares and the general considerations in sections 1.2.3.1. and 1.2.3.2., which also apply to Germany and Sweden, the transaction would not raise competition concerns in any segment where the parties overlap. In particular the parties are not close competitors and are presently primarily constrained by third party competitors.

### Ireland, the Netherlands, Portugal and Spain

54. The common characteristic of the market structure in these countries is that the parties would achieve moderately high market shares (35-50%), but with a small ([0-5]%) increment by Thermo Fisher in the overall segment of autoimmune disease tests. The parties' combined market shares in thyroid autoimmune tests would be below 35% ([10-30]%) which is not indicative of competition concerns in this narrower segment pursuant to recital 43 above. The market shares for the overall segment of autoimmune disease tests are as follows: Ireland (combined [40-50]%, Thermo Fisher [0-5]%); the Netherlands (combined [30-40]%, Thermo Fisher [0-5]%); Portugal (combined [30-40]%, Thermo Fisher [0-5]%). In each of these countries there would remain at least three competitors with significantly higher market shares than Thermo Fisher.

- 55. The small market shares of Thermo Fisher already indicate that it does not exercise a significant competitive constraint on Phadia for autoimmune disease testing in general. This was confirmed by the market investigation.
- 56. For the supply of individual thyroid autoimmune tests, the parties would have a combined market share of just over [30-40]% only in Spain, and in particular for the supply of anti-TGs (combined [30-40]%; Phadia [30-40]%, Thermo Fisher [0-5]%). Roche (30-35%), Siemens ([10-20]%) and Abbott ([10-20]%) would also be present in this market. These remaining competitors were confirmed as credible and sufficient by the market investigation.
- 57. Based on the above and taking into account the general considerations in sections 1.2.3.1. and 1.2.3.2. above, which also apply to Ireland, Portugal and Spain, the transaction would not raise competition concerns in any segment where the parties overlap in these countries.

# Finland and Norway

- 58. In Finland and Norway, the parties would achieve relatively high market shares in autoimmune disease testing with a small, but not insignificant increment by Thermo Fisher. The transaction would not, on the other hand, lead to high market shares in thyroid autoimmune disease testing where the parties directly compete.
- 59. In autoimmune disease testing the parties would achieve a combined market share of [60-70]% in Finland ([0-5]% increment by Thermo Fisher) and [50-60]% in Norway (with a [5-10]% increment by Thermo Fisher). Competitors include Abbott ([10-20]%), Inova ([10-20]%) and some other competitors with smaller market shares in Finland and Roche ([10-20]%), Inova ([10-20]%), BioRad ([5-10]%) and Siemens ([5-10]%) in Norway. The parties are not close competitors and Phadia is primarily constrained by third party competitors as indicated by the market investigation.
- 60. It is only in Finland that the transaction would lead to combined market shares of over 35% in thyroid autoimmune tests. The parties would have a combined market share of [30-40]% with an increment of [10-20]% by Phadia. Other competitors include Roche (30-40%), Siemens ([20-30]%) and Abbott ([0-5]%). [90-100]% of the sales of Thermo Fisher in Finland are of TSH receptors, which Phadia does not supply. Based on the results of the market investigation, the merged entity would be constrained sufficiently by the remaining competitors (in particular Roche, which offers TSH receptor tests).
- 61. Based on the above and taking into account the general considerations in sections 1.2.3.1. and 1.2.3.2. above, which also apply to Finland, the transaction would not raise competition concerns in any segment where the parties overlap.

### Slovenia

62. In Slovenia the transaction would only lead to combined market shares of 35% or over in thyroid autoimmune diagnostics. Whilst the parties would have a high combined market share of [60-70]%, the increment added by Phadia is small (only [0-5]%). Other competitors include Abbott ([10-20]%), Roche ([20-30]%) and some smaller competitors. [90-100]% of Thermo Fisher's sales are TSH receptors, which Phadia does

not offer and all other competitor have products of the kind of Phadia's products in their portfolios. Based on this, the market structure and indications from the market investigation, it can be concluded that Thermo Fisher is currently constrained primarily by competitors other than Phadia. In light of this and the general considerations in sections 1.2.3.1. and 1.2.3.2. above, the transaction would not therefore raise competition concerns in thyroid autoimmune tests in Slovenia.

#### 1.3. Conclusion - horizontal effects

- 63. Considering that the parties are not close competitors and are currently primarily constrained by other competitors, which would continue to constrain the merged entity, the transaction does not raise concerns in the EEA and in any EEA Member State where the parties overlap in any of the following market segments:
  - i) EDMA 1<sup>st</sup> level: Immunochemistry (12);
  - ii) EDMA 2<sup>nd</sup> level: Autoimmune Diseases (12.10);
  - iii) EDMA 3<sup>rd</sup> level: Thyroid Autoimmune Diseases (12.10.03); and
  - iv) EDMA 4<sup>th</sup> level: individual thyroid autoimmune assays (anti-TPO, anti-TG and TSH receptor antibodies.

#### 2. VERTICAL EFFECTS

#### 2.1. Relevant markets

# 2.1.1. Microplates

64. Thermo Fisher supplies microplates (including microplates for diagnostic applications) to several companies, active in the markets for IVD Immunochemistry diagnostics, including IVD autoimmune disease diagnostics and IVD allergy diagnostics.

- 65. Microplates are trays with individual wells made either of moulded plastic forming a single piece of plastic or made of individual wells which are removable from the plate. Samples are injected in microplates together with an assay and subsequently measured using a microplate reader. Microplates come in different sizes and with different number of individual wells ranging, for example, from 96 to 1536 wells. Microplates can be used for a wide variety of applications (e.g., general laboratory purposes, cell culture, microbiology, storage, drug discovery) with immunochemistry diagnostics being only one of these applications.
- 66. The plates developed for use in immunochemistry are injection molded using a select grade of virgin polystyrene. The combination of mold design, the injection molding process, the polystyrene raw material, and the secondary processing using different levels of gamma radiation determine whether the plates will be considered high, medium, low or multi-binding. Overall, it is the combination of customer's reagents, coatings, sample preparation, etc., that would determine the actual application, e.g. IVD allergy or autoimmune disease diagnostics. The suppliers sell both coated and uncoated microplates for use in IVD assays.
- 67. The Commission previously considered<sup>16</sup> that all plastic microplates belong to the same relevant product market without a further distinction based on the application. For the sake

<sup>16</sup> COMP/M.4242 Thermo Electron/Fisher Scientific, decision of 9.11.2006, paragraphs 23, 69 and 70.

- of completeness, the parties presented separate market shares for microplates for general use and microplates for diagnostic applications, including IVD allergy and autoimmune disease diagnostics.
- 68. The findings of the market investigation support the view that from a demand side microplates for diagnostic applications are not substitutable with general purpose products. In particular, the microplates for diagnostics generally present higher quality characteristics, surface treatment, higher technical specification for raw material, traceability, validations. On the other hand, the suppliers often provide various types of microplates, both for general and diagnostic applications. For the purposes of this decision, the exact scope of the relevant product market definitions can be left open, as the proposed transaction does not raise concerns under any alternative.
- 69. The parties claim that the geographic scope of the market for plastic microplates, including the microplates for diagnostics, is at least EEA wide, if not worldwide. The market investigation in this case has confirmed that these markets are wider than national in scope, but the exact scope of the geographic market can be left open as serious doubts do not arise either on the basis of an EEA-wide market, or a worldwide market.

# 2.1.2. Bulk reagents

- 70. Thermo Fisher supplies key ingredients (bulk reagents) to be used in [...] assays of [name of company]. These products could be considered similar to active pharmaceutical ingredients (APIs) in finished dose pharmaceuticals. The products are customised for [name of company]'s assays, but the parties submit that the process is relatively standardised. This means that another manufacturer could also produce these products based on the specifications of [name of company].
- 71. The parties submit that from the demand-side there is no substitutability between the different bulk reagents. However, given flexibilities on the supply-side, the market could be defined as wider than the supply of bulk reagents used in [...] respectively.
- 72. The parties claim that the relevant geographic market is wider than national and possibly worldwide in scope. In particular, the parties rely on a number of Commission decisions on active pharmaceutical ingredients (APIs) from previous pharmaceutical cases<sup>17</sup> where such markets were defined as at least EEA- and possibly worldwide.
- 73. The market investigation in this case has confirmed that these markets are wider than national in scope, but the exact scope of the geographic market can be left open as serious doubts do not arise either on the basis of an EEA-wide market, or a worldwide market.

# 2.1.3. Contract manufacturing

- 74. Thermo Fisher manufactures [...] assay kits for [name of company].
- 75. According to the Commission's previous pharmaceutical decisions, contract manufacturing of finished dose pharmaceuticals consists of the manufacturing under contract, on behalf of third party pharmaceutical companies, of finished pharmaceutical products which may or

<sup>&</sup>lt;sup>17</sup> COMP/M.3751 Novartis/Hexal, decision of 27.5.2005; COMP/M.3928 TEVA/Ivax, decision of 27.11.2005; Abbott/Solvay Pharmaceuticals op cit.

may not include final packaging<sup>18</sup>. 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.<sup>19</sup> In these previous decisions, the geographic market was considered to be at least EEA-wide, and possibly wider.

- 76. In view of the notifying party, the relevant product market is at least contract manufacturing services for immunochemistry assays, reagents and systems, which is EEA wide, if not worldwide. The technology, know-how and manufacturing conditions required to contract manufacture thyroid autoimmune assays/reagents/systems do not differ substantially from the technology, know-how and manufacturing conditions required to contract manufacture most other immunochemistry assays.
- 77. The exact product and geographic market definitions can be left open, as no concerns arise irrespective of the product market definition.

# 2.2. Competitive Assessment

# 2.2.1. Microplates

- 78. The Commission examined the vertically affected markets arising due to Thermo Fisher's position upstream in the supply of microplates and the parties' position in the downstream markets for IVD autoimmune disease and allergy diagnostics, where Phadia is active and Thermo Fisher supplies certain downstream rivals with microplates.
- 79. The market share estimates provided by the parties point to a relatively strong upstream position of Thermo Fisher only in the supply of microplates for diagnostic applications, where the market share of Thermo Fisher in the EEA would be around [50-60]% and [30-40]% worldwide. There are other significant competitors present in this market, including Greiner Bio-One (EEA: [20-30]%; worldwide: [20-30]%), Corning Inc. (EEA: [10-20]%, worldwide: [20-30]%), Perkin Elmer (EEA and worldwide: [5-10]%) and others (EEA: [5-10]%, worldwide: [10-20]%).<sup>20</sup>
- 80. If the market is defined for all microplates irrespective of their application, the parties estimate that Thermo Fisher's market share would be well below [20-30]% ([10-20]% in the EEA and [10-20]% worldwide).
- 81. In the downstream markets for IVD autoimmune disease diagnostics (EDMA 12.10), the parties' combined market shares amount to [30-40]% in the EEA and range between [0-5]% to [60-70]% in a number of Member States.<sup>21</sup> In the area of IVD allergy diagnostics (EDMA 12.02), where only Phadia is active, the market shares of Phadia amount to [70-

See case COMP/M.5253 Sanofi-Aventis/Zentiva, decision of 4.2.2009.

<sup>19</sup> Abbott/Solvay op cit.

<sup>&</sup>lt;sup>20</sup> Biomat, SPL Life Sciences, Jet Biofil, and others.

<sup>&</sup>lt;sup>21</sup> I.e., Austria ([20-30]%), Denmark ([60-70]%), Finland ([60-70]%), France ([20-30]%), Germany [30-40]%), Ireland ([40-50]%), Italy ([20-30]%), the Netherlands [30-40]%), Norway ([50-60]%), Portugal ([30-40]%), Spain ([40-50]%), Sweden ([30-40]%). In other countries the market shares are much lower: the UK (Phadia: [20-30]%), Belgium ([10-20]%), Bulgaria ([0-5]%), Czech Republic ([5-10]%), Greece ([0-5]%), Hungary ([0-5]%), Poland ([0-5]%), Romania (Phadia: [0-5]%), Slovakia ([10-20]%), and Slovenia ([10-20]%).

80]% in the EEA and range between [0-5]% to [90-100]% in several Member States.<sup>22</sup> The transaction therefore gives rise to a number of vertically affected markets.<sup>23</sup>

# 2.2.1.1. Input foreclosure

- 82. The market investigation showed that microplates for diagnostic applications constitute an important component without which final diagnostic products could not be manufactured and effectively sold in the market, and that switching to alternative suppliers might be relatively costly and time consuming.<sup>24</sup> However, Thermo Fisher's upstream position does not seem indicative of its market power that could be used to foreclose access to inputs for its downstream rivals in the markets for IVD autoimmune and allergy diagnostics. In particular, this is due to the fact that microplates are only one type of a consumable used by downstream players for various diagnostic purposes, IVD autoimmune disease and/or allergy diagnostics being one of them. In addition, as previously mentioned, certain autoimmune and allergy diagnostic products of strong players, such as Phadia, are designed as proprietary systems and are not used with standardized microplates.
- 83. In reply to the market investigation, three credible upstream suppliers confirmed that they would be able to increase their output for microplates for diagnostic applications in case of a hypothetical price increase or input foreclosure by Thermo Fisher. Thermo Fisher's products were not generally considered as significantly superior compared to others. It is therefore unlikely that the merged entity would have an ability to substantially affect overall availability of microplates for IVD autoimmune disease and/or allergy diagnostics markets.
- 84. As previously mentioned, the parties' market shares are significant in the areas of IVD autoimmune disease and allergy diagnostics mainly due to the existing market position of Phadia. Therefore, it is only in countries where Thermo Fisher supplies credible Phadia's downstream rivals, where the incentives of Thermo Fisher may change following the transaction.
- 85. In the markets for IVD autoimmune disease diagnostics, the Commission has identified [...] credible players who might use Thermo Fisher's plates, amongst other things, for their IVD autoimmune disease assays, and are active in the markets, where the increments added by Phadia are significant ([10-50]%).<sup>25</sup> The market shares of those [...] companies do not exceed 15% in any national market or the EEA while at least two or three other strong

Le., Austria ([90-100]%), Belgium ([70-80]%), Denmark ([90-100]%), Finland ([90-100]%), France ([80-90]%), Germany ([50-60]%), Ireland ([90-100]%), Italy ([80-90]%), the Netherlands ([80-90]%), Norway ([80-90]%), Portugal ([90-100]%), Spain ([90-100]%), Sweden ([90-100]%), the UK ([90-100]%), Czech Republic ([80-90]%), Greece ([5-10]%), Poland ([0-5]%), Romania ([5-10]%), and Slovenia ([30-40]%).

The transaction would also give rise to technically affected markets due to parties' position in overall IVD Immunochemistry (EDMA 12), IVD thyroid autoimmune disease diagnostics (EDMA 12.10.03), and individual thyroid antibody assay categories. Based on the information available to the Commission, Thermo Fisher does not supply any significant Phadia's competitors in those categories.

According to respondents, the costs would relate to the validation of a new supplier, re-alignment of instruments at customer place, or even product re-validation. The amount of costs would depend on various factors, including specific product characteristics. The exact time and investment required for changing suppliers constitutes third party business secrets.

The identity of the companies that use Thermo Fisher's plates for their IVD autoimmune disease assays constitutes a third party business secret.

players, including close competitors to Phadia, confirmed that they do not source Thermo Fisher's microplates for their IVD autoimmune disease tests and are not capacity constrained. The market shares of these competitors are in the range of 10-20%.<sup>26</sup>

- 86. In the markets for IVD allergy diagnostics, the Commission has identified only one credible player, supplied by Thermo Fisher, which might use microplates for some of its IVD allergy diagnostic products, [name of name of company]. According to the parties [...] has no or only minimal sales of allergy diagnostics assays using the microtiter plate format. Therefore it is very unlikely that the microplates purchased from Thermo Fisher by this company are used for allergy diagnostic assays. In addition, [name of name of company] is not the closest competitor to Phadia in terms of price, customer focus, ancillary services, and customised products' offering. Therefore, in response to a price increase in [name of company]'s allergy diagnostic products, the customers are more likely to switch to other competing products, e.g. products of Siemens. The competitive position of [...] is relatively strong in five national markets, i.e. Germany ([10-20]%), Poland ([10-20]%), Greece ([20-30]%), Romania ([20-30]%) and Slovenia ([10-20]%). In Germany and Poland, other strong competitors are present (Germany: Siemens [10-20]%, Allergopharma [10-20]%; Poland: Siemens [30-40]%, Biocheck [10-20]%). In all other countries, Siemens has a leading position with market shares of 30-50%.
- 87. In view of the above, other competitors, whose input costs can not be raised by the merged entity, can equally benefit from any attempts by the merged entity to foreclose supply of microplates to a small number of Phadia's rivals. Therefore, even in a hypothetical worst-case scenario (where Thermo Fisher would restrict supply of its microplates to certain firms and the firms concerned would find the changing of suppliers as prohibitively restrictive), the competition from other downstream players would constrain the merged entity from raising output prices downstream above pre-merger levels. This would also undermine the incentives of the merged entity to deploy an input foreclosure strategy.

#### 2.2.1.2. Customer foreclosure

88. As for customer foreclosure, the parties have confirmed that Phadia is not a significant customer of standard microplates. Instead, as mentioned above, Phadia's focus is on its closed proprietary EliA system which is different from open systems using standard microplates. Thermo Fisher's sales to Phadia of its legacy microplates for Varelisa ELISA open system account for EUR [...], i.e. only around [0-5]% of Thermo Fisher's overall sales of microplates for diagnostic purposes (EUR [...] million). Competition concerns based on customer foreclosure can therefore be excluded.

#### 2.2.1.3. Conclusion

market power by the merged entity, the presence of unconstrained upstream suppliers and

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89. Based on the above, given in particular the lack of indications to a sufficient upstream

Even if the narrower markets for IVD autoimmune disease segments, i.e. Autoimmune Connective Tissue Disease (EDMA 12.10.01), Other Autoimmune Disease (EDMA 12.10.90), or IVD thyroid autoimmune disease diagnostics (EDMA 12.10.03) were considered, the assessment would not be materially different from the one described in recital 86, as sufficient number of other credible competitors, including close competitors to Phadia, do not rely on Thermo Fisher's microplates and are not capacity constrained.

downstream competitors, which do not rely on Thermo Fisher's inputs, the merged entity is unlikely to have an ability and incentive to foreclose access to inputs and raise output prices downstream.

- 2.2.2. Supply of bulk reagents and contract manufacturing services related to [...]
- 90. The Commission examined the vertically affected markets arising due to Thermo Fisher's position upstream in the markets for supply of bulk reagents and related contract manufacturing services related to [...]. Thermo Fisher supplies reagents used in [...] assays to [name of company] and provides contract manufacturing services to [name of company]. The competitive assessment is the same for supply of bulk reagents and contract manufacturing services.
- 91. Due to the lack of transparency with respect to the sourcing of raw materials and contract manufacturing services for immunochemistry assays, Thermo Fisher could not provide reliable estimates for their upstream market positions. Based on downstream sales of the finished products, Thermo Fisher estimates that it would have the following market shares in various possible segments of <u>contract manufacturing services</u>: (i) for finished immunochemistry assays, reagents or systems below [0-5]%, (ii) for finished thyroid autoimmune assays, reagents or systems below [0-5]%, (iii) for finished individual [...] assays, reagents or systems below 10%. For the <u>supply of thyroid reagents</u> used in [...] the market share of Thermo Fisher is less than [10-20]%.
- 92. The parties' combined market shares downstream would exceed 25% in several Member States in the markets for IVD thyroid autoimmune (EDMA 12.10.03) and the markets for individual thyroid autoimmune assays (i.e. [...]).<sup>27</sup> The transaction therefore gives rise to a number of vertically affected markets.<sup>28</sup>

### 2.2.2.1. Input foreclosure

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93. The market investigation supports the view that bulk reagents constitute a critical component without which final diagnostic products could not be manufactured and effectively sold in the market, and that the switching to alternative suppliers may be cost-intensive and time consuming. However, the market shares of Thermo Fisher upstream do not exceed [10-20]% and do not seem indicative of any upstream market power and, consequently, its ability to foreclose input to [name of company]. The market shares in contact manufacturing are even lower. In any event, the parties submit that a number of upstream players exist such as Fujirebio, Axis Shield, Randox, Sekisui, Horiba, ABX, Bionostics, Sentinel, Streck, Wako and vertically integrated downstream players (Abbot, Beckman Coulter, Johnson & Johnson, Roche, Siemens) which would be able to offer reagents for thyroid conditions (including intermediate products) and contract

<sup>&</sup>lt;sup>27</sup> I.e. for IVD thyroid autoimmune segment: Denmark ([70-80]%), Finland ([30-40]%), France ([30-40]%), Germany ([30-40]%), Slovenia ([60-70]%), Spain ([20-30]%). For anti-TPO: Denmark ([50-60]%), Finland ([40-50]%), Spain ([20-30]%). For anti-Tg: Spain ([30-40]%).

The transaction would also give rise to technically affected markets due to parties' position in overall IVD autoimmune disease (EDMA 12.10) category. However, as Thermo Fisher vertical link concerns supply of reagents used in [...] assays[...] and related contract manufacturing services, IVD thyroid autoimmune (EDMA 12.10.03) and individual thyroid autoimmune assays (i.e. [...]) market segmentations are the most relevant for the assessment.

manufacturing services without constraints. Furthermore, the market investigation has not brought any elements suggesting that [names of companies supplied by Thermo Fisher] could not deploy sufficient and timely counter strategies, such as changing the suppliers or shifting production in-house.

- 94. Irrespective of Thermo Fisher's ability, there are also no indications that the merged entity would have an incentive to deploy an input foreclosure strategy. The market shares in downstream markets exceed [20-30]% mainly due to the existing market position of Thermo Fisher. Where Phadia is not active or has only limited activities with small market shares ([0-5]%), the incentives of Thermo Fisher are unlikely to change following the transaction. It is only in countries where Phadia adds a significant increment, where the incentives of Thermo Fisher may change following the transaction.
- 95. The countries where Phadia adds significantly to Thermo Fisher's existing position are Spain ([product]: Phadia [30-40]%, Thermo Fisher [0-5]%; [product]: Phadia [20-30]%, Thermo Fisher [0-5]%) and Finland ([product]; Phadia [40-50]% and Thermo Fisher [0-5]%). In Spain, [Competitor "A"] has similar market position as Phadia for [product] ([30-40]%) and a leading share for [product] ([30-40]%) with [Competitor "B"] having [10-20]% and [Competitor "C] 5-10%. In Finland, [Competitor "A"] has a market share of 20-30% while [Competitor "B"] has [10-20]%.
- 96. Should Thermo Fisher attempt a foreclosure strategy against [Competitors "B" and "C"], [Competitor "A"] is likely to benefit as much from this strategy as the parties. This weakens the incentives to foreclose and the likelihood that such foreclosure would have an affect on downstream output prices. Furthermore, the value of the downstream sales of [Competitors "B" and "C"] in these countries is significantly lower than the value of Thermo Fisher's overall contracts with them (i.e. including other countries).<sup>29</sup> It is therefore unlikely that Thermo Fisher would jeopardise their income with these two customers in favour of uncertain and, in any event, small gains downstream. Thermo Fisher also could not worsen the conditions of supply for its customers only for the final products sold in specific countries, given that its customers are supplied on a worldwide basis.

### 2.2.2.2. Customer foreclosure

97. As for customer foreclosure, the Commission considers that the notified operation is unlikely to raise competition concerns because the upstream markets for the supply of bulk reagents and provision of contract manufacturing services are likely to be EEA or even wider, whereas vertically affected downstream markets are national<sup>30</sup>. This means that even if the merged entity holds a large share of a given national market, this share would represent only a fraction of the total EEA or worldwide demand for the reagents or contract manufacturing services. Consequently, even if the merged firm would try to foreclose a competing upstream supplier, such supplier would still have numerous alternatives to sell in other countries. Furthermore, Phadia and Thermo Fisher do not have

The downstream sales of [name of company] (for Spain ~ EUR [...] million) and [name of company] (Spain: ~ [...] million, Finland: ~ [...] million) are low compared to the overall sales of Thermo Fisher to [name of company] (EUR [...] million for [...] and [...] and EUR [...] million for overall supply) and [name of company] (EUR [...] million).

By analogy see pharmaceutical decisions, e.g. *Sanofi-Aventis/Zentiva* op cit, recital 520 and *Teva/Barr* op cit, recital 201.

an existing customer relationship in this area. Competition concerns based on customer foreclosure can therefore be excluded.

#### 2.2.2.3. Conclusion

98. Based on the above, given in particular the absence of upstream market power by the merged entity, the presence of [...], a credible downstream competitor, and the relatively low value of possible downstream gains compared to overall Thermo Fisher's contracts with [names of companies], the merged entity is unlikely to have an ability and incentive to foreclose input to its rivals.

### 2.3. Conclusion – vertical effects

99. Based on the elements outlines above, the Commission concludes that the transaction is unlikely to significantly impede competition due to vertical effects.

#### VI. CONCLUSION

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

For the Commission (signed) Cecilia MALMSTROEM Member of the Commission