# Case M.10304 - THERMO FISHER/PPD

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# REGULATION (EC) No 139/2004 MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION

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# **EUROPEAN COMMISSION**



Brussels, 07.12.2021 C(2021) 9267 final

# **PUBLIC VERSION**

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

Thermo Fisher 168 Third Avenue Waltham, MA 02451 United States of America

Subject:

Case M.10304 – THERMO FISHER / PPD Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004<sup>1</sup> and Article 57 of the Agreement on the European Economic Area<sup>2</sup>

Dear Sir or Madam,

(1) On 29 October 2021, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which the undertaking Thermo Fisher Scientific Inc. ("Thermo Fisher" or the "Notifying Party", United States) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the undertaking PPD, Inc. ("PPD" or the "Target", United

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.

<sup>&</sup>lt;sup>2</sup> OJ L 1, 3.1.1994, p. 3 (the "EEA Agreement").

States) by the way of purchase of shares (the "Transaction").<sup>3</sup> Thermo Fisher and PPD are designed hereinafter as the "Parties".

### 1. THE PARTIES

- (2) Thermo Fisher, a company listed on the New York Stock Exchange and headquartered in Waltham, Massachusetts, USA, is a global manufacturer and supplier of a broad range of analytical, research and bioprocessing products, and pharmaceutical contract development and manufacturing services. Thermo Fisher serves customers such as pharmaceutical and biotech companies, hospitals and clinical diagnostic laboratories, universities, research institutions and government agencies, as well as customers in the areas of environmental, industrial quality and process control.
- (3) PPD, a company listed on the NASDAQ Global Select Market ("NASDAQ") and headquartered in Wilmington, North Carolina, USA, is a contract research organisation ("CRO") that supports pharmaceutical and biotech companies (also referred to as sponsors) in the organisation and evaluation of clinical trials. CROs offer customised strategies, covering certain aspects of clinical trials such as biostatistics, clinical data management, clinical trial monitoring, clinical trial project management, global clinical supplies, regulatory affairs, pharmacovigilance, consulting and medical writing. Sponsors outsource these activities to CROs while remaining ultimately responsible for the (bio-)pharmaceutical products under development. In addition, PPD operates a small number of laboratories where it offers a range of testing services, including bioanalytical, biomarker, central laboratory, good manufacturing practice ("GMP"), and vaccine science services.

### 2. THE CONCENTRATION

(4) The Transaction involves the proposed acquisition by Thermo Fisher of sole control of PPD within the meaning of Article 3(1)(b) of the Merger Regulation. The Transaction will be carried out as a so-called reverse triangular merger under the laws of Delaware, United States. Upon closing, Powder Acquisition Corp., a special-purpose subsidiary of Thermo Fisher, will be merged with and into PPD, with the latter being the surviving entity. As a result, PPD will be a wholly owned subsidiary of Thermo Fisher.

### 3. EU DIMENSION

(5) The undertakings concerned have a combined aggregate worldwide turnover of more than EUR 5 000 million (Thermo Fisher: EUR 28 249 million; PPD: EUR 4 104 million). Each of them has an EU-wide turnover in excess of EUR 250 million, (Thermo Fisher: EUR [...]; PPD: EUR [...]), and neither achieves more than two-thirds of its aggregate EU-wide turnover within one and the same Member State. The notified Transaction therefore has an EU dimension.

Publication in the Official Journal of the European Union No C 451, 8.11.2021, p. 8.

### 4. INTRODUCTION TO THE PARTIES' ACTIVITIES

- (6) **PPD** is active as a laboratory service provider and a CRO service provider.
- (7) PPD's laboratory services represent [...] of PPD's worldwide revenues. PPD operates eight laboratories worldwide, of which two in the EEA (Brussels, Belgium and Athlone, Ireland). Internally, PPD distinguishes between the following types of laboratory services:
  - (a) Bioanalytical laboratory services: analysis of drug and metabolite concentrations in biological samples to provide a quantitative measure of the active drug and/or its metabolites.
  - (b) Biomarker laboratory services: measurement of changes in biological function or the concentration of desired biomarker molecule(s) to assess how a drug is working or measure disease progression.
  - (c) Central laboratory services: laboratory testing on human clinical trial samples, as well as provision of laboratory kits to clinical sites that are operating clinical trials.
  - (d) Good manufacturing practice ("GMP") laboratory services: analytical testing of pharmaceutical products and their inputs during the pharmaceutical product development and manufacturing process.
  - (e) Vaccine science services: testing services dedicated to vaccine development, with the goals of helping customers to determine how well a vaccine works and the type of immune response that a vaccine generates over time.
- (8) The main customers for PPD's laboratory services are pharmaceutical companies developing new products as well as other CRO service providers working on their behalf (or, in the case of GMP laboratory services, contract development and manufacturing organisation ("CDMO") service providers).
- (9) CRO services represent [...] of PPD's worldwide revenue. With its CRO services, PPD support pharmaceutical and biotechnology companies, called sponsors, with running clinical trials to obtain regulatory approval for new medicine products. Sponsors can either outsource specific services to PPD or outsource the entire clinical trial. PPD supports early clinical development (Phase I) as well as Phase II-Phase IV clinical trials. It also provides services such as consulting, patient recruitment, periand post-approval services and medical communications.
- (10) CRO service providers provide a broad set of services over the course of a clinical trial, including, *inter alia*, protocol design, project management, site selection, patient recruitment, provision of medical supplies, data capture and management.
- (11) Depending on the preferences of the sponsor, a CRO such as PPD can either use its own laboratories for testing in the course of a clinical trial, or use third party

laboratories. Some CRO service providers do not operate laboratories and outsource all testing to third party laboratories.<sup>4</sup>

- (12) **Thermo Fisher** manufactures and supplies a broad range of supplies for laboratories, such as instruments, consumables, reagents and plastics. Thermo Fisher also has a distribution business, which distributes its own and third party products.
- (13) PPD, as a laboratory service provider, sources a broad range of products from Thermo Fisher. By combining Thermo Fisher and PPD, the Transaction gives rise to a wide range of vertical links between Thermo Fisher's products upstream, and PPD's laboratory services downstream.<sup>5,6</sup>

### 5. RELEVANT MARKETS

(14) This section will set out the relevant product and geographic market definitions for the assessment of the Transaction. It will first cover the downstream markets, in which PPD is active, followed by the relevant upstream markets, in which Thermo Fisher is active.

### 5.1. Downstream markets (PPD)

(15) As set out in Section 4, PPD is active in two areas: (i) CRO services and (ii) laboratory services.

# 5.1.1. Clinical research organisation ("CRO") services

(16) CRO services consist in assisting pharmaceutical or biotech companies in conducting and evaluating clinical trials. This mainly involves organising the interaction between patients and doctors at clinical trial sites. CROs typically offer customised strategies, covering certain aspects of clinical testing such as biostatistics, clinical data management, clinical trial monitoring, clinical trial project management, global clinical supplies, regulatory affairs, pharmacovigilance, consulting and medical writing. Sponsors outsource these services to CROs while remaining ultimately responsible for the product under development.

<sup>4</sup> For example, Rho Inc. and Pharm-Olam only provide CRO services and not laboratory services.

The Transaction also gives rise to very limited horizontal overlaps, of which two lead to technically affected markets: (i) comparator sourcing (combined market share worldwide and EEA-wide of [20-30]% including in-house sourcing and [30-40]% excluding in-house sourcing, increment brought by PPD of less than [0-5]%), and (ii) clinical trial packaging (combined market share worldwide and EEA-wide of [10-20]% including in-house sourcing and [20-30]% excluding in-house sourcing, increment brought by PPD of less than [0-5]%). The Commission's market investigation confirmed that these may constitute separate product markets. The combined market shares for the horizontal overlaps are modest, and the increments brought by PPD negligible. As such, these horizontal overlaps are extremely unlikely to lead to competitive concerns The Commission's market investigation did not surface concerns for these horizontal overlaps. Therefore, these will not be further assessed in the present Decision.

The Transaction gives rise to one vertical link that is not related to PPD's laboratory services downstream, but rather to its CRO services, which are vertically related to Thermo Fisher's upstream clinical trial support services. However, the Parties' market shares are significantly below 30% both up- and downstream, so this vertical link is not affected by the Transaction and is not further discussed in the present Decision.

# 5.1.1.1. Relevant product market definition

### (A) Previous Commission decisions

(17) In the past, the Commission defined an overall market for CRO services, as the market definition did not suggest a further segmentation based on specific services provided by CROs.<sup>7</sup>

# (B) Notifying Party's view

(18) The Notifying Party submits that CRO services consist of services provided for several types of products, customers or types of trials in different stages of a product's lifecycle. However, the Notifying Party considers, in line with past practice, that such segmentation is not appropriate and that there is a single relevant market for CRO services, as CRO service providers would typically offer a similar range of services and customers would expect CRO service providers to do so. The Notifying Party submits that the market definition can be left open in any event, as PPD's market shares would not exceed 30% under any plausible market definition.<sup>8</sup>

### (C) The Commission's assessment

- (19) The Commission notes that CRO services and laboratory services are related in the sense that both services are required in the context of clinical trials, and pharmaceutical and biotech companies frequently outsource both services to third-party providers. Some competitors, including PPD, offer both services to customers, while others act only as either CRO or laboratory service provider. In any event, the market investigation clearly indicated that CRO services and laboratory services are two separate product markets. From a *demand-side perspective*, sponsors consider these services separately and do not generally source both services in combination. From a *supply-side perspective*, the Commission considers that both services require very different expertise and infrastructure, and are therefore not substitutable.
- (20) The Commission also notes that the business activities of Thermo Fisher are predominantly upstream to the provision of laboratory services, but not to CRO services. One exception may be products that form part of testing kits to be sent to patients participating in the clinical trial. One customer who provides both CRO and laboratory services explained: "Thermo Fisher supplies all sorts of laboratory products, as well as contents of kits required for medical trials, e.g. reagents, gloves, band aids. However, [customer name] considers Thermo Fisher primarily a supplier of laboratory equipment, consumables and reagents, more than a supplier of kit contents." The Commission further notes that all products discussed in the context of this decision in the context of this decision used in laboratories, such as machines and their consumables, as well as storage equipment and equipment for cell growth.

<sup>&</sup>lt;sup>7</sup> Case M.8061 – *IMS Health / Quintiles* – paragraph 39 et seq.

Form CO, paragraph 217 et seq.

<sup>&</sup>lt;sup>9</sup> Response to questionnaire Q3 to pharmaceutical companies, question 5.

Minutes of a call with a customer, 8 September 2021, paragraph 18.

With the exception discussed in footnote 6.

(21) Based on the above, and in line with the Commission's past practice, CRO services and laboratory services will be considered as two separate markets for the purpose of this Decision. The Commission notes that, in any event, vertically affected links only arise between products that are upstream to laboratory services and the latter.

# 5.1.1.2. Relevant geographic market definition

- (A) Previous Commission decisions
- (22) In the past, the Commission has considered the market for CRO services to be EEA-wide in scope.<sup>12</sup>
  - (B) Notifying Party's view
- (23) The Notifying Party appear to consider the market for CRO services as EEA-wide or global, as it provides market shares for both geographic market definitions.
  - (C) The Commission's assessment
- (24) In the market investigation, the large majority of responding customers (*i.e.* pharmaceutical companies) of CRO services indicated that the geographic market for CRO services is global.<sup>13</sup>
- (25) For the purpose of this Decision, it can be left open whether the geographic market for CRO services is EEA-wide or global, as the Transaction does not raise concerns under either market definition.
- 5.1.2. *Laboratory services*
- (26) PPD is active in the provision of laboratory testing services, primarily to pharmaceutical and biotechnology companies, but also to other CROs as well as CDMOs. As set out in paragraph (7), PPD internally segments its laboratory services into (i) bioanalytical, (ii) biomarker, (iii) central laboratories, (iv) GMP, (v) vaccine.
- 5.1.2.1. Relevant product market definition
  - (A) Previous Commission decisions
- (27) The Commission has not previously assessed laboratory testing services.
  - (B) Notifying Party's view
- (28) The Notifying Party submits that laboratory services for diagnostic purposes are distinct from laboratory services related to clinical development. PPD is not active in laboratory services for diagnostic purposes. The Notifying Party submits the following arguments for this distinction:<sup>14</sup>

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<sup>&</sup>lt;sup>12</sup> Case M.8061 – *IMS Health / Quintiles* – paragraph 39 et seq.

Response to questionnaire Q3 to pharmaceutical companies, question 7.

<sup>14</sup> Form CO, paragraphs 213-214.

- (a) The customers for laboratory services for diagnostic purposes are primarily hospitals and clinics, whereas customers for laboratory services related to clinical development are pharmaceutical and biotechnology companies;
- A different footprint is required for both activities; a far more localised (b) footprint is needed to provide laboratory services for diagnostic purposes to ensure geographic coverage and access to patients. In contrast, PPD only has eight laboratories globally;
- Pricing is different, as laboratory services for diagnostic purposes are priced, (c) sold and regulated in accordance with the different healthcare systems and government imposed standards, whereas laboratory services related to clinical development are bespoke and negotiated on a case-by-case basis; and
- (d) While laboratory services for diagnostic purposes are mainly driven by an effort to "industrialise" services (large volumes, automated and standardised testing) to drive costs down, laboratory services related to clinical development contain more of an individualised and case-by-case approach to tailor for the specific needs of each clinical trial.
- The Notifying Party submits that there is no universally accepted segmentation of (29)laboratory testing services for clinical development. While PPD internally segments its laboratory services into (i) bioanalytical, (ii) biomarker, (iii) central laboratories, (iv) GMP, (v) vaccine, and considers that each service meets different customer demands, it considers that there is significant supply-side substitutability between these segments.<sup>15</sup>
- For the purpose of the present Transaction, the Notifying Party submits that the (30)relevant product market with respect to laboratory services for clinical development can be left open, as no competition concerns exist under any plausible product market definition.16

#### (C) The Commission's assessment

- The Commission's market investigation confirmed that laboratory services for (31)diagnostic purposes constitute a separate market from laboratory services related to clinical development. A majority of laboratory and CRO service providers that replied to the Commission's market investigation indicated to consider them separate markets.17
- (32)Respondents pointed out that the customers for the two services are different, as for laboratory services for clinical development the customers are pharmaceutical companies, biotechnology companies, or CRO service providers, while for laboratory services for diagnostic purposes the customers are physicians or hospitals. The required footprint is different as well - laboratory service providers for clinical development typically have few laboratories globally (PPD has eight), while for

<sup>15</sup> Form CO, paragraph 169.

<sup>&</sup>lt;sup>16</sup> Form CO, paragraph 167.

Replies to question 4 of questionnaire Q1 to CRO and laboratory service providers.

diagnostic purposes a more regional presence is required. Respondents also pointed out that different accreditations and standards apply, and that instruments are more easily substitutable in diagnostics laboratories as there is not the same criticality associated with consistency of testing results and patient data.<sup>18</sup>

- (33) Therefore, while they may employ some of the same testing methods, the Commission considers that laboratory services for diagnostic purposes and laboratory services for clinical development (*i.e.* laboratory services in the context of clinical trials and compliance with pharmaceutical GMP) constitute separate product markets.
- (34) Within the area of laboratory services related to clinical development, it can be left open whether any further segmentation is required, as PPD's market share is well under 30% for the overall market as well as for any plausible segmentation. Therefore, the Transaction does not give rise to affected vertical links by virtue of PPD's downstream market position. As mentioned previously, PPD is not active in laboratory services for diagnostic purposes.

### 5.1.2.2. Relevant geographic market definition

- (A) Notifying Party's view
- (35) The Notifying Party submits that the relevant geographic scope for laboratory testing services related to clinical development is global or at least EEA-wide due to the following factors:<sup>19</sup>
  - (a) Laboratories typically locate their laboratory testing facilities in a small number of locations, from which their services are provided to many countries;
  - (b) There are no country-specific technical standards or regulatory differences within the EEA, and laboratories typically comply with regulatory and certification requirements in all major jurisdictions;
  - (c) There are numerous competitors that offer analytical testing services worldwide; and
  - (d) Price is negotiated on an individual customer basis or based on a standard price list, but price dynamics are the same globally.
    - (B) The Commission's assessment
- (36) For the purpose of the present Decision, the relevant geographic scope of laboratory services related to clinical development can be left open between EEA-wide and worldwide, as PPD's market share is well under 30% for either geographic scope. Therefore, the Transaction does not give rise to affected vertical links by virtue of PPD's downstream market position.

<sup>&</sup>lt;sup>18</sup> Replies to question 4.1 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>19</sup> Form CO, paragraph 173.

### 5.2. Upstream markets (Thermo Fisher)

- (37) Thermo Fisher is active in numerous markets that are upstream to laboratory services. This section sets out the markets that are affected as a result of the Transaction.
- 5.2.1. High-resolution (Sanger) capillary electrophoresis instruments and consumables
- (38) Electrophoresis is the differential movement of charged molecules in an electric field, used to separate molecules (*e.g.* DNA, RNA and proteins) based on size, density and charge. There are two major types of electrophoresis: gel electrophoresis and capillary electrophoresis. Gel electrophoresis will be discussed in Section 5.2.5 of this Decision. Capillary electrophoresis employs a narrow capillary tube filled with a gel through which the molecules pass.
- (39) High-resolution (Sanger) capillary electrophoresis is used for DNA sequencing purposes, *i.e.* determining the order of base pairs in a given strand of DNA. Fluorescently labelled nucleotides are attached to the DNA fragment to be sequenced. When passed through the capillary, the fluorescent nucleotides are excited by a laser and the emitted light is detected. The type of base (adenine (A), cytosine (C), guanine (G), and thymine (T)) can then be detected based on the colour of light emitted.

# 5.2.1.1. Relevant product market definition

### (A) Previous Commission decisions

(40) The Commission has not previously assessed high-resolution (Sanger) capillary electrophoresis. In one decision, it has briefly addressed capillary electrophoresis in the context of analytical separation instruments. However, the market definition was ultimately left open.<sup>20</sup>

# (B) The Notifying Party's view

- (41) The Notifying Party considers that capillary electrophoresis could be segmented into high-resolution (1 base pair) and lower resolution (3-5+ base pairs) instruments, on the basis of the lack of demand- and supply-side substitutability between the two types of instruments.<sup>21</sup>
- (42) Lower resolution capillary electrophoresis instruments have a significantly lower cost and are used for different purposes (*e.g.* quality control for DNA or RNA, certain plant biology applications, understanding protein-ligand interactions). High-resolution capillary electrophoresis instruments are used where it is necessary to identify smaller fragments of DNA (*e.g.* genotyping, mutation analysis, microsatellites variability, amplicon screening, splicing variants, loci mapping, genomic fingerprinting etc.).<sup>22</sup>

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<sup>&</sup>lt;sup>20</sup> Case M.6175 – Danaher / Beckman Coulter, paragraph 31.

<sup>&</sup>lt;sup>21</sup> Form CO, paragraph 646.

<sup>&</sup>lt;sup>22</sup> Form CO, paragraphs 647-648.

- (43)From a supply-side perspective, it would be costly and difficult for a supplier of a standard capillary electrophoresis instrument to develop an instrument with a resolution of 1 base pair.<sup>23</sup>
- (44)Therefore, the Notifying Party submits that the relevant product market consists of the market for high-resolution (Sanger) capillary electrophoresis instruments, regardless of whether they are low, medium or high throughput.<sup>24</sup>
- (45)Concerning consumables, the Notifying Party considers these constitute a separate market. Consumables can either be sold separately as stand-alone items; or as prepackaged consumables for use in one specific instrument. Whether stand-alone or prethere is no substitutability between consumables for high-resolution electrophoresis instruments and lower-resolution (Sanger) capillary electrophoresis instruments.
- The Notifying Party submits that there is no need to distinguish between different (46)used for high-resolution (Sanger) types of consumables that are electrophoresis instruments because competitive conditions for these different consumables are largely similar and customers need several or the entire range of these consumables in the testing workflow.

#### (C) The Commission's assessment

- (47) For the purpose of the current Decision, it can be left open whether the appropriate product market definition for capillary electrophoresis instruments is (i) all capillary electrophoresis instruments, (ii) high-resolution capillary electrophoresis instruments, or (iii) high-resolution capillary electrophoresis instruments further segmented by their throughput.
- (48)Thermo Fisher is not active in lower-resolution capillary electrophoresis instruments.. Therefore, for the purpose of this Decision, the Commission will assess the market on the basis of high-resolution capillary electrophoresis instruments. As the Transaction does not give rise on serious doubts on this narrow market definition, it also does not give rise to serious doubt when including lower-resolution instruments in the product market definition – an area in which Thermo Fisher is not active.
- (49) In the past, when the Commission has found that the markets for consumables and instruments was closed, meaning that Thermo Fisher instruments only worked with Thermo Fisher consumables, the Commission has defined a single "systems" As Thermo Fisher's high-resolution capillary electrophoresis instruments market.<sup>25</sup> constitute an open system, meaning that third party manufacturers can supply consumables for use with Thermo Fisher devices, the Commission will assess the market for high-resolution capillary electrophoresis consumables separately from the one high-resolution capillary electrophoresis instruments.

Form CO, paragraph 649.

<sup>&</sup>lt;sup>24</sup> Form CO, paragraph 650.

<sup>&</sup>lt;sup>25</sup> Case M.6175 – Danaher / Beckman Coulter, paragraph 20.

consumables for high-resolution capillary electrophoresis are not substitutable with consumables for lower resolution capillary electrophoresis.<sup>26</sup>

(50) Finally, the Commission notes that high-resolution (Sanger) capillary electrophoresis instruments form a separate product market from next generation sequencing ("NGS"). NGS is a more recent development that allows massively parallel sequencing of DNA, and therefore has a cost per analysed base pair that is significantly lower (a difference that exceeds an order of magnitude) than high-resolution (Sanger) capillary electrophoresis instruments. The devices therefore serve different purposes and the supplier landscape is different. NGS is not affected as a result of the Transaction.<sup>27</sup>

### 5.2.1.2. Relevant geographic market definition

# (A) The Notifying Party's view

(51) The Notifying Party submits that the relevant geographic market for the high-resolution (Sanger) capillary electrophoresis instruments and consumables is global or at least EEA-wide in scope because high-resolution (Sanger) capillary electrophoresis instruments and consumables are identical wherever customers are located.<sup>28</sup>

### (B) The Commission's assessment

(52) For the purpose of the current Decision, it can be left open whether the appropriate geographic scope of the markets for high-resolution capillary electrophoresis instruments and consumables is global or EEA-wide, as this does not affect the outcome of the competitive assessment.

### 5.2.2. Laboratory in vitro diagnostic allergy and autoimmune disease systems

(53) In vitro diagnostics ("TVD") systems comprise analysers (instruments), tests (called reagents or assays) and accessories for the purpose of testing blood, urine or other samples outside the human or animal body. This section concerns IVD systems specifically for the testing of allergies and autoimmune diseases.

### 5.2.2.1. Relevant product market definition

# (A) Previous Commission decisions

(54) In case M.7982 – *Abbott / Alere*, the Commission found a market for laboratory IVD systems separate from point-of-care (POC) IVD systems, used by healthcare professionals in a medical environment. The Commission further discussed whether analysers and reagents would be considered separate markets, or would belong to a combined market for IVD systems. The Commission concluded that the latter was the

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<sup>&</sup>lt;sup>26</sup> From CO, paragraph 653.

Thermo Fisher is active in NGS with its Ion Torrent platform. However, its market share is low (around [10-20]%), and the market leader in NGS with by far the largest market share is Illumina. NGS is therefore not affected as a result of the Transaction and not further discussed in the present Decision, except in the context of companion diagnostics (see Section 6.5.2).

<sup>&</sup>lt;sup>28</sup> Form CO, paragraphs 655-656.

case for POC IVD analysers and reagents, as they are typically supplied in closed systems so that customers need to purchase both from the same supplier. The Commission left open whether laboratory IVD analysers and reagents would constitute separate product markets or a combined systems market.

- (55) With respect to laboratory IVD products, the Commission considered that a distinction can be made between six main categories, namely clinical chemistry, immune-chemistry, haematology / haemostasis / immunohaematology / histology / cytology, microbiology culture, infectious diseases and genetic testing. It further considered a segmentation by test panels or specific tests.<sup>29</sup>
- (56) This approach is in line with previous decisions by the Commission, specifically M.6293 *Thermo Fisher / Phadia* and M.4865 *Siemens / Dade Behring*. In both decisions, a potential further segmentation by test panels<sup>30</sup> or specific tests was considered based on the classification of IVD tests used by the European Diagnostics Manufacturers' Association<sup>31</sup> ("EDMA").<sup>32</sup>

### (B) The Notifying Party's view

- (57) The Notifying Party submits that Thermo Fisher's IVD products are closed systems, meaning that Thermo Fisher analysers have to be used with Thermo Fisher reagents and accessories, and Thermo Fisher reagents and accessories cannot be used with third-party instruments. It would therefore not be meaningful to look into analysers, reagents and accessories separately, and in any event, market shares would not differ significantly from market shares for overall systems markets.
- (58) The Notifying Party further submits that IVD products for which affected markets were identified, namely allergy and autoimmune disease tests, would all be classified under the category of immunochemistry. The Notifying Party further submits that no additional affected markets would arise if a further distinction would be made between specific test panels or specific tests.
- (59) Therefore, the Notifying Party submits that the exact product market definition can be left open in the present case.<sup>33</sup>

## (C) The Commission's assessment

(60) First of all, the Commission notes that the Transaction concerns laboratory IVD systems, but not POC IVD systems, as PPD is only active in the former.<sup>34</sup>

 $<sup>^{29}</sup>$  Case M.7982 -Abbott/Alere, paragraph 19 et seq.

Test panels refer to thematic panels of tests (for example for cardiac, cancer, allergy or fertility testing). Within each thematic panel, a number of different assay tests can be conducted; M.4865 – *Siemens / Dade Behring*, paragraphs 20 et seq.

<sup>31</sup> Since 2012 MedTech Europe.

<sup>&</sup>lt;sup>32</sup> Case M.6293 – *Thermo Fisher / Phadia*, paragraphs 8 et seq., and M.4865 – *Siemens / Dade Behring*, paragraphs 7 et seq.

Form CO, paragraph 603 et seq.

The Notifying Party further provides that it estimates its market shares for POC IVD systems globally and at EEA level to be lower than [0-5]%.

- (61) Secondly, results of the market investigation indicate the existence of a market for IVD systems also for laboratories, including both instruments and reagents. From a demand-side perspective, a small majority of respondents confirmed that the market would indeed include both instruments and reagents.<sup>35</sup> One customer explained that "immunological testing for allergy and autoimmune disease are performed using only vendor-approved reagents for that instrument."<sup>36</sup> From a supply-side perspective, this view was supported by the large majority of competitors to Thermo Fisher, i.e. manufacturers of such products, that responded to the Commission's market investigation.<sup>37</sup> The Commission further notes that IVD products by Thermo Fisher are closed systems in the sense that instruments and reagents, as well as key accessories like calibrators and conjugate, have to be used in conjunction with each other, and cannot be used with third-party products.<sup>38</sup> Therefore, the Commission considers it appropriate to assess the IVD laboratory products at system level for the purpose of this Decision.
- Thirdly, the Commission notes that both IVD allergy testing as well as IVD (62)autoimmune disease testing can be performed on the same device. In the market investigation, the Commission received feedback that instruments for both IVD autoimmune and allergy testing are part of the same product market.<sup>39</sup> The Commission still considers that IVD autoimmune disease systems on the one hand and IVD allergy testing systems on the other hand form two separate product markets. From the demand-side point of view, the Commission notes that Thermo Fisher's instruments may be substitutes for both applications, but not the tests, which are sold under two different brands.<sup>40</sup> From a *supply-side point of view*, the Commission notes that manufacturers of IVD autoimmune disease testing system are not necessary able to provide a similarly competitive IVD allergy testing system. This is indicated by the very different market structure for both products, which was confirmed in the market investigation. One competitor explained that for both tests there are "same customers but different application and market, different competitive landscape. In Allergy Thermo has a strong Monopoly, in Al there are many more major players".41
- (63) For the purpose of this Decision, the Commission will therefore conduct the assessment for the market for IVD allergy testing systems, and notes that no competition concerns will arise in a market for IVD autoimmune disease testing systems.
- (64) Fourthly, the Commission notes that a further segmentation by test panels or specific tests would not change the outcome of the competitive assessment.<sup>42</sup>

Replies to question 22 of questionnaire Q1 to CRO and laboratory service providers.

Reply to question 22.1 of questionnaire Q1 to CRO and laboratory service providers.

Replies to question 17 of questionnaire Q2 to Thermo Fisher competitors.

Form CO, footnote 396.

Replies to question 20 of questionnaire Q1 to CRO and laboratory service providers; replies to question 15 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>40</sup> ImmunoCAP Allergy Tests and EliA Autoimmune Disease Tests; Form CO, paragraph 599.

Replies to question 15.1 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>42</sup> Form CO, footnote 400.

- (65) Fifthly, the Commission has indication that, for IVD laboratory instruments, a further segmentation by customer type may be appropriate. From a *supply-side point of view*, the Commission notes indication that purchasing patterns of laboratory service providers for clinical development differ from those of diagnostics laboratories. As explained in Section 5.1.2 above, clinical development laboratories generally have fewer, centralised laboratories compared to diagnostics laboratory service providers. The Commission notes that the majority of PPD's competitors do not operate any IVD allergy testing systems at all in the EEA.<sup>43</sup> In the view of the Commission, this may explain why clinical development laboratories are willing to source IVD allergy testing systems over longer distances, and do no place the same value on sourcing locally as diagnostics laboratory providers did in previous cases.<sup>44</sup>
- (66) It has to be noted that PPD is only active in the provision of clinical development laboratory services. The Commission therefore considers appropriate to assess the narrower market of sales to such customer group for the purpose of this Decision.
- (67) Based on the above, the Commission will assess the markets for IVD allergy systems to clinical development laboratory service providers. It can be left open whether a further segmentation by test panels or specific tests is appropriate, as it does not change the competitive assessment of this case.

# 5.2.2.2. Relevant geographic market definition

### (A) Previous Commission decisions

(68) In the past, the Commission has considered markets for IVD products to be national in geographic scope. In M.4865 – *Siemens / Dade Behring*, the Commission found that most respondents to the market investigation consider markets to be national in scope, due to price differences, national reimbursement schemes and the preference for local service. In M.6293 – *Thermo Fisher / Phadia*, it found that customers tend to source within the country, while some competitors pointed at an EEA-wide market from a supply-side of view. The geographic market definition was ultimately left open. In case M.7982 – *Abbott / Alere*, the Commission concluded that geographic markets for IVD products are national. The reason was that customers would predominantly use national sales to source those products, as well as to a lesser degree national regulation and price differences. The Commission acknowledged, however, that "some elements of the market investigation point towards an increasingly broader than national scope of the IVD market as the most important IVD suppliers are active on a worldwide basis." 46

# (B) Notifying Party's view

(69) The Notifying Party submits that the geographic markets for laboratory IVD allergy testing today is EEA-wide because the main competitors for IVD test systems supply the same equipment and reagents in identical form across the EEA and operate EEA-

<sup>&</sup>lt;sup>43</sup> Replies to question 25 of questionnaire Q1 to CRO and laboratory service providers.

The Commission notes that this assessment would also apply for IVD autoimmune disease systems.

<sup>&</sup>lt;sup>45</sup> Case M.4865 – *Siemens / Dade Behring*, paragraphs 36 et seq.

<sup>&</sup>lt;sup>46</sup> Case M.7982 – *Abbott/Alere*, paragraph 62 et seq.

wide sales and distribution networks. Thermo Fisher supplies allergy tests to all customers [Thermo Fisher's product distribution].

(70) The Notifying Party further argues that in M.7982 – *Abbott / Alere*, the Commission would have looked at a different customer group, including blood banks and hospitals. The purchasing behaviour of companies as PPD, which offers laboratory services in the context of clinical trials, was not even mentioned in that decision. The Notifying Party is of the view that local sourcing is not relevant for PPD and its competitors, and that price differences as a result of national reimbursement regimes would not play a role as those would not apply in the context of clinical trials.<sup>47</sup>

### (C) The Commission's assessment

- (71) The results of the market investigation strongly suggest that the market for IVD allergy systems to laboratory service providers for clinical development is wider than national, *i.e.* EEA-wide or global.<sup>48</sup> All such customers responding to the market investigation indicated that they would source IVD allergy and autoimmune instruments and reagents at global level.<sup>49</sup> Similarly, all but one manufacturer or distributor of such products indicated that markets were global or EEA-wide in geographic scope.<sup>50</sup> The Commission further notes that all competitors of Thermo Fisher responding to the market investigation supply IVD allergy and autoimmune instruments and reagents in all EEA countries.<sup>51</sup>
- Oifferently from the previous cases above mentioned, in the present case customers responding to the market investigation were laboratories providing services in the context of clinical trials (but not diagnostics customers such as doctors or hospitals). As discussed in the competitive assessment in Section 6.4.2 in more detail, IVD allergy testing instruments and reagents are not very frequently used in the context of clinical trials. The majority of customers (*i.e.* PPD's competitors in the provision of laboratory services in the context of clinical trials) responding to the market investigation do not operate any IVD allergy and autoimmune disease testing instrument within the EEA, 3 and those who do operate them only in a limited number of countries. Similarly, [PPD's operations].
- (73) In light of the indication that laboratories use IVD allergy systems only infrequently, and operate them only in few geographic areas, and many of them outside the EEA, criteria such as national price differences, national reimbursement schemes and

<sup>47</sup> Form CO, paragraph 608 et seq.

<sup>&</sup>lt;sup>48</sup> This assessment would also apply for IVD autoimmune disease systems.

Reply to question 24 of questionnaire Q1 to CRO and laboratory service providers.

Replies to question 19 of questionnaire Q2 to Thermo Fisher competitors.

Replies to question 20 of questionnaire Q2 to Thermo Fisher competitors.

The Notifying Party provides that of [...] clinical trials in 2020 that PPD's clinical trial services business was involved in. PPD estimates that [...] required allergy testing and [...] of those used PPD's laboratories for the allergy testing; Form CO, paragraph 621.

Replies to question 25 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>54</sup> Form CO, paragraph 601.

- national services<sup>55</sup> may be less important compared to customers active in the field of diagnostics.
- (74) The Commission further notes that already in previous cases, competitors appeared to have pointed to a broader than national geographic market definition from a supply-side point of view,<sup>56</sup> which is in line with findings in this case.
- (75) In light of the above, the Commission considers appropriate to define the geographic market for IVD allergy and autoimmune disease testing instruments and reagents specifically for clinical trial laboratories as EEA-wide or global for the purpose of this Decision.<sup>57</sup>

### 5.2.3. CO2 incubators

(76) CO2 incubators are basic metal containers that maintain a controlled environment above ambient temperature but below temperatures of laboratory ovens. CO2 incubators are used to propagate or expand cell cultures.

### 5.2.3.1. Relevant product market definition

### (A) Previous Commission decisions

(77) The Commission has not defined a product market for CO2 incubators in the past. In M.4242 – *Thermo Electron / Fisher Scientific*, the Commission named CO2 incubators as a product in the broader area of laboratory equipment and consumables, but did not investigate this product specifically and therefore did not define a separate market for CO2 incubators.<sup>58</sup>

# (B) The Notifying Party's view

(78) The Notifying Party submits that CO2 incubators belong to a broader category of general laboratory equipment that also includes other cell growth, protection and separation equipment instruments. This is because customers would often purchase a variety of combinations of such products when outfitting or expanding a cell culture laboratory. Furthermore, there would be significant supply-side substitutability regarding these products, as key suppliers would be active across the broader segment of cell growths, protection and separation equipment instruments. For the purpose of the case, however, the exact product market definition can be left open, as no concerns arise under any plausible product market definition.<sup>59</sup>

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The Commission notes that IVD allergy and autoimmune testing instruments need periodical maintenance services; see replies to question 26 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>56</sup> Case M.6293 – Thermo Fisher / Phadia, paragraph 22; Case M.7982 – Abbott / Alere, paragraph 62.

The Commission notes further that in its market investigation, it has asked customers and competitors about potential concerns at national level and about relevant country-specific information. No such concerns or information were brought to the Commission's attention.

<sup>&</sup>lt;sup>58</sup> Case M.4242 – Thermo Electron / Fisher Scientific, paragraph 11 et seq.

<sup>&</sup>lt;sup>59</sup> Form CO, paragraph 252 et seq.

### (C) The Commission's assessment

- (79) The Commission notes that the majority of customers responding to the market investigation indicate that CO2 incubators belong to the same product market as biological safety cabinets, and may form a market for cell growth, protection and separation equipment. The Commission nevertheless considers this market definition as likely too broad in the light of the different product features, and doubts that all products that may fall into such market would be indeed substitutable from a demand-side point of view. This assessment is supported by competitors of Thermo Fisher responding to the market investigation, of which a majority submit that biological safety cabinets and CO2 incubators belong to different product markets. For the purpose of this case, this question can be left open in any event, as an affected market would only arise for the plausible narrower market of CO2 incubators, for which the Commission has carried out an assessment.
- (80) Further, all customers expressing an opinion in the market investigation consider all CO2 incubators part of the same product market. Responses from competitors, in turn, are mixed in this regard. One competitor points at the existence of "specialty incubators that are not readily substituted for other types". Other than that, the Commission received no indication of plausible sub-segments of the CO2 incubator product market. Specifically, customers and competitors did not raise concerns related to specific types of CO2 incubators in the market investigation, which further supports the conclusion of a CO2 incubator product market without further segmentation.
- (81) In light of the above, the Commission considers appropriate to define the product market as CO2 incubators for the purpose of this Decision.

### 5.2.3.2. Relevant geographic market definition

### (A) Previous Commission decisions

(82) The Commission has not defined a geographic market for CO2 incubators in the past. In M.4242 – *Thermo Electron / Fisher Scientific*, the Commission assumed generally EEA-wide markets for the products covered by that decision, which includes laboratory equipment in general, but noted "it cannot be excluded that at least for some products affected by the transaction [...], the relevant geographic market should be defined at national instead of EEA-wide level." The geographic market definition for all products was ultimately left open.<sup>64</sup> The Commission did not discuss a geographic market for the production of CO2 incubators specifically, nor did it suggest that CO2 incubators would be among the products for which the geographic market would be narrower than EEA-wide.<sup>65</sup>

 $<sup>^{60}</sup>$  Reply to question 38 of questionnaire Q1 to CRO and laboratory service providers.

Reply to question 29 of questionnaire Q2 to Thermo Fisher competitors.

Reply to question 39 of questionnaire Q1 to CRO and laboratory service providers.

Replies to question 30 of questionnaire Q2 to Thermo Fisher competitors.

<sup>64</sup> Case M.4242 – Thermo Electron / Fisher Scientific, paragraph 35 et seq.

The decision lists market shares for the production of CO2 incubators at national level to discuss a potential input foreclosure of downstream laboratory equipment distributors, for which the Commission considered the geographic market to be national.

#### (B) The Notifying Party's view

(83)The Notifying Party submits that the market for the production of CO2 incubators, and more generally cell growths, protection and separation equipment instruments should be considered at least EEA-wide, because (i) suppliers typically locate their manufacturing facilities in a small number of locations, from which the products are shipped worldwide. Thermo Fisher typically manufactures these products at a small number or sites and ships globally; (ii) there are no country-specific technical standards or regulatory differences within the EEA; (iii) numerous competitors to a global customer base; (iv) price dynamics would be the same globally.66

#### (C) The Commission's assessment

- The Commission notes that all customers expressing an opinion in the market (84)investigation submit that they source CO2 incubators at either EEA or global level.<sup>67</sup> Similarly, competitors predominantly point at a global or EEA wide geographic market for CO2 incubators, and no competitor submitted that the market should be narrower than EEA-wide.68
- (85)In light of the above, the Commission considers that the market for CO2 incubators is EEA-wide or global in geographic scope.

### 5.2.4. *Chromatography instruments and columns*

- Chromatography is a separation technique based on the different distribution of the (86)constituents of a mixture between two phases, one of which moves relative to the other. The moving phase is referred to as the mobile phase, while the other is referred to as the stationary phase. This technique is therefore used to separate a mixture of compounds in analytical chemistry and biochemistry so as to identify, quantify or purify the individual components of the mixture.
- (87)The chromatography process requires the use of instruments in combination with consumables. Key consumables used in chromatography are chromatography columns, which are containers holding the resin and/or silica (which is the stationary phase) in which the chromatography process takes place when plugged into the instrument. The resin can be of different material, depending on the nature of the separation.

### 5.2.4.1. Relevant product market definition

#### (A) Previous Commission decisions

Concerning chromatography instruments, in previous decisions the Commission (88)found that liquid chromatography instruments are to be assessed separately from gas chromatography instruments. Within liquid chromatography Commission found that ion chromatography instruments form a separate product market. Furthermore, the Commission found that liquid chromatography could be

<sup>&</sup>lt;sup>66</sup> Form CO, paragraph 260 et seq.

<sup>67</sup> Replies to question

Replies to question 31 of questionnaire Q2 to Thermo Fisher competitors.

further segmented in the following segments, but left the exact market definition open:<sup>69</sup>

- (a) High pressure liquid chromatography ("HPLC"), with possible sub-segments:
  - Analytical HPLC;
  - Nano-LC;
  - Ultra-HPLC;
  - Preparation HPLC;
  - Gel permeation / size exclusion chromatography; and
  - Amino acid analyser systems.
- (b) Low pressure liquid chromatography ("LPLC");
- (c) Supercritical fluid chromatography; and
- (d) Flash chromatography.
- (89) The Commission found that chromatography consumables constitute a separate market from chromatography instruments, which include (i) columns, (ii) vials and (iii) reagents and consumables. Within columns, the Commission found that there are separate markets for pre-filled columns and non-pre-filled columns. Pre-filled columns are sold pre-filled with resins, while non-pre-filled columns are sold without resin and can be filled with resin by the customer. Thermo Fisher is only active in pre-filled columns. Within resins, the Commission found that there are separate markets for (i) protein A resins, (ii) other affinity resins, (iii) ion-exchange resins and (iv) mixed mode resins. In the case of columns pre-filled with resin, which are columns pre-filled with a specific resin, this distinction can be applied to the pre-filled columns.
  - (B) The Notifying Party's view
- (90) The Notifying Party follows the Commission's previous decisional practice concerning chromatography instruments and columns, and submits that the exact scope of the relevant product markets can be left open.<sup>73</sup>
  - (C) The Commission's assessment
- (91) The Commission's market investigation did not give reason to depart from the Commission's previous decisional practice with regard to the product market

<sup>69</sup> Case M.6126 – Thermo Fisher / Dionex Corporation, paragraphs 10-19.

<sup>&</sup>lt;sup>70</sup> Case M.6126 – Thermo Fisher / Dionex Corporation, paragraphs 32-34.

<sup>71</sup> Case M.9331 – Danaher / GE Healthcare Life Sciences Biopharma, paragraph 370.

<sup>&</sup>lt;sup>72</sup> Case M.9331 – Danaher / GE Healthcare Life Sciences Biopharma, paragraph 374.

<sup>&</sup>lt;sup>73</sup> Form CO, paragraphs 454, 470 and 500.

definition for chromatography instruments and columns. Applying these product market definitions, the Transaction gives rise to vertically affected markets for (i) **ion chromatography instruments** and (ii) **pre-filled ion chromatography columns**, *i.e.* chromatography columns pre-filled with ion exchange resin.

# 5.2.4.2. Relevant geographic market definition

### (A) Previous Commission decisions

(92) In its previous decisions, the Commission found that the relevant geographic market for liquid chromatography instruments (which includes ion chromatography instruments) and chromatography consumables (which includes pre-filled ion chromatography columns) are EEA-wide or worldwide in scope. It left the exact market definition open.<sup>74</sup>

# (B) The Notifying Party's view

- (93) The Notifying Party submits that the relevant geographic market for chromatography instruments and consumables and any of its relevant segments is at least EEA-wide because: 75
  - (a) Suppliers typically locate their manufacturing facilities in a small number of locations, from which the products are shipped worldwide;
  - (b) There are no country-specific technical standards or regulatory differences within the EEA;
  - (c) There are numerous competitors that offer chromatography consumables to a global customer base and supply different types of chromatography consumables worldwide and within the EEA in competition with Thermo Fisher:
  - (d) Price is negotiated on an individual customer basis or based on a standard price list, but price dynamics are the same globally.
- (94) The Notifying Party further submits that the exact scope of the relevant geographic market can be left open between EEA-wide and worldwide, because the Transaction does not give rise to competitive concerns under either geographic scope.<sup>76</sup>

### (C) The Commission's assessment

(95) For the purpose of the present Decision, and in line with the Commission's previous decisional practice, the relevant geographic product market can be left open between EEA-wide and worldwide for ion chromatography instruments and pre-filled ion chromatography columns, as this distinction does not affect the outcome of the competitive assessment.

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Case M.6126 – Thermo Fisher / Dionex Corporation, paragraph 48 and case M.9331 – Danaher / GE Healthcare Life Sciences Biopharma, paragraph 381.

<sup>&</sup>lt;sup>75</sup> Form CO, paragraphs 456-457, 471 and 501-502.

<sup>&</sup>lt;sup>76</sup> Form CO, paragraph 457, 472 and 503.

### 5.2.5. *Electrophoresis gels*

- (96) Electrophoresis as a technique is a nucleic acid purification technique, which aims to separate molecules, such as DNA, RNA or proteins based on their size, density, and charge through the differential movement of charged molecules in an electric field. It is used for purification, quality control or analytical purposes within different applications. There are two major types of electrophoresis: gel electrophoresis and capillary electrophoresis. In gel electrophoresis, samples are loaded into wells at one end of a gel slab, and by applying an electric field, molecules separate across the gel. Gel electrophoresis can be sub-divided into horizontal and vertical gel electrophoresis. While horizontal gel electrophoresis is typically used for DNA and RNA, vertical gel electrophoresis is typically used for proteins. Gels can either be purchased precast by the supplier, or in self-pourable form, called DIY gels.
- (97) Supporting this process are molecular weight standards (also referred to as molecular weight size ladders or markers) which are used to identify the approximate size of a molecule (e.g. DNA or RNA) run on a gel during electrophoresis.

# 5.2.5.1. Relevant product market definition

### (A) Previous Commission decisions

(98) Among nucleic acid purification techniques, of which gel electrophoresis is an example, the Commission previously identified separate markets for (i) liquid-based instruments, (ii) column-based instruments, (iii) magnetic bead-based instruments, and (iv) electrophoresis gel boxes. Within gel electrophoresis consumables, the same case identified a separate market for molecular weight standards (DNA ladders). The Commission has not reviewed the other main gel electrophoresis consumable, electrophoresis gels, in detail in the past.

# (B) The Notifying Party's view

- (99) The Notifying Party submits that a distinction can be made between agarose gels, which are the most used type of horizontal electrophoresis gels, and acrylamide gels, which are the most used type of gel for vertical gel electrophoresis. Both types can be sub-segmented in pre-cast gels and do it yourself ("DIY") gels.<sup>78</sup>
- (100) Despite the above differences, the Notifying Party argues that there is significant supply-side substitutability, as most manufacturers supply consumables for both horizontal and vertical gel electrophoresis. Ultimately, the Notifying Party considers that the exact market definition can be left open as the Transaction does not give rise to competitive concerns under any product market definition.

### (C) The Commission's assessment

(101) The market investigation gave no reason to depart from the Commission's previous decisional practice concerning a separate market for molecular weight standards within gel electrophores is consumables.

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<sup>&</sup>lt;sup>77</sup> Case M.6944 – *Thermo Fisher / Life Technologies*, paragraphs 178-183.

<sup>&</sup>lt;sup>78</sup> Form CO, paragraphs 556-557.

- (102) Concerning a distinction between gels and molecular weight ladders for horizontal and vertical gel electrophoresis, the product market definition can be left open, as this distinction does not affect the outcome of the competitive assessment. The same applies for a potential distinction between pre-cast and DIY gels.
- (103) For the purpose of the present Decision, the Commission will perform its assessment on the basis of the narrowest product markets in which Thermo Fisher is primarily active, *i.e.* (i) **precast protein gels for vertical gel electrophoresis** and (ii) **molecular weight standards for vertical gel electrophoresis**. The Transaction does not give rise to any affected markets for horizontal gel electrophoresis or DIY gels and it can be left open whether the appropriate product market would be broader (*i.e.* including precast and DIY gels, or including horizontal and vertical gels / molecular weight standards) as this distinction does not affect the outcome of the competitive assessment.

# 5.2.5.2. Relevant geographic market definition

### (A) Previous Commission decisions

(104) In its previous decisional practice, the Commission considered that the appropriate geographic scope for DNA ladders and markers is at least EEA-wide.<sup>79</sup>

# (B) The Notifying Party's view

(105) The Parties submit that any relevant product markets for gel electrophoresis consumables are global or at least EEA-wide in scope but considers that the exact geographic scope can be left open as the Transaction does not give rise to competitive concerns under either geographic scope.<sup>80</sup>

# (C) The Commission's assessment

(106) For the purpose of the current decision and in line with its previous decisional practice, the exact geographic scope for precast protein gels for vertical gel electrophoresis and molecular weight standards for vertical gel electrophoresis can be left open between EEA-wide and worldwide, as this distinction does not affect the outcome of the competitive assessment.

### 5.2.6. Cell culture sera

(107) Cell culture sera are liquid blood-based animal products that are used to grow cells in both research and bio-production applications.

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<sup>79</sup> Case M.5263 – *Invitrogen / Applied Biosystems*, paragraph 68 and case M.6944 – *Thermo Fisher / Life Technologies*, paragraphs 184-186.

<sup>80</sup> Form CO, paragraphs 560-563.

# 5.2.6.1. Relevant product market definition

### (A) Previous Commission decisions

- (108) In M.6944 Thermo Fisher Scientific / Life Technologies, the Commission found a likely segmentation of the sera market on the basis of three criteria. First, on the basis of the customer groups to which the product is supplied, sera can be divided into sera sold to bio-production customers and sera sold to the research sector, as differences exist in terms of purchasing patterns, pricing and expected quality. Second, a segmentation can be made on the basis of animal type, i.e. FSB (foetal bovine serum), calf sera, bovine adult sera and other species, as those sera would fulfil different needs.
- (109) *Third*, sera can be segmented on the basis of their geographic origin, into (i) a potential product market encompassing sera from Australia, (ii) a potential product market encompassing sera from New Zealand, (iii) a potential product market encompassing sera from Australia and New Zealand, (iv) a potential product market encompassing sera from the US, (v) a potential product market encompassing sera from Canada, (vi) a potential product market encompassing sera from the US and Canada, and (vii) a potential product market encompassing sera from South American countries (EU approved).<sup>81</sup>

### (B) The Notifying Party's view

(110) The Notifying Party submits that customers in the area of research would have, in many circumstances, the flexibility to substitute among sera from different geographies. However, it ultimately considers that the exact product market definition can be left open, as no concerns arise under any plausible market definition.<sup>82</sup>

### (C) The Commission's assessment

(111) The market investigation gave no reason to depart from the Commission's previous decisional practice. The Commission notes that, for the assessment of this case, only sera for research purposes are relevant, as PPD uses sera exclusively for research purposes.<sup>83</sup> For the purpose of this decision, the Commission will further consider a segmentation of sera based on animal type and based on geographic origin, as detailed in paragraphs (108) and (109).

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<sup>81</sup> Case M.6944 – *Thermo Fisher Scientific / Life Technologies*, paragraphs 45 et seq. Based on this market definition, the Commission looked at cell culture sera and media in Case M.8541 - *Thermo Fisher Scientific / Patheon*, paragraphs 12 et seq., where the exact market definition was left open.

<sup>82</sup> Form CO, paragraphs 298 et seq.

<sup>83</sup> Form CO, paragraph 297.

### 5.2.6.2. Relevant geographic market definition

### (A) Previous Commission decisions

(112) In M.6944 – *Thermo Fisher Scientific / Life Technologies*, the Commission considered EEA-wide or global markets for sera, but ultimately left the exact market definition open.<sup>84</sup>

# (B) The Notifying Party's view

(113) The Notifying Party appears to consider sera markets to be either EEA-wide or global in scope, but submits that the exact market definition can be left open, as no concerns would arise under any plausible market definition.<sup>85</sup>

### (C) The Commission's assessment

(114) In the market investigation, manufacturers and distributors confirmed that the geographic market for sera is global or at least EEA-wide in scope. 86 Further, the market investigation did not give reason to depart from the Commission's previous decisional practice. For the purpose of this decision, the geographic market for sera will therefore be defined as global or EEA-wide.

# 5.2.7. Cell culture media

(115) Cell culture media are water-based liquids that are used to facilitate the growth of cells. It can be provided in liquid or in dry powder format.

# 5.2.7.1. Relevant product market definition

### (A) Previous Commission decisions

- (116) In M.6944 Thermo Fisher Scientific / Life Technologies, the Commission found a likely segmentation of the cell culture media market on the basis of four criteria. First, on the basis of the customer groups to which the product is supplied, media can be divided into media sold to bio-production customers and media sold to the research sector, as differences exist in terms of purchasing patterns, pricing and expected quality. Second, a segmentation can be made between liquid and dry media, as there would be significant differences between those two forms in terms of pricing, performance, suitability, purchasing patterns and equipment required for their production.
- (117) *Third*, media can be divided into a potential product market encompassing standard basal media, a potential market for custom media, and a potential market for proprietary media. *Fourth*, media can be divided into chemically defined and non-chemically defined media. Finally, the Commission found that process liquids appear

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<sup>&</sup>lt;sup>84</sup> Case M.6944 – Thermo Fisher Scientific / Life Technologies, paragraph 52 et seq.

<sup>85</sup> Form CO, paragraphs 300 and 301.

<sup>&</sup>lt;sup>86</sup> Replies to question 70 of questionnaire Q2 to Thermo Fisher competitors.

to form a product market distinct from media for cell culture. The exact product market definition was ultimately left open.<sup>87</sup>

#### The Notifying Party's view (B)

(118) The Notifying Party follow the Commission's past practice and submit that the exact scope of the relevant product market can be left open.<sup>88</sup>

#### (C) The Commission's assessment

- (119) The market investigation provided indications that media for bio-production and media for research may be substitutable at least for some purposes, as submitted by a majority of customers.<sup>89</sup> The Commission notes that business activities of respondents to this market investigation focus on research. As one customer pointed out that media for bio-production may need to fulfil higher quality standards<sup>90</sup>, it may be that media for research purposes can be substituted by media for bio-production, but not vice versa.
- (120) The Commission notes that PPD uses media for research purposes, 91 and that an assessment of media for bio-production is therefore not relevant. For the purpose of this Decision, and in line with past practice, the Commission will assess a separate market for research media, and a potential segmentation by liquid and dry media as well as by standard basal media, custom media, proprietary media, as well as chemically defined and non-chemically defined media. It will further assess a distinct product market for process liquids. In any event, the exact product market definition can be left open, as this does not affect the outcome of the competitive assessment.

# 5.2.7.2. Relevant geographic market decisions

#### (A) Previous Commission decisions

(121) In M.6944 - Thermo Fisher Scientific / Life Technologies, the Commission considered EEA-wide or global markets for media, but ultimately left the exact market definition open.92

#### (B) The Notifying Party's view

(122) The Notifying Party submits that the relevant geographic market for cell culture media was considered in Thermo Fisher Scientific / Life Technologies and it was left open. The market investigation showed that manufacturers processed the relevant products at centralised sites, and products were subsequently shipped from sites to regional distribution hubs around the world, and EEA and non-EEA customers had the same preferences and technical/commercial needs, thus, supporting a view that the market for media products is global or, in any event, at least EEA-wide. Since the

<sup>89</sup> Replies to question 89 of questionnaire Q1 to CRO and laboratory service providers.

<sup>87</sup> Case M.6944 – Thermo Fisher Scientific/Life Technologies, paragraph 20 et seq.

Form CO, paragraph 321 et seq.

Replies to question 89.1 of questionnaire Q1 to CRO and laboratory service providers.

Form CO, paragraph 317.

<sup>&</sup>lt;sup>92</sup> Case M.6944 – Thermo Fisher Scientific / Life Technologies, paragraph 31 et seq.

Transaction does not raise competitive concerns under any plausible geographic delineation, the Parties submit that the exact scope of the relevant geographic market can be left open.<sup>93</sup>

### (C) The Commission's assessment

(123) In the market investigation, manufacturers and distributors confirmed that the geographic market for media is global or at least EEA-wide in scope.<sup>94</sup> Further, the market investigation did not give reason to depart from the Commission's previous decisional practice. For the purpose of this Decision, the geographic market for media will therefore be left open between global and EEA-wide.

### 5.2.8. Plastics for magnetic bead-based instruments

- (124) As discussed in paragraph (98), magnetic bead-based instruments are a technique for nucleic acid purification. In magnetic bead-based purification, a liquid sample is combined with magnetic beads. The separation solution causes the desired particle to bind to the beads. The beads are then separated from the liquids by magnetic force. The beads containing the bound particles are then washed and the desired particles are released from the beads. Finally, the magnetic beads are removed and discarded.
- (125) Magnetic bead-based instruments require consumables, primarily reagents and plastic consumables. The primary plastic consumables used with magnetic bead-based instruments are microplates and tip combs. Plastic microplates are interoperable with magnetic bead-based instruments of different manufacturers as well as other laboratory instruments.

# 5.2.8.1. Relevant product market definition

### (A) Previous Commission decisions

(126) As set out in paragraph (98), the Commission has previously found a separate market for magnetic bead-based instruments. The Commission has never specifically assessed the area of plastics for magnetic bead-based instruments. However, in a previous decision it concluded that there was a product market for microplates, 96 without distinguishing the type of instrument the microplates could be used with. 97

### (B) The Notifying Party's view

(127) The Notifying Party submits that the definition of the relevant product market for plastic for magnetic bead-based instruments can be left open.<sup>98</sup>

<sup>93</sup> Form CO, paragraph 324 et seq.

Replies to question 70 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>95</sup> Case M.6944 – Thermo Fisher / Life Technologies, paragraphs 178-180.

<sup>&</sup>lt;sup>96</sup> Microplates and tip combs are plastic trays that hold samples.

<sup>&</sup>lt;sup>97</sup> Case M.4242 – Thermo Electron / Fisher Scientific, paragraph 23.

<sup>98</sup> Form CO, paragraph 408.

### (C) The Commission's assessment

(128) For the purpose of the current Decision, the exact product market definition for plastics for magnetic bead-based instruments can be left open, as the Transaction does not give rise to competitive concerns with respect to this market for any plausible product market definition. For the purpose of the current Decision, the Commission will analyse the narrower market of **plastics for magnetic bead-based instruments**. A broader product market for all consumables for magnetic bead-based instruments would not be affected.

# 5.2.8.2. Relevant geographic market definition

# (A) Previous Commission decisions

(129) In the *Thermo Electron / Fisher Scientific* decision, the Commission left open the relevant geographic market definition for microplates and tip combs.<sup>99</sup> In a more recent decision, the Commission concluded that the appropriate geographic scope for the relevant markets related to nucleic acid purification are at least EEA-wide, but left the exact market definition open.<sup>100</sup>

### (B) The Notifying Party's view

(130) The Notifying Party further submits that the appropriate geographic market definition is most likely global as (i) prices for plastics for magnetic bead-based instruments do not differ substantially by region, (ii) transport costs are low, and (iii) customers in the EEA often source plastics for magnetic bead-based instruments from other geographies. However, as it considers that the Transaction does not raise competitive concerns under any plausible geographic delineation, the Notifying Party submits that the exact scope of the relevant geographic market can be left open.<sup>101</sup>

### (C) The Commission's assessment

(131) For the purpose of the current Decision and in line with its previous decisional practice, the exact geographic scope for plastics for magnetic bead-based instruments can be left open between EEA-wide and worldwide, as this distinction does not affect the outcome of the competitive assessment.

# 5.2.9. Mass spectrometers

(132) Mass spectrometry products are used to separate compounds into their separate component parts and to detect the separated components. Mass spectrometers can be used in conjunction with methods that separate the constituent molecules of a sample before they are introduced in the mass spectrometer, including liquid chromatography and gas chromatography instruments. High-resolution accurate mass ("HRAM") spectrometers are used primarily for qualitative research characterising complex

<sup>&</sup>lt;sup>99</sup> Case M.4242 – Thermo Electron / Fisher Scientific, paragraph 40.

<sup>&</sup>lt;sup>100</sup> Case M.5264 – *Invitrogen / Applied Biosystems*, paragraphs 67-68.

<sup>101</sup> Form CO, paragraphs 409-413.

<sup>102</sup> Form CO, paragraphs 521 et seq.

molecules or identifying proteins, for example in the discovery of new drug targets, because of their high resolution. $^{103}$ 

# 5.2.9.1. Relevant product market definition

### (A) Previous Commission decisions

(133) In M.5611 – *Agilent / Varian*, the Commission found that within the mass-spectrometry ("MS") field, a segmentation can be made based on the respective analytical technic used, *i.e.* gas chromatography ("GC") and liquid chromatography ("LC"), and has considered combined GC-MS and LC-MS markets. <sup>104</sup> In M.6126 – *Thermo Fisher / Dionex Corporations*, the Commission found appropriate to assess chromatography and spectrometry instruments separately, but noted again that mass spectrometry instruments used with liquid chromatography are not substitutable with those used in gas chromatography. <sup>105</sup> In M.8541 - *Thermo Fisher Scientific / Patheon*, the Commission left the market definition open in this regard. <sup>106</sup> In none of the decisions cited in this paragraph, the Commission discussed a separate market for HRAM spectrometers.

# (B) The Notifying Party's view

(134) The Notifying Party indicates that there may be a separate market for HRAM spectrometers. 107 It further submits that HRAM spectrometers used with liquid chromatography would generally not be interchangeable with HRAM spectrometers used with gas chromatography, and that both devices would be technically different. On this basis, it may be possible to define separate product markets for HRAM LC and HRAM GC spectrometers. 108 The Notifying Party submits that the precise market definition for mass spectrometry instruments can ultimately be left open. 109

### (C) The Commission's assessment

- (135) Qualitative feedback from the market investigation substantiates the Notifying Party's claim that within the market for all mass spectrometers, there may be a distinct market for HRAM spectrometers, as the level of analytical capability of such device may play an important role in their suitability to laboratories.<sup>110</sup>
- (136) Further, the market investigation did not provide reason to deviate from past practice to define separate product markets for LC and GC mass spectrometers. In the view of the Commission, this differentiation may also apply to HRAM spectrometers, which is confirmed by the Notifying Party.

<sup>103</sup> Form CO, paragraph 525.

<sup>104</sup> Case M.5611 – Agilent/Varian, paragraphs 10 et seq.

<sup>&</sup>lt;sup>105</sup> Case M.6126 – *Thermo Fisher/Dionex Corporation*, paragraphs 22 et seq.

<sup>106</sup> Case M.8541 – Thermo Fisher Scientific / Patheon, paragraph 29.

<sup>107</sup> Form CO, paragraph 533.

<sup>108</sup> Response to RFI 13, paragraph 1.

<sup>109</sup> Form CO, paragraph 533.

 $<sup>^{110}</sup>$  Replies to question 56.1 of questionnaire Q1 to CRO and laboratory service providers .

(137) Based on the above, the Commission considers that mass spectrometry instruments for LC and GC form different product markets, and considers a likely existence of a separate HRAM market for both products for the purpose of this Decision. The Commission notes that affected markets would only arise for LC HRAM spectrometers<sup>111</sup>, but not for LC or GC mass spectrometers, and not on an overall market for mass spectrometry instruments.

### 5.2.9.2. Relevant geographic market definition

### (A) Previous Commission decisions

(138) In M.5611 – *Agilent / Varian*, the Commission concluded that markets for mass spectrometry instruments are EEA-wide in geographic scope. In *Thermo Fisher/Dionex* and M.8541 - *Thermo Fisher Scientific / Patheon*, the Commission left the precise geographic market open, but considered markets to be at least EEA-wide.

# (B) The Notifying Party's view

(139) The Notifying Party submits that the exact scope of the relevant geographic market can be left open since no competitive concerns arise under any plausible geographic definition.<sup>114</sup>

### (C) The Commission's assessment

(140) In the market investigation, a majority of customers and competitors indicated that the geographic market definition for mass spectrometers is global, and all other respondents considered markets to be EEA-wide. For the purpose of this Decision, the geographic market definition can be left open between global and EEA-wide.

### 5.2.10. *Cryogenic storage tubes*

(141) Storage tubes are a piece of consumable laboratory equipment that are used to store or keep samples. Cryogenic storage tubes (also freezers storage tubes) are small, capped tubes designed to withstand ultra-low temperatures.

### 5.2.10.1. Relevant product market definition

### (A) Previous Commission decisions

(142) The Commission has not defined a product market for cryogenic storage tubes, or storage tubes in general, in the past. In M.4242 – *Thermo Electron / Fisher Scientific*, the Commission made reference to "cryogenic storage" as a product in the broader

<sup>111</sup> PPD [PPD's operations], response to RFI 13, paragraph 4.

<sup>112</sup> Case M.5611 – Agilent/Varian, paragraphs 51 et seq.

<sup>113</sup> Case M.6126 – Thermo Fisher/Dionex Corporation, paragraph 42; Case M.8541 – Thermo Fisher Scientific / Patheon, paragraph 34.

<sup>114</sup> Form CO, paragraph 535.

Replies to question 52 of questionnaire Q1 to CRO and laboratory service providers; Replies to question 41 of questionnaire Q2 to Thermo Fisher competitors.

area of laboratory equipment and consumables, but did not consider this product any further. 116

# (B) The Notifying Party's view

(143) The Notifying Party submits storage tubes could be differentiated according to various characteristics, such as size, durability and ability to withstand ultra-low temperatures. There would be, however, a significant degree of supply and demand-side substitutability between different storage tubes. In the Notifying Parties view, the primary feature on which storage tubes can be meaningfully distinguished is the tubes' ability to withstand ultra-low temperatures. Therefore, a potential segmentation may be made between cryogenic storage tubes and transport tubes. However, for the present case, the exact market definition can be left open, as neither a potential segment for transport tubes, nor a potential wider market including cryogenic storage tubes and other types of tubes, would be affected.

### (C) The Commission's assessment

(144) The market investigation confirmed that cryogenic storage tubes are a product market separate from other storage tubes because they cannot be substituted with other tubes due to their product specifies, *i.e.* their ability to withstand ultra-low temperatures. Market feedback did not suggest a further segmentation of cryogenic storage tubes to be appropriate. All customers responding to the market investigation agree that cryogenic storage tubes form a separate product market from other storage tubes without further segmentation.<sup>118</sup> All but one manufacturer or distributor of such tubes confirm that view.<sup>119</sup> Based on the above, the Commission considers a separate market for cryogenic storage tubes without further segmentation for the purpose of this Decision.

### 5.2.10.2. Relevant geographic market decisions

# (A) Previous Commission decisions

(145) The Commission has not defined a product market for cryogenic storage tubes, or storage tubes in general, in the past.

# (B) The Notifying Party's view

(146) The Notifying Party submits that the relevant market for cryogenic storage tubes is global, or at least EEA-wide in scope because cryogenic storage tubes are identical wherever customers are located. There are no country-specific or region-specific products and there is no regional branding or packaging. 120

<sup>116</sup> Case M.4242 – Thermo Electron / Fisher Scientific, paragraph 11.

<sup>117</sup> Form CO, paragraph 709 et seq.

<sup>118</sup> Replies to question 104 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>119</sup> Replies to question 83 of questionnaire Q2 to Thermo Fisher competitors; one respondent point at a potentially narrower product market definition, without suggesting a clear further segmentation.

<sup>120</sup> Form CO, paragraph 713 et seq.

### (C) The Commission's assessment

(147) The market investigation indicated that the market for cryogenic storage tubes is global or at least EEA-wide in geographic scope. A majority of customers consider global market for such tubes, and all other customers responding to the market investigation submit geographic markets to be EEA-wide. This view is confirmed by all manufacturers or distributors responding to the market investigation who formed an opinion about this question. Therefore, the Commission concludes that the geographic market for cryogenic storage tubes is global or EEA-wide, and leaves the exact market definition open between the two.

### 5.2.11. General purpose benchtop centrifuges

(148) A laboratory centrifuge is a piece of laboratory equipment, driven by a motor, which spins liquid samples at high speeds, to separate substances of greater and lesser density. Centrifuges may differ with respect to parameters such as size, sample capacity or speed.

### 5.2.11.1. Relevant product market definition

### (A) Previous Commission decisions

(149) The Commission did not define markets for laboratory centrifuges in the past.

# (B) The Notifying Party's view

- (150) The Notifying Party submits that laboratory centrifuges can be differentiated according to various characteristics, such as size, speed or space requirements. It considers that three main centrifuges can be distinguished, namely benchtop, floor and large scale continuous flow centrifuges, for which there would be limited demand-side substitutability, but a significant degree of supply-side substitutability.
- (151) The Notifying Party considers that benchtop centrifuges are an established category of laboratory equipment and well understood by market participants. In any event, the exact product market definition can be left open, as no affected market would arise in a potential broader market comprising all laboratory centrifuges.<sup>123</sup>

### (C) The Commission's assessment

(152) The market investigation confirmed that general purpose benchtop centrifuges form a product market separate from other centrifuges such as floor centrifuges or large scale continuous flow centrifuges, as these would typically not be substituted with each

<sup>121</sup> Replies to question 105 of questionnaire Q1 to CRO and laboratory service providers.

<sup>122</sup> Replies to question 84 of questionnaire Q2 to Thermo Fisher competitors.

For completeness, the Notifying Party notes that Thermo Fisher manufactures other types of centrifuges for which market shares exceed 30% on global and/or EEA wide level, but remain in any case below 50% market share, namely large capacity centrifuges, super speed centrifuges, which are all floor centrifuges, and industrial centrifuges, which are ultra-speed centrifuges with a higher capacity. The Notifying Party provides that PPD [PPD's operations]. In any event, during the market investigation, the Commission asked customers or competitors for their view on any other type of centrifuges, and no market participant raised any concern. In the light of the above, those products will not be further discussed in the present Decision.

other. All customers responding to the market investigation agree to this product market definition, and do not suggest that the market for general purpose benchtop centrifuges should be further segmented. 124 All but one manufacturer or distributor of such centrifuges confirm that view. One competitor suggests that the market may be further segmented by capacity and/or intended use, for example blood sample centrifuges, cell culture or mini-spin centrifuges. 125

(153) Based on market feedback on balance, the Commission considers a separate market for general purpose benchtop centrifuges without further segmentation. This conclusion is further supported by the fact that customers or competitors did not raise concerns related to a specific type of general purpose benchtop centrifuges.

# 5.2.11.2. Relevant geographic market definition

### (A) Previous Commission decisions

(154) The Commission did not define geographic markets for general purpose benchtop centrifuges in the past.

# (B) The Notifying Party's view

(155) The Notifying Party submits that the relevant market for general purpose centrifuges, and in general, all laboratory centrifuges, is global, or at least EEA-wide in scope. 126

General purpose centrifuges are identical wherever customers are located and similar models of general purpose centrifuges are being marketed globally. 127

### (C) The Commission's assessment

(156) The market investigation indicated that the market for general purpose benchtop centrifuges is EEA-wide or even global in geographic scope. A small majority of customers consider an EEA-wide market for such centrifuges, and all other but one customers responding to the market investigation submit geographic markets to be global. A majority of responding manufacturers or distributors responding to the market investigation who formed an opinion about this question propose global markets for such centrifuges, and all other respondents point at EEA-wide markets. Pherefore, the Commission concludes that the geographic market for general purpose benchtop centrifuges is EEA-wide or even global, and leaves the exact market definition open between the two.

# 5.2.12. Thermal cyclers

(157) Thermal cyclers are used in a process called nucleic acid amplification, which refers to the technologies designed for amplifying (copying) targeted DNA or RNA

127 Form CO, paragraphs 694 et seq.

<sup>124</sup> Replies to question 99 of questionnaire Q1 to CRO and laboratory service providers.

<sup>125</sup> Replies to question 78 of questionnaire Q2 to Thermo Fisher competitors.

<sup>126</sup> Form CO, paragraph 693.

Replies to question 100 of questionnaire Q1 to CRO and laboratory service providers; the other customer did not provide clear indication for an alternative geographic market definition.

<sup>129</sup> Replies to question 79 of questionnaire Q2 to Thermo Fisher competitors.

- sequences to allow further analysis. Nucleic acid amplification is most commonly achieved by a technique called polymerase chain reaction ("PCR").
- (158) There are various types of PCR including conventional (or end-point) PCR ("ePCR"), quantitative PCR ("qPCR") and digital PCR ("dPCR"). 130
- (159) A thermal cycler (also known as an ePCR instrument) comprises a heating block with holes into which tubes holding the reagents can be placed. The cycler increases and lowers the temperature of the block in discrete, pre-programmed steps, each of which aligns with a cycle of the reaction. The cycle is the repeated multiple times to create the required sample size.<sup>131</sup>

### 5.2.12.1. Relevant product market definition

### (A) Previous Commission decisions

(160) In a previous decision, the Commission defined separate markets for nucleic acid amplification for research and diagnostic applications. Furthermore, the Commission found that there are separate markets for PCR reagents and instruments, and that within instruments, there are separate markets for thermal cyclers (ePCR instruments) and qPCR instruments. 133

# (B) The Notifying Party's view

(161) For the purposes of the Transaction, the Notifying Party agrees with the Commission's previous decisional practice as concerns thermal cyclers. 134

# (C) The Commission's assessment

(162) The Commission's market investigation did not give any reasons to depart from the Commission's previous decisional practice with respect to the product market definition for PCR instruments. Applying this product market definition, the Transaction gives rise to an affected market for **thermal cyclers** (ePCR instruments).

### 5.2.12.2. Relevant geographic market definition

### (A) Previous Commission decisions

(163) In its previous decisions, the Commission considered that the appropriate geographic scope for thermal cyclers is at least EEA-wide, but left the exact market definition open.<sup>135</sup>

33

<sup>&</sup>lt;sup>130</sup> qPCR, also called real-time or quantitative PCR, monitors the amplification of a targeted DNA molecule during the reaction and not at its end, as in conventional PCR (ePCR). Digital PCR or dPCR digitally measures the number of individual target molecules.

<sup>131</sup> Form CO, paragraph 747 et seq.

<sup>132</sup> Case M.5264 – *Invitrogen / Applied Biosystems*, paragraph 51.

<sup>133</sup> Case M.5264 – Invitrogen / Applied Biosystems, paragraph 51 and case M.6944 – Thermo Fisher / Life Technologies, paragraph 125.

<sup>134</sup> Form CO, paragraph 754.

# (B) The Notifying Party's view

(164) The Notifying Party submits that the relevant market for thermal cyclers is global, or at least EEA-wide in scope. As they are identical around the world, there is no regional branding or packaging, they are not generally subject to national regulatory requirements and most manufacturers are able to supply globally. 136

### (C) The Commission's assessment

(165) For the purpose of the current decision and in line with its previous decisional practice, the exact geographic scope for plastics for thermal cyclers can be left open between EEA-wide and worldwide, as this distinction does not affect the outcome of the competitive assessment.

### 5.2.13. *Infrared spectrometers*

(166) Spectrometers are used for recording and measuring spectra as a method of analysis. There are broadly three types of spectrometers, namely (i) mass spectroscopy, (ii) molecular spectroscopy, and (iii) atomic spectroscopy. One technology within molecular spectroscopy is infrared spectroscopy ("IR"). In IR spectrometry, a beam of infrared radiation intersects with and is absorbed by an unknown sample. The absorption rates are unique to the properties of the chemical group being analysed, and the results can be compared to a library of known IR spectra. FT-IR (also Fourier Transform IR) are a type of IR spectrometers with a high degree of efficiency. 137

# 5.2.13.1. Relevant product market definition

### (A) Previous Commission decisions

(167) In M.5611 – *Agilent / Varian*, the Commission identified nine sectors within the analytical and life science instrumentation field, one of them being molecular spectroscopy, without further discussing this product area. <sup>138</sup> In M.6175 – *Danaher / Beckman Coulter*, the Commission noted that molecular spectroscopy can be further segmented into visible and ultraviolet-visible (Vis and UV-Vis), near-infrared (NIR), infrared (IR) fluorescence & luminescence, colour measurement, nuclear magnetic resonance (NMR), raman, polarimetry & refractometry, and ellipsometry. <sup>139</sup>

### (B) The Notifying Party's view

(168) The Notifying Party submits that the market for IR spectrometers should not be further segmented. It further notes, however, that FT-IR spectrometers are the dominant form in the IR spectrometers field, and that market shares of Thermo Fisher

<sup>135</sup> Case M.5264 – *Invitrogen / Applied Biosystems*, paragraph 68 and case M.6944 – *Thermo Fisher / Life Technologies*, paragraph 140.

<sup>136</sup> Form CO, paragraphs 756-758.

<sup>137</sup> Form CO, paragraphs 726 et seq.

<sup>138</sup> Case M.5611 – Agilent / Varian, paragraphs 9 et seq.

<sup>139</sup> Case M.6175 – Danaher / Beckman Coulter, paragraph 25.

would be higher specifically for FT-IR spectrometers compared to an overall IR spectrometer market. 140

### (C) The Commission's assessment

(169) The market investigation did not produce arguments that contradict the Commission's past practice to define a market for molecular spectroscopy, and within it, a market for IR spectroscopy. Market feedback further did not suggest that that the product market would be narrower than IR spectrometers. Therefore, the Commission considers in line with past findings, that a product market definition at the level of IR spectrometers as appropriate. For the purpose of this Decision, it can be left open whether FT-IR spectrometers would form a separate product market, as this would not change the competitive assessment.

# 5.2.13.2. Relevant geographic market definition

# (A) Previous Commission decisions

(170) In previous decisions, the Commission considered markets for analytical and life science instruments EEA-wide or global in geographic scope. 141

# (B) The Notifying Party's view

(171) The Notifying Party submits that the relevant market for IR spectrometers is global, or at least EEA-wide in scope.<sup>142</sup>

# (C) The Commission's assessment

(172) In the market investigation, the Commission received limited responses from customers as to the appropriate geographic market for IR spectrometers, and those customers that did provide a view indicated markets would be either EEA-wide or global. A majority of responding manufacturers and distributors indicated for IR spectrometers would be global in geographic scope, and all other respondents active in this product area indicated EEA-wide markets. Based on past practice and market feedback, the Commission considers geographic markets for IR spectrometers to be either EEA-wide or global in scope, and leaves the exact market definition open between the two.

<sup>140</sup> Form CO, paragraphs 732 et seq.

<sup>141</sup> M.5611 – *Agilent / Varian*, paragraphs 51 et seq.; M.6126 - *Thermo Fisher/Dionex Corporation*, paragraphs 42 et seq.; M.6175 – *Danaher / Beckman Coulter*, paragraph 32.

<sup>&</sup>lt;sup>142</sup> Form CO, paragraphs 735 et seq.

<sup>&</sup>lt;sup>143</sup> Replies to question 52 of questionnaire Q1 to CRO and laboratory service providers.

Replies to question 41 of questionnaire Q2 to Thermo Fisher competitors.

#### 6. COMPETITIVE ASSESSMENT

#### 6.1. Analytical framework

- (173) Article 2 of the Merger Regulation requires the Commission to examine whether notified concentrations are compatible with the internal market, by assessing whether they would significantly impede effective competition in the internal market or in a substantial part of it, in particular as a result of the creation or strengthening of a dominant position.
- (174) In the assessment of non-horizontal mergers, the Commission distinguishes between two broad types of such mergers: vertical mergers and conglomerate mergers.
- (175) Vertical mergers involve companies operating at different levels of the supply chain. For example, when a manufacturer of a certain product (the "upstream firm") merges with one of its distributors (the "downstream firm"), this is called a vertical merger. 145
- (176) Conglomerate mergers are mergers between firms that are in a relationship that is neither horizontal (as competitors in the same relevant market) nor vertical (as suppliers or customers). In practice, the Commission focusses on mergers between companies that are active in closely related markets (e.g. mergers involving suppliers of complementary products or products that belong to the same product range). The Transaction does not lead to markets where a conglomerate effects assessment is warranted.
- (177) In assessing potential vertical effects of a merger, the Commission analyses whether a merger results in foreclosure so that actual or potential rivals' access to supplies or markets is hampered or eliminated as a result of the merger, thereby reducing these companies' ability and/or incentive to compete. Such foreclosure may discourage entry or expansion of rivals or encourage their exit. Foreclosure thus can be found even if the foreclosed rivals are not forced to exit the market: it is sufficient that the rivals are disadvantaged and consequently led to compete less effectively. Such foreclosure is regarded as anti-competitive where the merging companies and, possibly, some of its competitors as well are as a result able to profitably increase the price charged to consumers. 147
- (178) Two forms of foreclosure can be distinguished. The first is where the merger is likely to raise the costs of downstream rivals by restricting their access to an important input (input foreclosure). The second is where the merger is likely to foreclose upstream rivals by restricting their access to a sufficient customer base (customer foreclosure). 148
- (179) In assessing both types of foreclosure, the Commission applies the ability, incentive, effects framework. This implies the assessment of whether (i) the merged entity would have the ability to engage in foreclosure, (ii) it would have the incentive to do

<sup>&</sup>lt;sup>145</sup> OJ C 265, 18.10.2008, p. 6-25 (the 'Non-horizontal Merger Guidelines'), paragraph 4.

<sup>&</sup>lt;sup>146</sup> Non-horizontal Merger Guidelines, paragraph 91.

Non-horizontal Merger Guidelines, paragraph 29.

<sup>&</sup>lt;sup>148</sup> Non-horizontal Merger Guidelines, paragraph 30.

so, and (iii) what would be the overall impact on effective competition in the affected markets. $^{149}$ 

## 6.2. Affected markets

(180) The Transaction gives rise to the following affected vertical relationships:

Table 1: Vertical links affected by the Transaction. 150

Section	Upstream market (Thermo Fisher)	Global market share	EEA market share	Downstream market (PPD)	Global market share	EEA market share
6.4.1	High resolution (Sanger) capillary electrophoresis instruments	[90- 100]%	[90- 100]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.1	High resolution (Sanger) capillary electrophoresis consumables	[90- 100]%	[90- 100]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.2	Laboratory IVD diagnostic allergy systems for clinical development laboratories	[80-90]%	[70-80]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.3	CO2 incubators	[60-70]%	[50-60]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.4	Ion chromatography instruments	[50-60]%	[40-50]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.4	Pre-filled ion chromatography columns	[50-60]%	[50-60]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.5	Precast protein gels for vertical gel electrophoresis	[40-50]%	[50-60]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.5	Molecular weight standards for vertical gel electrophoresis	[30-40]%	[40-50]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.6	All cell culture sera for research	[40-50]%	[30-40]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.6	Australian and New	[30-40]%	[20-30]%	Laboratory	[5-10]%	[0-5]%

<sup>149</sup> Non-horizontal Merger Guidelines, paragraphs 32 and 59.

<sup>150</sup> Market shares for 2020 expressed in value. A more detailed assessment of market structure is provided in the relevant competitive assessment sections in Section 6.4.

Section	Upstream market	Global market	EEA market	Downstream	Global market	EEA market
Section	(Thermo Fisher)	share	share	market (PPD)	share	share
	Zealand fetal bovine sera			services for	3 2232 2	
				clinical		
				development		
				Laboratory		
6.4.6	Australian fetal bovine	[30-40]%	[20-30]%	services for	[5-10]%	[0-5]%
0.4.0	sera	[50-10]/0	[20-30]/0	clinical	[3-10]/0	[0-3]/0
				development		
				Laboratory		
6.4.6	New Zealand fetal	[40-50]%	[30-40]%	services for	[5-10]%	[0-5]%
	bovine sera		[]	clinical	[]	[]
				development		
	TIG 16 1 641			Laboratory		
6.4.6	US and Canadian fetal	[40-50]%	[20-30]%	services for	[5-10]%	[0-5]%
	bovine sera	' '	. ,	clinical	. ,	
				development		
				Laboratory services for		
6.4.6	US fetal bovine sera	[40-50]%	[20-30]%	clinical	[5-10]%	[0-5]%
		-		development		
				Laboratory		
	Canadian fetal bovine			services for		
6.4.6	sera	[40-50]%	[0-5]%	clinical	[5-10]%	[0-5]%
	Sera			development		
				Laboratory		
	South American fetal	F 40 #070 /	F#0 colo.	services for	F# 4070 /	Fo. #30 /
6.4.6	bovine sera	[40-50]%	[50-60]%	clinical	[5-10]%	[0-5]%
				development		
				Laboratory		
6.4.6	New Zealand adult	[30-40]%	[10-20]%	services for	[5-10]%	[0-5]%
0.4.0	bovine sera	[30-40]%	[10-20]%	clinical	[3-10]%	[0-3]%
				development		
				Laboratory		
6.4.6	Porcine sera	[30-40]%	[10-20]%	services for	[5-10]%	[0-5]%
0. 1.0	1 of the serie	[50 10]/0	[10 20]/0	clinical	[3 10]/0	[0 3]/0
				development		
				Laboratory		
6.4.6	Equine sera	[30-40]%	[30-40]%	services for	[5-10]%	[0-5]%
	•			clinical		
				development		
	All cell culture media for			Laboratory services for		
6.4.7	research	[40-50]%	[30-40]%	clinical	[5-10]%	[0-5]%
	research			development		
				Laboratory		
		F. 10	Fa	services for	F	Fo -3
6.4.7	Liquid cell culture media	[40-50]%	[30-40]%	clinical	[5-10]%	[0-5]%
				development		
				Laboratory		
647	Derrooft16	[20, 40]0/	[20, 40]0/	services for	[6 10]0/	[O 5]0/
6.4.7	Dry cell culture media	[30-40]%	[30-40]%	clinical	[5-10]%	[0-5]%
				development		

Section	Upstream market (Thermo Fisher)	Global market share	EEA market share	Downstream market (PPD)	Global market share	EEA market share
6.4.7	Process liquids	[50-60]%	[40-50]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.7	Custom cell culture media	[40-50]%	[40-50]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.7	Proprietary cell culture media	[30-40]%	[30-40]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.7	Standard basal cell culture media	[50-60]%	[40-50]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.7	Chemically defined cell culture media	[30-40]%	[30-40]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.8	Plastics for magnetic bead-based instruments	[40-50]%	[40-50]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.9	LC high-resolution accurate mass spectrometers <sup>151</sup>	[40-50]%	[30-40]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.10	Cryogenic storage tubes	[30-40]%	[20-30]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.11	General purpose benchtop centrifuges	[30-40]%	[20-30]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.12	Thermal cyclers	[30-40]%	[20-30]%	Laboratory services for clinical development	[5-10]%	[0-5]%
6.4.13	FT-IR spectrometers	[20-30]%	[30-40]%	Laboratory services for clinical development	[5-10]%	[0-5]%

Source: Notifying Party

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<sup>151</sup> The Notifying Party provides that market shares would be slightly below these levels for a potential market for all HRAM spectrometers, including GC spectrometers. [...]; response to RFI 13 et seq.

- (181) All vertical relationships are affected by virtue of Thermo Fisher's market position in the upstream market.
- (182) PPD's market share in the downstream market is always well under 30%. As set out in the Commission's Non-Horizontal Merger Guidelines, the Commission is unlikely to find concern in non-horizontal mergers where the market share post-Transaction is below this level. Therefore, the Transaction does not give rise to any customer foreclosure concerns.
- (183) The Commission's assessment will focus on the possibility of an input foreclosure scenario.

# 6.3. Market investigation feedback by pharmaceutical companies (clinical trial sponsors)

- (184) In its market investigation, the Commission sent requests for information to CRO and laboratory service providers competing with PPD as well as laboratory equipment suppliers competing with Thermo Fisher on each of the product markets identified above; this is discussed in the below sections. In addition, the Commission sent requests for information to pharmaceutical companies, who ultimately are the sponsor of clinical trials and the primary customer of PPD's CRO and laboratory services, to obtain their views on the Transaction.
- (185) The large majority of pharmaceutical companies that responded to the Commission's market investigation did not consider that access to Thermo Fisher products is essential for CRO or laboratory service providers to provide services to them. The large majority did not consider that Thermo Fisher would have the ability or incentive to engage in input foreclosure vis-à-vis PPD's competitors post-Transaction, and did not consider that such strategy would have a major impact.
- (186) Concerning a potential input foreclosure strategy, pharmaceutical companies also point out the broad reputational harm on Thermo Fisher this would entail, explaining: "It would be unlikely that this would happen as the pharmaceutical companies represent much more market share than the clinical labs/CROs, and this would not be tolerated by the industry" and "This sounds unlikely. Since the services and products that Thermo Fisher offers for the most part have competition, sponsors of the services and products have alternatives. While PPD may be able to leverage some additional business by a unique offering they would likely do this without aggressive action by services/product withdrawal to Thermo Fisher's client base. If they were to take this approach, they would also have to consider the adverse effect on any industry relationships in terms of good business practices & relationships."155
- (187) The majority of pharmaceutical companies that responded to the Commission's market investigation also indicated that in the event of such foreclosure, they would employ their buying power vis-à-vis Thermo Fisher, either by themselves procuring

Replies to questions 9 and 10 of questionnaire Q3 to pharmaceutical companies.

<sup>152</sup> Non-horizontal Merger Guidelines, paragraph 25.

<sup>154</sup> Replies to questions 13, 14 and 15 of questionnaire Q3 to pharmaceutical companies.

Replies to question 14.1 of questionnaire Q3 to pharmaceutical companies.

the required products and making them available to CRO and / or laboratory providers, and by moving business away from Thermo Fisher and/or PPD.<sup>156</sup>

# 6.4. Vertical relationships - input foreclosure

- (188) This section analyses the possibility of an input foreclosure scenario for each vertical link affected by the Transaction. As set out in the previous section, the downstream market for all affected vertical links is laboratory services for clinical development. This section is organised by the upstream product markets. Table 1 provides an overview of which products are covered in each section.
- 6.4.1. High resolution (Sanger) capillary electrophoresis instruments and consumables

## 6.4.1.1. Market structure

(189) The tables below show the Notifying Party's market share estimates for high-resolution (Sanger) capillary electrophoresis instruments and consumables.

Table 2: 2020 value-based market shares for high-resolution (Sanger) capillary electrophoresis instruments.<sup>157</sup>

	Worl	dwide	EEA		
Competitor	Sales value (USD)	Share	Sales value (USD)	Share	
Thermo Fisher	[]	[90-100]%	[]	[90-100]%	
Promega	[]	[0-5]%	[]	[0-5]%	
Total	[]	100%	[]	100%	

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

- (190) On the market for high-resolution capillary electrophoresis instruments, Thermo Fisher has the same market share regardless of device throughput (i.e. [90-100]%).
- (191) The Notifying Party submits that Promega started offering high-resolution (Sanger) capillary electrophoresis instruments in the fall of 2020 but is unable to provide revenue or market share estimates for Promega.

<sup>156</sup> Replies to questions 11 and 12 of questionnaire Q3 to pharmaceutical companies.

<sup>157</sup> Volume-based market shares and market shares for 2018 and 2019 are similar to the ones shown here.

Table 3: 2020 value-based market shares for high-resolution (Sanger) capillary electrophoresis consumables. 158

	Worl	dwide	EEA		
Competitor	Sales value (USD)	Share	Sales value (USD)	Share	
Thermo Fisher	[]	[90-100]%	[]	[90-100]%	
Qiagen	[]	[0-5]%	[]	[0-5]%	
Millipore	[]	[0-5]%	[]	[0-5]%	
Edge Bio / ADS	[]	[0-5]%	[]	[0-5]%	
MCLAB	[]	[0-5]%	[]	[0-5]%	
Nimagen	[]	[0-5]%	[]	[0-5]%	
Surefire	[]	[0-5]%	[]	[0-5]%	
Total	[]	100%	[]	100%	

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

(192) The Notifying Party submits that it had strong intellectual property protection in place for high-resolution (Sanger) capillary electrophoresis consumables until 2014, but that this protection has since expired and multiple competitors have started supplying these products.

# 6.4.1.2. The Notifying Party's view

- (193) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure for the following reasons:<sup>159</sup>
  - (a) High-resolution Sanger capillary electrophoresis instruments and consumables are not an essential input for the activity of a CRO like PPD. PPD and companies like it do not typically use high-resolution (Sanger) capillary electrophoresis products but low-resolution capillary electrophoresis products for their everyday processes. PPD only owns [...] high-resolution (Sanger) capillary electrophoresis instruments;
  - (b) To the limited extent that PPD competitors do use high-resolution (Sanger) capillary electrophoresis in their processes, they could turn to alternative sources of supply. Many laboratories have a device in use, and life span is long (15-20 years). Additionally, instruments may be sourced from Promega, through distributors, or from the secondary market (refurbished devices);
  - (c) With respect to consumables, there are competitive alternatives to Thermo Fisher providing equivalent products for use with its devices; and
  - (d) For some applications (c. 30% of processes), customers could turn away from high-resolution (Sanger) capillary electrophoresis entirely, and use next generation sequencing instead;

<sup>158</sup> Market shares for 2018 and 2019 are similar to the ones shown here. The Notifying Party is unable to provide an estimate of volume-based market shares.

<sup>159</sup> Form CO, paragraph 664 et seq.

- (e) CROs or clinical trial sponsors can outsource high-resolution (Sanger) capillary electrophoresis to third party laboratories, as is often done today.
- (194) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure for the following reasons:<sup>160</sup>
  - (a) High-resolution (Sanger) capillary electrophoresis has very limited relevance for CROs such as PPD; Thermo Fisher's sales of high-resolution (Sanger) capillary electrophoresis instruments and consumables made up less than [a very small percentage] of product sales to PPD and competitors and less than [a very small percentage] of PPD's clinical trials involve the testing method;
  - (b) High-resolution (Sanger) capillary electrophoresis is primarily relevant in areas where PPD does not compete, such as diagnostic testing. As Thermo Fisher cannot discriminate between use cases for the device, it would have to foreclose all these customers and incur significant losses. Furthermore, these laboratories procure a broad range of other products from Thermo Fisher, which they could shift to other suppliers in retaliation;
  - (c) The losses described above could not be recouped downstream; the Notifying Party estimates that this would require PPD's profit and revenues for services using high-resolution (Sanger) capillary electrophoresis to grow by a factor of [...] for the instruments and a factor [...] for the consumables excluding any broader retaliation; and
  - (d) Given the limited relevance of high-resolution (Sanger) capillary electrophoresis to CRO service providers, being foreclosed would not affect their ability to compete.

#### 6.4.1.3. The Commission's assessment

- (195) For high-resolution (Sanger) capillary electrophoresis instruments and consumables, the Commission's market investigation will separately assess the scenarios of (i) total foreclosure, *i.e.* foreclosing all Thermo Fisher customers (including customers such as diagnostic laboratories, pharmaceutical companies and research laboratories), and (ii) targeted foreclosure, *i.e.* foreclosing only PPD's direct competitors in laboratory services for clinical development.
- (196) Concerning **total foreclosure**, the Commission considers it is likely that Thermo Fisher would have the **ability** to implement such a strategy. Considering its market share of essentially [90-100]% for high-resolution (Sanger) capillary electrophoresis instruments globally and in the EEA, customers would have limited alternatives to turn to. While the Notifying Party argues the devices have a long life span (15-20 years), a majority of respondents to the Commission's market investigation indicated that the instruments require regular maintenance by Thermo Fisher. <sup>161</sup> For the consumables, contrary to the Notifying Party's arguments, a majority of respondents to the Commission's market investigation did not consider that they could use third

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<sup>160</sup> Form CO, paragraph 670 et seq.

Replies to question 10 of questionnaire Q1 to CRO and laboratory service providers.

party consumables with Thermo Fisher's devices. 162 Outsourcing of high-resolution (Sanger) sequencing would also no longer be an option in case Thermo Fisher would foreclose its entire customer base, as there would be [...]. Finally, while the majority of respondents to the Commission's market investigation did confirm that they can use NGS devices instead for their applications, this was not seen as equivalent, as it would be more expensive and labour intensive. 163

- (197) However, even if Thermo Fisher has the ability to engage in total input foreclosure in the areas of high-resolution (Sanger) capillary electrophoresis instruments and consumables, it would not have the incentive to do so. Considering the very limited relevance of the technique in the context of clinical trials (PPD only used it in [...] out of [...] trials since 2018, and in [...] of those cases it outsourced the technique to a third party laboratory), Thermo Fisher would not be able to recoup its losses upstream with any potential gains downstream. Thermo Fisher's revenues for high-resolution (Sanger) capillary electrophoresis instruments and consumables in 2020 amounted to EUR [...] in 2020 with a margin of [...] for the instruments and [...] for the consumables. By contrast, PPD's revenues in services for which it used the technique only amounted to EUR [...].
- (198) Furthermore, Thermo Fisher can expect broader retaliation on other product groups if it were to engage in such strategy, both by CRO / laboratory providers and their sponsors (pharmaceutical companies), leading to further upstream losses. The majority of pharmaceutical companies that replied to the Commission's market investigation indicate that in the event of their CRO or laboratory service providers being foreclosed, they would consider to use their buyer power in response, for example by moving business for other products away from the merged entity. <sup>164</sup> In line with the above, respondents to the Commission's market investigation did not indicate that they consider Thermo Fisher's incentive to foreclose to increase as a result of the Transaction. <sup>165</sup>
- (199) Considering a **targeted foreclosure** strategy, which specifically targets PPD competitors in the area of clinical development, Thermo Fisher would not have the ability to engage in such strategy. It would have to foreclose both PPD's direct competitors, as well as distributors that make up [...] of EEA instrument sales and [...] of consumables sales in 2020. However, the majority of respondents to the Commission's market investigation indicated that they can outsource their needs for high-resolution (Sanger) capillary electrophoresis. PPD itself also outsources the activity [...] (out of the [...] times it was required since 2018, it outsourced [...] times). Therefore, to implement an input foreclosure strategy successfully, Thermo Fisher would have to implement it broader, which, as discussed above, it does not have the incentive to do.
- (200) Even if the merged entity were to implement a total or targeted input foreclosure strategy, such strategy would likely have a limited *impact* on PPD's competitors in

 $<sup>^{162}</sup>$  Replies to question 8 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>163</sup> Replies to question 7 of questionnaire Q1 to CRO and laboratory service providers.

<sup>164</sup> Replies to question 12 of questionnaire Q3 to pharmaceutical companies.

<sup>&</sup>lt;sup>165</sup> Replies to question 16 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>166</sup> Replies to question 15 of questionnaire Q1 to CRO and laboratory service providers.

laboratory services for clinical development. As set out in paragraph (197), high-resolution (Sanger) capillary electrophoresis is only very rarely used by CRO and laboratory service providers in clinical trials. Therefore, PPD's competitors would be able to compete effectively even if access to high-resolution (Sanger) capillary electrophores is instruments and consumable would be restricted.

- (201) Furthermore, as set out in Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicate that they would consider taking counter-measures in such event.
- (202) In line with the above, respondents to the Commission's market investigation did not raise any concerns in the areas of high-resolution (Sanger) capillary electrophoresis instruments and consumables.<sup>167</sup>

#### 6.4.1.4. Conclusion

(203) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for (i) high-resolution (Sanger) capillary electrophoresis instruments and (ii) high-resolution (Sanger) capillary electrophoresis consumables globally and in the EEA.

#### 6.4.2. Laboratory in vitro diagnostic allergy systems

#### 6.4.2.1. Market structure

(204) The table below show the Notifying Party's market share estimates for laboratory IVD allergy systems overall

Table 4: 2020 value-based market shares for laboratory IVD allergy systems. 168

	Worl	dwide	EEA		
Competitor	Sales value (USD)	Share	Sales value (USD)	Share	
Thermo Fisher	[]	[80-90]%	[]	[70-80]%	
Siemens	[]	[5-10]%	[]	[10-20]%	
Micro Array Diagnostics	[]	[0-5]%	[]	[0-5]%	
Hycor	[]	[0-5]%	[]	[0-5]%	
Total	[]	100%	[]	100%	

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

167 Replies to question 18 of questionnaire Q1 to CRO and laboratory service providers and question 13 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>168</sup> Volume-based market shares and market shares for 2018 and 2019 are similar to the ones shown here.

- (205) The Commission notes that the Thermo Fisher offers tests for more than 550 different allergens. The Notifying Party submits that it has no indication suggesting that suppliers' shares would significantly differ for individual tests, but notes that there are allergy tests, typically for rarer types of allergens, and forming [...] of Thermo Fisher's overall sales of allergy tests, where Thermo Fisher is the only supplier. The Commission notes that market shares for IVD allergy systems at global and EEA level are already very high, and that the outcome of the assessment would not change for specific tests, even if they would be only provided by Thermo Fisher. The Commission further notes the Notifying Party's submission to have no indication that market shares would significantly differ for the customer group of laboratory service providers for clinical development in particular. 169
- (206) As shown in Table 5 below, a potential market for autoimmune disease systems would not be affected at either global or EEA-wide level.<sup>170</sup> The Notifying Party further provides that no affected markets would arise if a further segmentation by specific tests, the narrowest plausible market definition, would be made.<sup>171</sup>

Table 5: 2020 value-based market shares for laboratory IVD autoimmune disease systems.  $^{172}$   $^{173}$ 

	Worl	dwide	EEA		
Competitor	Sales value (USD)	Share	Sales value (USD)	Share	
Thermo Fisher	[]	[5-10]%	[]	[10-20]%	
Euroimmun	[]	[10-20]%	[]	[20-30]%	
Inova	[]	[10-20]%	[]	[10-20]%	
Roche	[]	[5-10]%	[]	[5-10]%	
Siemens	[]	[5-10]%	[]	[5-10]%	
Biorad	[]	[5-10]%	[]	[5-10]%	
Menarini	[]	[0-5]%	[]	[5-10]%	
Abbott	[]	[0-5]%	[]	[5-10]%	
Others	[]	[40-50]%	[]	[10-20]%	
Total	[]	100%	[]	100%	

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

(207) The Commission notes that, in a potential combined market for IVD allergy and autoimmune disease testing systems, Thermo Fisher's market shares would be lower. Market shares levels, and the existence of stronger competitors based on market shares, as indicated in Table 5 above, clearly indicate that customers will be able to

<sup>169</sup> Response to RFI 15, paragraph 1. This submission also applies for IVD autoimmune disease testing systems.

Further, the Commission notes that affected markets would arise if markets were defined national in geographic scope. As explained in Section 5.2.2.2 above, it is unlikely that IVD allergy and autoimmune disease testing systems markets for clinical trial laboratories are narrower than EEA-wide. The Commission did not receive concerns for such instruments in relation to specific national markets.

<sup>171</sup> Form CO, footnote 400.

<sup>172</sup> Volume-based market shares and market shares for 2018 and 2019 are similar to the ones shown here.

<sup>173</sup> The Notifying Party provides that market shares for instruments, reagents and accessories would not differ significantly from market shares at system level for both allergy and autoimmune disease testing products; Form CO, footnote 396.

source IVD autoimmune disease systems from other suppliers, which is confirmed by the market investigation, as explained below in this section. Therefore, the Commission will conduct the competitive assessment on the narrower market for IVD allergy systems, where Thermo Fisher has a significantly stronger market position.

# 6.4.2.2. The Notifying Party's view

- (208) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure, because customers of laboratory IVD allergy systems could turn to another manufacturer. Furthermore, allergy testing is not an essential input for the activity of a company like PPD, and it is not critical to have in-house testing capabilities. If competitors to PPD did not have access to testing products, testing can be outsourced to large laboratory companies, which is already an everyday practice. <sup>174</sup>
- (209) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure. Most sales in the EEA and globally in the area of allergy testing would be generated by providers of diagnostic testing. Given that allergy testing accounts for only a small part of testing undertaken in clinical trials, PPD could not gain additional revenues that would compensate for the sales that the Notifying Party would lose if they wold stop selling to PPD's competitors.<sup>175</sup>

#### 6.4.2.3. The Commission's assessment

- (210) Market shares of Thermo Fisher exceed 30% significantly in a potential global or EEA-wide market for IVD allergy systems to clinical development laboratories, as well as for specific tests. A potential concern arising from these market share levels is therefore input foreclosure of IVD allergy systems. However, it is unlikely that Thermo Fisher would have the ability to foreclose PPD's competitors of IVD allergy systems (targeted foreclosure), but it would need to foreclose a significant part of other market participants as well, *e.g.* laboratories active in the field of diagnostics. It is unlikely that Thermo Fisher would have the incentive to pursue such broad market foreclosure strategy. Further, it is unlikely that input foreclosure of IVD allergy systems would have a significant impact on the downstream market of laboratory services for clinical development, as it is questionable whether such products are important inputs for downstream competitors.
- (211) Firstly, Thermo Fisher has a very strong position in the market for IVD allergy testing systems with very high market shares of [80-90]% at global level and [70-80]% in the EEA, which may be at a similar or, in instances even higher, level for specific tests, as well as to clinical development laboratories, and which is indicative of dominance. Customers<sup>176</sup> rate other manufacturers of IVD allergy testing systems, such as Micro Array, Siemens and Hycor, as being clearly less competitive than Thermo Fisher, which is in line with the market structure.<sup>177</sup> The Commission received mixed

<sup>174</sup> Form CO, paragraph 617 et seq.

<sup>175</sup> Form CO, paragraph 619 et seq.

<sup>&</sup>lt;sup>176</sup> The Commission notes that customers responding to the market investigation are laboratories active in the field of clinical development, in line with the market definition.

<sup>177</sup> Replies to question 28 of questionnaire Q1 to CRO and laboratory service providers.

responses by customers as regards the ability to switch suppliers of IVD allergy testing systems in a scenario in which Thermo Fisher increases prices or restrict access to those products. In any event, three downstream customers indicated they would not be able to switch suppliers. The Commission understands from qualitative feedback that switching is especially difficult once a clinical trial has started. Thermo Fisher's IVD allergy testing devices require regular maintenance by Thermo Fisher. Therefore, it is likely that Thermo Fisher has the ability to foreclose inputs to PPD's competitors at least by way of a broad market foreclosure, which would also apply for specific tests.

- (212) However, it is unlikely that Thermo Fisher would have the ability to target such foreclosure strategy specifically to PPD's customers. The Commission takes note of the fact that a majority of responding customers consider IVD allergy testing systems as essential inputs for laboratory services in the context of clinical trials, and that they would use such products often in the context of clinical trials. 181 However, when quantifying the use of IVD allergy testing systems, those customers who provided a response indicate that they would use such products only in a small number of instances (i.e. below 1% of the total number of trials), or described the number of trials where IVD allergy testing systems are used as "several globally". 182 The Commission further takes note of the Notifying Party's submission that, according to PPD's estimation, [...] of all allergy testing takes place during respiratory and dermatology trials, which represent less than [...] of the clinical trials space, and that allergy testing would be expected to feature in approximately [...] of these types of trials. Of the [...] clinical trials in 2020 that PPD's clinical trial services business was involved in, PPD estimates that [...] required allergy testing. Out of the [...] clinical trials in 2020 for which tests were carried out in PPD's laboratories globally, allergy testing was required in [...] studies. 183 These numbers would be equal or even smaller if a further segmentation by specific tests was made. The Commission finally notes that some significant competitors to PPD in laboratory services in clinical trials, and in fact the majority of customers responding to this question in the market investigation, do not operate any IVD allergy testing devices within the EEA.<sup>184</sup> Similarly, PPD owns [...] Thermo Fisher allergy (and autoimmune testing) device located in the US, [PPD's operations]. 185
- (213) Against this background, the Commission takes note of the fact that a majority of responding competitors of PPD, though not all, indicate that they would be able to outsource IVD allergy testing to third-party laboratories if these services were

<sup>&</sup>lt;sup>178</sup> Replies to question 30 of questionnaire Q1 to CRO and laboratory service providers. The Commission notes that this number appears to be higher for autoimmune disease testing systems, where customers have the ability to source from other suppliers.

<sup>179</sup> Replies to question 30.1 of questionnaire Q1 to CRO and laboratory service providers. The Commission notes that this barrier likely also exist for IVD autoimmune testing products.

<sup>&</sup>lt;sup>180</sup> Replies to question 26 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>181</sup> Replies to question 31 and 32 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>182</sup> Replies to question 31.1 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>183</sup> Form CO, paragraph 621.

<sup>&</sup>lt;sup>184</sup> Replies to question 25 of questionnaire Q1 to CRO and laboratory service providers.

<sup>185</sup> Form CO, paragraph 601.

required in the context of a clinical trial. <sup>186</sup> The Commission notes that in 2020, PPD outsourced [...] of the allergy testing, and performed such services in-house in [...] of the [...] clinical trials for which it carried out tests in its laboratories and of the [...] trials its clinical trial service business was involved in. <sup>187</sup> Consequently, Thermo Fisher would not have the ability to target a potential foreclosure strategy to customers of PPD, which still could outsource IVD allergy testing to third-party laboratories, but would need to foreclose a broad spectrum of the market to prevent PPD's competitors from accessing such services.

- (214) In the market investigation, the Commission received concerns by customers specifically also for IVD autoimmune diseases testing systems, 188 and notes that Thermo Fisher supplies a device that can be used for both IVD allergy and IVD autoimmune disease testing. As for IVD autoimmune testing systems, however, the Commission notes that customers rate at least one other supplier (Bio-Rad) as very suitable for the demand of their company, and other competitors as generally suitable, even though to a significantly lesser degree then Thermo Fisher. The Commission further notes that a majority of customers indicate they would be able to switch to other suppliers for autoimmune testing systems in case of a foreclosure strategy by Thermo Fisher. 189 This is in line with the market shares as presented in Table 5. One customer explained: "The auto immune panel can be moved to BioPlex 200 from Biorad. For allergy, Thermo Fisher is the leader, trusted by clients and physicians". 190 Responses to the market investigation did not suggest that such assessment would change for any specific test. Against this background, and in light of Thermo Fisher's moderate market shares for autoimmune disease testing systems, it is unlikely that Thermo Fisher would have the ability to foreclose downstream competitors of this product.
- (215) Secondly, the Commission takes note of the Notifying Party's submission regarding the loss of upstream revenue it would need to recoup by winning additional downstream business for PPD. In 2020, Thermo Fisher generated a turnover of approximately EUR [...] with sales to CROs and laboratories in the area of clinical development and diagnostics, the latter to which PPD's customers could potentially outsource allergy testing services. <sup>191</sup> As Thermo Fisher's upstream margin for allergy testing systems was [...], those sales equal a profit of approximately EUR [...] that Thermo Fisher would lose upstream in the event of such foreclosure. Further, the Notifying Party notes that the total revenues for clinical trials that used IVD allergy systems and in which PPD was involved in 2020 amount to approximately EUR [...]. As PPD's downstream margin for clinical trial and laboratory services is approximately [...], the corresponding profit was approximately EUR [...] in 2020. Therefore, PPD would need to increase its business from clinical trials using IVD

 $<sup>^{186}</sup>$  Replies to question 33 of questionnaire Q1 to CRO and laboratory service providers; this assessment also applies to IVD autoimmune disease testing.

<sup>&</sup>lt;sup>187</sup> Form CO, paragraphs 621 and 623.

<sup>&</sup>lt;sup>188</sup> Replies to question 36 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>189</sup> Replies to question 27 and 30 of questionnaire Q1 to CRO and laboratory service providers.

<sup>190</sup> Replies to question 30.1 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>191</sup> The figure does not include sales to, for example, hospitals, to which PPD's competitors would likely not outsource allergy testing services.

allergy testing by approximately [...] times to make up for its upstream losses. <sup>192</sup> In the view of the Commission, it appears unlikely that the merged entity would be able to recoup upstream losses by additional downstream business in the event of input foreclosure to CRO's and laboratories in the area of clinical development and diagnostics. Therefore, the merged entity will likely not have the incentive for such strategy.

- (216) Thirdly, it is questionable whether input foreclosure of IVD allergy testing products would indeed have an impact on the laboratory service market for clinical development. Three customers raised concerns in relation to allergy testing systems in the context of the market investigation. One customer (i.e. competitor of PPD) substantiates these concerns with the access to information PPD may obtain via Thermo Fisher as regards the business of a competitor. The concern of information sharing is further discussion in Section 6.5.1 of this Decision. A second customer submitted that switching suppliers would entail additional costs, but also explains that "there are alternatives to Thermo Fisher" and that it would therefore be "not particularly concerned". A third customer explained its concerns inter alia with a potential impact of input foreclosure on ongoing trials. However, the customer also provides that Thermo Fisher's incentive to sell IVD allergy disease testing products to its company would likely remain the same, unless there were issues in the supply chain or manufacturing of such products, in which case Thermo Fisher may grant PPD preferential treatment. 193 The Commission considers that, on balance, these concerns, while considered carefully in the assessment of the Transaction, may not suggest a strong and direct impact on the laboratory service market in the context of clinical development linked to the supply of IVD allergy systems.
- (217) Further, the Commission notes the fact that IVD allergy systems, for which Thermo Fisher has high market shares, are not frequently used in the context of clinical development, as explained in paragraph (212). The number of use cases would be equal or even lower for specific tests. Therefore, input foreclosure may have an impact on competition between laboratory service providers for few specific clinical trials. However, it is questionable whether not having access to such products would in fact drive costs of downstream rivals upwards and thereby harm competition in an overall laboratory service market for clinical development.
- (218) Furthermore, as set out Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher

Replies to question 36, 36.1 and 37 of questionnaire Q1 to CRO and laboratory service providers. The Commission notes that no customer and no competitor has experienced any significant shortages in IVD allergy or IVD autoimmune testing devices in the past three years, and only one customer, forming a clear minority, and no competitor, has experienced shortages in IVD allergy and autoimmune testing reagents; replies to question 29 of questionnaire Q1 to CRO and laboratory service providers, and to question 23 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>192</sup> Form CO, paragraphs 619 et seq. The Notifying Party notes that this calculation does not include potential retaliation by PPD's competitors or other market participants (*e.g.* sponsors of clinical trials), which would make an input foreclosure strategy even less profitable.

would suffer if it would foreclose PPD's downstream competitions, and indicate that they would consider taking counter-measures in such event.

(219) Lastly, the Commission notes that, during the market investigation, three upstream competitors of Thermo Fisher, forming the minority of all such respondents, raised concerns with regard to IVD allergy and autoimmune testing instruments, and two of them also on the respective reagents. All three companies substantiated their concerns with potential customer foreclosure, *i.e.* PPD not sourcing IVD allergy and autoimmune testing products from third parties. While the potential loss of a theoretical or actual customer may be a commercial concern, the Commission considers it highly unlikely that the merged entity will have the ability to impede effective competition by engaging in customer foreclosure. This is because PPD's market shares in the market for laboratory services for clinical development are small at both global ([5-10]%) and EEA-wide ([0-5]%) level. It has to be noted that IVD allergy and autoimmune testing products are not only used for clinical development, but also in other areas of laboratory services, where PPD is not active, such as diagnostics, and that, as explained above, PPD [PPD's operations] only accounts for a negligible share of the overall demand for such products.

#### 6.4.2.4. Conclusion

(220) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for IVD allergy testing systems<sup>195</sup>, or any specific tests, in an EEA-wide or global market.

# 6.4.3. CO<sub>2</sub> incubators

#### 6.4.3.1. Market structure

(221) The table below shows the Notifying Party's market share estimates for CO2 incubators.

 $<sup>^{194}</sup>$  Replies to question 27 and 27.1 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>195</sup> The Commission notes that, as explained in this section, no such concerns would arise neither for IVD autoimmune diseases testing systems under any plausible market definition.

Table 6: 2020 value-based market shares for CO2 incubators. 196

	Worl	dwide	EEA		
Competitor	Sales value (USD)	Share	Sales value (USD)	Share	
Thermo Fisher	[]	[60-70]%	[]	[50-60]%	
Panasonic	[]	[10-20]%	[]	[10-20]%	
Eppendorf	[]	[5-10]%	[]	[10-20]%	
Binder	[]	[5-10]%	[]	[5-10]%	
Memmert	[]	[5-10]%	[]	[5-10]%	
NuAire	[]	[0-5]%	[]	[0-5]%	
Esco	[]	[0-5]%	[]	[0-5]%	
Others	[]	[0-5]%	[]	[0-5]%	
Total	[]	100%	[]	100%	

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

# 6.4.3.2. The Notifying Party's view

- (222) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure. [...] of Thermo Fisher's CO2 incubator sales are generated through third-party distributors, and [...] Thermo Fisher's CO2 incubators sold directly are also available for purchase through third-party distributors. Furthermore, there is significant competition for the sale of CO2 incubators and there are no significant technological or functional differences between Thermo Fisher and other manufacturers' products. Lastly, Thermo Fisher's CO2 incubators are not critical inputs for PPD's competitors' services overall PPD's conservatively estimates that services using CO2 incubators account for approximately [...] of its total clinical trial services revenues, which indicated that CO2 incubators are not a major component of CRO services.<sup>197</sup>
- (223) The Notifying Party submits that it would also not have the incentive to do so because the losses from a hypothetical foreclosure strategy would far outweigh any gains in profit. If Thermo Fisher attempted to foreclose PPD's competitors, it would lose significant revenues, as it would also need to foreclose its third-party distributors for CO2 incubators. 198

#### 6.4.3.3. The Commission's assessment

(224) Market shares of Thermo Fisher exceed 30% in a potential global or EEA-wide market for CO2 incubators. A potential concern arising from these market share levels is therefore input foreclosure. It is, however, questionable if Thermo Fisher would have the ability to foreclose downstream customers, and unlikely that it would have the incentive to do so. Further, market participants do not foresee a negative impact as a result of the Transaction.

<sup>196</sup> Volume-based market shares and market shares for 2018 and 2019 are similar to the ones shown here.

<sup>197</sup> Form CO, paragraph 269 et seq.

<sup>198</sup> Form CO, paragraph 273 et seq.

- (225) Firstly, Thermo Fisher holds a very strong position in the market for CO2 incubators both at global and EEA-wide level with market shares of [60-70]% and [50-60]% respectively, as shown in Table 6 above, which is indicative of dominance. Even though two significant competitors (Panasonic and Eppendorf) would remain available to downstream customers, the market power of Thermo Fisher suggests that it may have the ability for input foreclosure.
- (226) On the other hand, downstream customers responding to the market investigation submit that they would not depend on the supply of CO2 incubators by Thermo Fisher. Apart from Thermo Fisher, customers rate a number of other manufacturers as equally suitable supplier to their company, namely Eppendorf, Esco, NuAire and Binder. 199 In line with this, all customers providing an opinion on this question indicate that they would be able to switch suppliers if Thermo Fisher were to increase prices or restrict access to CO2 incubators post-Transaction. One reason for this view may be that CO2 incubators appear to be easier to exchange compared to other products, as they may not have a potential impact on the testing results in clinical trials. One customer explained: "CO2 incubators are part of sample processing and do not generate patient results. As long as the specifications are the same, and they are suitable qualified they can be substituted."200 All upstream competitors active in the supply of CO2 incubators responding to the market investigation indicate that they would be able to significantly increase supply of CO2 incubators in case of increased demand, but submit at the same time that entry into the market for CO2 incubators would be difficult or very difficult.<sup>201</sup>
- (227) On balance, the Commission considers that the market structure indicates that Thermo Fisher may have the ability for input foreclosure. However, in the light of the clear market feedback, it appears questionable if Thermo Fisher would, in practice, be able to use its market power upstream for such a strategy, and more likely that downstream customers would be able to switch away to other suppliers, who would be able to take market shares from Thermo Fisher.
- (228) Secondly, the Commission takes note of the Notifying Party's submission that [...] of Thermo Fisher's sales of CO2 incubators would be made through third-party distributors. <sup>202</sup> In the light of this, Thermo Fisher would not have the ability for a targeted foreclosure of PPD's competitors, as it does not control to what end customer its products are supplied to, but would need to foreclose independent distributors as well, which would result in a loss of sales to other end-customers for CO2 incubators, for example laboratories active in areas other than clinical development. However, it is unlikely that Thermo Fisher would have the incentive for such broad foreclosure. In such scenario, Thermo Fisher would lose upstream profit of approximately EUR [...]. PPD's downstream profit associated with clinical trial services using CO2 incubators was EUR [...] approximately. The Notifying Party submits that this calculation was highly conservative, as CO2 incubators would only be an incremental input to such services. <sup>203</sup> Even in such scenario, PPD would have to grow its profit connected to

<sup>&</sup>lt;sup>199</sup> Replies to questions 41 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>200</sup> Replies to questions 44 and 44.1 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>201</sup> Replies to questions 32 and 34 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>202</sup> Form CO, paragraph 269.

<sup>&</sup>lt;sup>203</sup> Form CO, paragraphs 275 et seq.

- CO2 incubators by [...] to recoup upstream losses, which in the Commission's view appear unlikely, also in the light of the fact that customers consider to be able to switch to other suppliers, as explained above.
- (229) Thirdly, the Transaction is unlikely to have an impact on the competitiveness on downstream companies competing with PPD or potential entrants into the downstream market with regard to the supply of CO2 incubators. In the market investigation, no responding customers expressed concerns with regard to CO2 incubators. Similarly, no upstream competitor to Thermo Fisher raised concerns connected to the supply of CO2 incubators. 205
- (230) Furthermore, as set out in Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider taking counter-measures in such event.

#### 6.4.3.4. Conclusion

(231) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for CO2 incubators in an EEA-wide or global market.

#### 6.4.4. *Chromatography instruments and columns*

#### 6.4.4.1. Market structure

(232) Below tables show the Notifying Party's market share estimates for ion chromatography instruments and pre-filled ion chromatography columns.

Table 7: 2020 value-based market shares for ion chromatography instruments.<sup>206</sup>

	Worl	dwide	EEA		
Competitor	Sales value (USD)	Share	Sales value (USD)	Share	
Thermo Fisher	[]	[50-60]%	[]	[40-50]%	
Metrohm	[]	[30-40]%	[]	[40-50]%	
Shimadzu	[]	[0-5]%	[]	[0-5]%	
Shine	[]	[0-5]%	Not available	Not available	
Others	[]	[0-5]%	[]	[5-10]%	
Total	[]	100%	[]	100%	

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

204 Replies to questions 47 of questionnaire Q1 to CRO and laboratory service providers.

<sup>205</sup> Replies to questions 37 of questionnaire Q2 to Thermo Fisher competitors.

<sup>206</sup> Volume-based market share and market shares for 2018 and 2019 are similar to the ones shown here. EEA market shares include the UK, as the Notifying Party is unable to provide market shares estimates for competitors excluding the UK.

Table 8: 2020 value-based market shares for pre-filled ion chromatography columns.<sup>207</sup>

	Worl	dwide	EEA		
Competitor	Sales value (USD)	Share	Sales value (USD)	Share	
Thermo Fisher	[]	[50-60]%	[]	[50-60]%	
Metrohm	[]	[30-40]%	[]	[30-40]%	
Others	[]	[5-10]%	[]	[5-10]%	
Total	[]	100%	[]	100%	

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

#### 6.4.4.2. The Notifying Party's view

- (233) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure for the following reasons:<sup>208</sup>
  - (a) PPD competitors have multiple competitive alternatives to Thermo Fisher for ion chromatography instruments and pre-filled ion chromatography columns and can procure pre-filled ion chromatography columns through distributors;
  - (b) PPD competitors could switch to other technologies, such HPLC, as an alternative to ion chromatography or purchase a Thermo Fisher ion chromatograph on the secondary market;
  - (c) Ion chromatographs are not critical inputs to PPD's competitors' services. PPD has not used Thermo Fisher ion chromatography instruments for clinical trials in the last [...] years;
  - (d) Switching providers of ion chromatography supplies does not incur significant switching costs and can be accomplished in 2-3 weeks; and
  - (e) Pharmaceutical and biotechnology companies could source ion chromatography supplies on behalf of the CROs they work with, or laboratories without CRO activities could perform the tests using ion chromatography instruments on behalf of PPD's competitors.
- (234) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure for the following reasons:<sup>209</sup>
  - (a) A foreclosure strategy related to ion chromatography instruments is unlikely to raise other CROs' costs. PPD estimates that the procurement cost of ion chromatographs accounts for less than [a very small percentage] of the annual total costs of its GMP laboratory, the segment that uses these instruments;
  - (b) Lost sales upstream would far outweigh any potential gains downstream. Thermo Fisher estimates that PPD's profits from services using ion

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<sup>207</sup> Volume-based market share and market shares for 2018 and 2019 are similar to the ones shown here.

<sup>&</sup>lt;sup>208</sup> Form CO, paragraph 479 et seq. and 511 et seq.

<sup>&</sup>lt;sup>209</sup> Form CO, paragraph 485 et seq. and 516 et seq.

- chromatography instruments need to grow by a factor of [...] and pre-filled ion chromatography columns by a factor of [...] to recoup upstream cost; and
- (c) PPD competitors and their pharmaceutical and biotechnology clients source a wide variety of products from Thermo Fisher, and could retaliate in response to any attempt at input foreclosure.

#### 6.4.4.3. The Commission's assessment

- (235) The Commission notes that in the markets for ion chromatography instruments and consumables, Thermo Fisher faces one competitor with a similar market share, Metrohm, as well as several smaller competitors.
- (236) CRO and laboratory service providers that responded to the Commission's market investigation rated these alternative competitors as suitable options to supply their company. Furthermore, respondents indicated that they are able to switch suppliers for ion chromatographs and pre-filled ion chromatography columns. 211
- (237) Considering the pre-filled ion chromatography columns specifically, a significant number of Thermo Fisher competitors that responded to the Commission's market investigation indicated to be able to supply pre-filled ion chromatography columns that are compatible with Thermo Fisher's instruments. Furthermore, the majority of Thermo Fisher competitors active in ion chromatography that responded to the Commission's market investigation indicated that they are able to significantly increase supply in case of surging demand. Figure 213
- Based on the above, it is unlikely that the merged entity will have the ability to engage in input foreclosure with respect to ion chromatography instruments and pre-filled ion chromatography columns post-Transaction. Even if Thermo Fisher did have the ability to do so, it likely would not have the incentive, and impact of such foreclosure would be limited. Ion chromatography only enjoys limited use in the context of clinical trials. PPD estimates that it used ion chromatography in less than [a very small percentage] of its laboratory activities by revenue, and that ion chromatography makes up less than [a very small percentage] of annual procurement cost.<sup>214</sup> Several CRO and laboratory service providers that responded to the Commission's market investigation indicated that while they do use chromatography in their business, they do not frequently use ion chromatography. One explains: "Our labs typically use HPLC and UPLC analytical columns but rarely have applications that need ion chromatography."215 Furthermore, respondents indicate that chromatography analyses can also be performed on high pressure liquid chromatographs.<sup>216</sup>

<sup>&</sup>lt;sup>210</sup> Replies to questions 57 and 58 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>211</sup> Replies to question 56 of questionnaire Q1 to CRO and laboratory service providers.

<sup>212</sup> Replies to question 40 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>213</sup> Replies to question 42 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>214</sup> Form CO, paragraph 517.

<sup>&</sup>lt;sup>215</sup> Replies to question 49 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>216</sup> Replies to question 51 of questionnaire Q1 to CRO and laboratory service providers.

- (239) Consistent with the above, the large majority of respondents to the Commission market investigation indicate that they do not expect Thermo Fisher's incentive to engage in input foreclosure with respect to ion chromatography instruments and consumables to change post-Transaction. Furthermore, the large majority of respondents did not express any concerns for these markets in response to the Commission's market investigation. A minority of Thermo Fisher competitors indicated concern about losing PPD as a customer for ion chromatography instruments and pre-filled ion chromatography columns. However, in view of PPD's limited market share on the downstream market and its limited purchases of ion chromatography instruments (EUR [...] globally and EUR [...] in the EEA) and pre-filled ion chromatography columns (EUR [...] globally and EUR [...] in the EEA) customer foreclosure concerns cannot arise.
- (240) Furthermore, as set out Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider taking counter-measures in such event.

#### 6.4.4.4. Conclusion

(241) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for (i) ion chromatography instruments and (ii) prefilled ion chromatography columns globally and in the EEA.

#### 6.4.5. Electrophoresis gels

#### 6.4.5.1. Market structure

(242) Below tables show the Notifying Party's market share estimates for precast electrophoresis gels for vertical gel electrophoresis and molecular weight standards for vertical gel electrophoresis.

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<sup>&</sup>lt;sup>217</sup> Replies to question 61 of questionnaire Q1 to CRO and laboratory service providers and question 46 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>218</sup> Replies to question 62 of questionnaire Q1 to CRO and laboratory service providers and question 47 of questionnaire Q2 to Thermo Fisher competitors.

Table 9: 2020 value-based market shares for precast electrophoresis gels for vertical gel electrophoresis.<sup>219</sup>

	Worl	dwide	EEA		
Competitor	Sales value (USD)	Share	Sales value (USD)	Share	
Thermo Fisher	[]	[40-50]%	[]	[50-60]%	
Bio-Rad	[]	[40-50]%	[]	[30-40]%	
GenScript	[]	[0-5]%	[]	[0-5]%	
Merck Millipore Sigma	[]	[0-5]%	[]	[0-5]%	
Others	[]	[5-10]%	[]	[5-10]%	
Total	[]	100%	[]	100%	

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

Table 10: 2020 value-based market shares for molecular weight standards for vertical gel electrophoresis.<sup>220</sup>

	Worl	dwide	EEA		
Competitor	Sales value (USD)	Share	Sales value (USD)	Share	
Thermo Fisher	[]	[30-40]%	[]	[40-50]%	
Bio-Rad	[]	[40-50]%	[]	[30-40]%	
Merck Millipore Sigma	[]	[0-5]%	[]	[0-5]%	
Others	[]	[10-20]%	[]	[20-30]%	
Total	[]	100%	[]	100%	

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

(243) The tables show that for both markets, Thermo Fisher is the second largest player worldwide after Bio-Rad. However, Thermo Fisher has a stronger position than Bio-Rad in the EEA for both markets.

## 6.4.5.2. The Notifying Party's view

- (244) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure for the following reasons:<sup>221</sup>
  - (a) Thermo Fisher sells its vertical gel electrophoresis consumables directly as well as through distributors, making it hard or impossible to selectively foreclose PPD's rivals;
  - (b) Market leader Bio-Rad, as well as other smaller suppliers, could easily increase their production capacities in response to new demand;
  - (c) PPD competitors could easily switch to a competitive alternative;

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Market shares for 2018 and 2019 are similar to the ones shown here. Thermo Fisher's volume market shares are slightly lower than the value market shares, at [30-40]% worldwide and [40-50]% in the EEA.

<sup>&</sup>lt;sup>220</sup> Volume-based market shares and market shares for 2018 and 2019 are similar to the ones shown here.

<sup>&</sup>lt;sup>221</sup> Form CO, paragraph 571 et seq.

- (d) Thermo Fisher's precast protein gels for vertical gel electrophoresis are not a critical input to any downstream service offered by a PPD competitor; and
- (e) PPD's competitors could switch to an alternative supplier of vertical gel electrophoresis instruments, which also provide all consumables.
- (245) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure for the following reasons:<sup>222</sup>
  - (a) Lost sales upstream would far outweigh any potential gains downstream. Stopping to supply PPD competitors would not lead to increased sales downstream as they have other options for vertical gel electrophoresis consumables; and
  - (b) PPD competitors and their pharmaceutical and biotechnology clients source a wide variety of products from Thermo Fisher, and could retaliate in response to any attempt at input foreclosure.

## 6.4.5.3. The Commission's assessment

- (246) The Commission notes that Thermo Fisher faces a strong competitor, Bio-Rad, in the areas of precast protein gels for vertical gel electrophoresis and molecular weight standards for vertical gel electrophoresis. Bio-Rad is the market leader on global basis in terms of market share. This reduces Thermo Fisher's ability to successfully engage in input foreclosure for these products.
- (247) CRO and laboratory services providers that responded to the Commission's market investigation rated Bio-Rad, as well as other suppliers such as Lonza and Merck Millipore Sigma, as strong suppliers. Additionally, they indicated that they would be able to switch away to alternative suppliers if Thermo Fisher were to increase prices or restrict access to these products. 224
- (248) Even if Thermo Fisher would have the ability to foreclose access to precast protein gels for vertical gel electrophoresis and molecular weight standards for vertical gel electrophoresis, it would likely not have incentive to do so and impact on the downstream markets would remain limited. PPD [...], showing that they do not play a significant role in the downstream markets. Thermo Fisher's total sales of the upstream product amounted to EUR [...] for precast protein gels for vertical gel electrophoresis and EUR [...] for molecular weight standards for vertical gel electrophoresis. Consistent with this, respondents to the Commission's market investigation did not anticipate that Thermo Fisher's incentive to engage in input foreclosure would change as a result of the Transaction. 225
- (249) In line with the above, the vast majority of respondents to the Commission's market investigation did not express any concerns with respect to precast protein gels for

<sup>&</sup>lt;sup>222</sup> Form CO, paragraph 572 et seq.

<sup>&</sup>lt;sup>223</sup> Replies to question 69 of questionnaire Q1 to CRO and laboratory service providers.

Replies to question 73 of questionnaire Q1 to CRO and laboratory service providers.

Replies to question 74 of questionnaire Q1 to CRO and laboratory service providers and question 57 of questionnaire Q2 to Thermo Fisher competitors.

- vertical gel electrophoresis and molecular weight standards for vertical gel electrophoresis. 226
- (250) Furthermore, as set out in Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider taking counter-measures in such event.

## 6.4.5.4. Conclusion

(251) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for (i) precast electrophoresis gels for vertical gel electrophoresis and (ii) molecular weight standards for vertical gel electrophoresis globally and in the EEA.

#### 6.4.6. Cell culture sera

#### 6.4.6.1. Market structure

(252) Table 11 below shows the Notifying Party's market share estimates for cell culture sera for the Parties and their main competitors. Table 12 shows market shares for all potential segments of cell culture sera affected by the Transaction.

Table 11: 2020 value-based market shares for cell culture sera for research. 227

	Worldwide		EEA	
Competitor	Sales value (USD)	Share	Sales value (USD)	Share
Thermo Fisher	[]	[40-50]%	[]	[30-40]%
Merck Millipore Sigma	[]	[10-20]%	[]	[10-20]%
Danaher-Cytiva	[]	[10-20]%	[]	[10-20]%
Corning	[]	[5-10]%	[]	[5-10]%
VWR	[]	[5-10]%	[]	[5-10]%
Moregate	[]	[0-5]%	[]	[0-5]%
Others	[]	[10-20]%	[]	[10-20]%
Total	[]	100%	[]	100%

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

226 Replies to question 76 of questionnaire Q1 to CRO and laboratory service providers and question 58 of questionnaire Q2 to Thermo Fisher competitors.

<sup>227</sup> Volume-based market shares and market shares for 2018 and 2019 are similar to the ones shown here.

Table 12: 2020 value-based market shares of Thermo Fisher for potential segments of cell culture sera for research. <sup>228</sup>

	Worldwide		EEA	
Product	Sales value (USD)	Share	Sales value (USD)	Share
All sera	[]	[40-50]%	[]	[30-40]%
Australian and New Zealand FBS	[]	[30-40]%	[]	[20-30]%
Australian FBS	[]	[30-40]%	[]	[20-30]%
NZ FBS	[]	[40-50]%	[]	[30-40]%
US and Canadian FBS	[]	[40-50]%	[]	[20-30]%
US FBS	[]	[40-50]%	[]	[20-30]%
Canadian FBS	[]	[40-50]%	[]	[0-5]%
South American FBS	[]	[40-50]%	[]	[50-60]% <sup>229</sup>
Adult bovine sera, New Zealand origin	[]	[30-40]%	[]	[10-20]%
Porcine sera	[]	[30-40]%	[]	[10-20]%
Equine sera	[]	[30-40]%	[]	[30-40]%

Source: Notifying Party, Form CO, Table 26.

## 6.4.6.2. The Notifying Party's view

(253) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure.<sup>230</sup> If Thermo Fisher attempted a foreclosure strategy, customers could easily switch sourcing for all types of research sera to other manufacturers and a number of smaller competitors. All of the major suppliers provide a range of different sera products for research and many of these competitors use distributors to sell their products in the EEA. Therefore, switching from one supplier of sera for research to another supplier of sera for research is not difficult.<sup>231</sup>

(254) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure. <sup>232</sup> Any potential gain to PPD would be small compared to the potential for lost sales for Thermo Fisher. Sera products typically constitute only a very small percentage of costs for laboratories and CROs so that changes in the price of sera do not significantly impact their overall cost position regarding the services for which they compete with PPD. Likewise, CROs, laboratories, and their

<sup>228</sup> Volume-based market shares and market shares for 2018 and 2019 are similar to the ones shown here.

As market shares are particularly high in the EEA-wide market for South American FBS, the Commission notes the following market shares for competitors in this market, as provided by the Notifying Party: Merck Millipore Sigma ([10-20]%), Danaher-Cytiva ([10-20]%); VWR ([0-5]%), Coming ([0-5]%), others ([10-20]%).

<sup>230</sup> Form CO, paragraph 310 et seq.

<sup>231</sup> In the Form CO, the Notifying Party provided equivalent and/or similar arguments for South American FBS sera for which Thermo Fisher holds [50-60]% market share, paragraph 312 et seq.

<sup>&</sup>lt;sup>232</sup> Form CO, paragraph 311 et seq.

pharmaceutical and biotech clients have various possibilities to punish or pressure Thermo Fisher if they were dissatisfied with Thermo Fisher's sera supply policy to PPD competitors.<sup>233</sup>

#### 6.4.6.3. The Commission's assessment

- (255) Market shares of Thermo Fisher exceed 30% in a market for all cell culture sera, and in ten potential segments of sera at worldwide level, and in three of such segments at EEA-level. A potential concern arising from these market share levels is therefore input foreclosure of cell culture sera overall and some types of sera. However, Thermo Fisher would likely not have the ability or incentive to engage in such a strategy, and such strategy would likely not have an impact on competition.
- (256) Firstly, the Commission notes that Thermo Fisher's upstream market shares for all types of sera combined [amount to 40-50%] at global level, and [amount to 30-40%] in an EEA-wide market. There are at least two other significant competitors in the market (Merck Millipore Sigma and Danaher-Cytiva), while other non-negligible competitors remain present. For some types of sera, Thermo Fisher's market shares [amount to 40-50%]. In the view of the Commission, such market structure as presented in Tables 11 and 12 above indicates significant market power by Thermo Fisher in some segments of the sera market, but also the presence of credible competitors.
- (257) In the market investigation, customers of Thermo Fisher indicated Merck Millipore Sigma and VWR as a more suitable supplier for sera to their company than Thermo Fisher, and attributed a still favourable rating to Corning. All customers that formed an opinion in the market investigation responded that they would be able to switch to other suppliers if Thermo Fisher would restrict access to cell culture sera. The Commission notes, however, that there are some barriers to switching a sera provider, as new products may need to be tested as to their suitability. All but one customer expressing an opinion in the market investigation further submit to be able to source Thermo Fisher cell culture sera via third-parties, *e.g.* distributors or sponsors of the respective clinical trial. Based on the above, and especially on market feedback, Thermo Fisher would likely not have the ability to foreclose downstream competitors of cell culture sera, despite considerable market shares especially for some segments of this market.

<sup>&</sup>lt;sup>233</sup> In the Form CO, the Notifying Party provided equivalent and/or similar arguments for South American FBS sera for which Thermo Fisher holds [50-60]% market share, paragraph 312 et seq.

<sup>&</sup>lt;sup>234</sup> The Commission received mixed reviews for Danaher-Cytiva based on only two responses for this particular competitor.

Replies to questions 94 of questionnaire Q1 to CRO and laboratory service providers. The Commission notes that one customer who indicated to not know whether the company could switch or not, provided in response to a different question concerning sera that, to the best if its knowledge, it would only be able to obtain cell culture sera from Thermo Fisher, and would not be able to source sera from a third party or sponsors of a clinical trial. The Commission notes that this particular respondent did not indicate to have concerns as regards the Transaction in relation to cell culture media, and that its view forms, in any event, a clear minority opinion among all customers responding to the market investigation.

<sup>&</sup>lt;sup>236</sup> Replies to question 94.1 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>237</sup> Replies to question 92 of questionnaire Q1 to CRO and laboratory service providers.

- (258) Secondly, because downstream competitors would have alternatives available to source cell culture sera from, as explained in paragraphs (256) and (257) above, the merged entity would likely not be able to recoup upstream losses by additional gains downstream, and therefore would likely not have the incentive for input foreclosure.
- (259) Particularly with respect to South American FBS, for which Thermo Fisher's market shares reach [50-60]% in an EEA-wide market, the Commission takes note of the Notifying Party's submission that PPD's profit associated with laboratory services that use South American FBS sera was approximately EUR [...] globally, while Thermo Fisher's upstream profit from sales to PPD's competitors amounted to EUR [...]. Consequently, PPD would approximately need to [...] its profit associated with the use of South American FBS to recoup upstream losses by Thermo Fisher. <sup>238</sup> The Commission acknowledges that this scenario appears unlikely, given the fact that other suppliers are available for PPD's competitors.
- (260) Thirdly, the Transaction is unlikely to have an impact on the competitiveness on downstream companies competing with PPD or potential entrants into the downstream market with regard to the supply of cell culture sera or any particular type thereof. In the market investigation, no responding customers expressed concerns with regard to cell culture sera or any potential market segment.<sup>239</sup> Similarly, the majority of upstream competitors to Thermo Fisher indicated to have no concerns as regards to any type of sera.<sup>240</sup>
- (261) The Commission notes that potential concerns based on customer foreclosure are likely not substantiated because of PPD's small downstream market shares in the market for laboratory services for clinical development both at global ([5-10]%) and EEA-wide ([0-5]%) level. Furthermore, cell culture sera may not only be used for clinical development, but also in other areas of laboratory services, where PPD is not active.
- (262) Furthermore, as set out Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider taking counter-measures in such event.

# 6.4.6.4. Conclusion

(263) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to

<sup>&</sup>lt;sup>238</sup> Form CO, paragraph 312.

<sup>&</sup>lt;sup>239</sup> Replies to questions 97 of questionnaire Q1 to CRO and laboratory service providers.

Replies to questions 76 of questionnaire Q2 to Thermo Fisher competitors. One upstream competitor submitted that Thermo Fisher may raise prices for downstream competitors, while acknowledging that this may provide other suppliers with the opportunity to win business. For the reasons set out in this section, however, such input foreclosure is an unlikely scenario.

vertical effects for cell culture sera or any potential segment of this market in an EEA-wide or global market.

# 6.4.7. Cell culture media

## 6.4.7.1. Market structure

(264) Below tables show the Notifying Party's market share estimates for cell culture media.

Table 13: 2020 value-based market shares for cell culture media for research. 241

	Worldwide		EEA	
Competitor	Sales value (USD)	Share	Sales value (USD)	Share
Thermo Fisher	[]	[40-50]%	[]	[30-40]%
Merck Millipore Sigma	[]	[10-20]%	[]	[10-20]%
Corning	[]	[5-10]%	[]	[5-10]%
Lonza	[]	[5-10]%	[]	[5-10]%
Danaher-Cytiva	[]	[5-10]%	[]	[5-10]%
FujiFilm Irvine	[]	[5-10]%	[]	[5-10]%
Others	[]	[20-30]%	[]	[30-40]%
Total	[]	100%	[]	100%

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

<sup>&</sup>lt;sup>241</sup> Volume-based market shares and market shares for 2018 and 2019 are similar to the ones shown here.

Table 14: 2020 value-based market shares of Thermo Fisher for potential segments of cell culture media for research. 242

	Worldwide		EEA	
Product	Sales value (USD)	Share	Sales value (USD)	Share
All media	[]	[40-50]%	[]	[30-40]%
Liquid media	[]	[40-50]%	[]	[30-40]%
Dry media	[]	[30-40]%	[]	[30-40]%
Process liquids	[]	[50-60]% <sup>243</sup>	[]	[40-50]%
Custom media	[]	[40-50]%	[]	[30-40]%
Proprietary media	[]	[30-40]%	[]	[30-40]%
Standard basal media	[]	[50-60]% <sup>244</sup>	[]	[40-50]%
Chemically defined media	[]	[30-40]%	[]	[30-40]%

Source: Notifying Party, Form CO, Table 28 and Annex 7.2-7.4 to the Form CO.

## 6.4.7.2. The Notifying Party's view

(265) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure.<sup>245</sup> Customers can source all types of cell culture media for research from other manufacturers and cell culture media for bio-production is identical to, and therefore exercises competitive pressure on, cell culture media for research. In addition, cell culture media products of different manufacturers are available for sale through distributors, which gives customers easy access to cell culture media and more choice.

(266) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure.<sup>246</sup> Any potential gain to PPD would be small compared to the potential for lost sales. PPD accounts for a negligible share of total demand for cell culture media for research, and in general, cell culture products typically constitute only a very small percentage of costs of laboratories and CROs so that change in the price of media do not significantly impact their overall cost position regarding the services for which they compete with PPD. In addition, CROs, laboratories, and their pharmaceutical and biotech clients have various possibilities to retaliate against or pressure Thermo Fisher.

<sup>242</sup> Volume-based market shares and market shares for 2018 and 2019 are similar to the ones shown here.

As market shares are particularly high in the global market for process liquids, the Commission notes the following market shares for competitors in this market, as provided by the Notifying Party: Merck Millipore Sigma ([10-20]%), Coming ([5-10]%); Lonza ([5-10]%), Danaher-Cytiva ([5-10]%), FujiFilm Irvine ([5-10]%) others ([10-20]%).

As market shares are particularly high in the global market for standard basal media, the Commission notes the following market shares for competitors in this market, as provided by the Notifying Party: Merck Millipore Sigma ([10-20]%), Coming ([5-10]%); Lonza ([5-10]%), Danaher-Cytiva ([5-10]%), FujiFilm Irvine ([5-10]%) others ([10-20]%).

<sup>&</sup>lt;sup>245</sup> Form CO, paragraph 333 et seq.

<sup>&</sup>lt;sup>246</sup> Form CO, paragraph 334 et seq.

#### 6.4.7.3. The Commission's assessment

- (267) Market shares of Thermo Fisher exceed 30% in a market for all cell culture media, and in seven potential markets of media both at global and EEA level. A potential concern arising from these market share levels is therefore input foreclosure of cell culture media overall and some types of such media. However, Thermo Fisher would likely not have the ability or incentive to engage in this foreclosure strategy, and such strategy would likely not have an impact on competition.
- (268) Firstly, the Commission notes that Thermo Fisher's upstream market shares for all types of cell culture media combined [amount to 40-50%] at global level, and [amount to 30-40%] in an EEA-wide market. However, Thermo Fisher is [based on market shares the market leader] in the market for cell culture media, with [...] the sales volume of the next biggest competitor. Still, the Commission notes that a number of competitors with non-negligible market shares are active in the market. For some types of media, Thermo Fisher's market shares are well above 40%, but do not exceed 50%. Such market structure indicates significant market power by Thermo Fisher in some segments of the cell culture media market as well as the overall market for such media, but also the presence of available alternative suppliers.
- (269) In the market investigation, customers of Thermo Fisher indicated, somewhat contrary to what market shares suggest, Merck Millipore Sigma to be a more suitable supplier for media to their company than Thermo Fisher.<sup>247</sup> All customers that expressed an opinion in the market investigation responded that they would be able to switch to other suppliers if Thermo Fisher would restrict access to cell culture media.<sup>248</sup> The Commission notes, however, that there are some barriers to switching a media provider, as new products may need to be tested as to their suitability.<sup>249</sup> Further, there appear to be occurrences of shortages in the supply of media in the past three years, which may make switching more difficult.<sup>250</sup> On the other hand, all but one customer expressing an opinion in the market investigation further submit to be able to source Thermo Fisher cell culture media via third-parties, *e.g.* distributors or sponsors of the respective clinical trial.<sup>251</sup> Based on the above, and especially on market feedback, Thermo Fisher would likely not have the ability to foreclose downstream competitors of cell culture media, despite having considerable market shares especially for some segments of this market.
- (270) Secondly, because downstream competitors would have alternatives available to source cell culture media from, as explained in paragraph (269) above, the merged entity would likely not be able to recoup upstream losses by additional gains downstream, and therefore would likely not have the incentive for input foreclosure.

<sup>&</sup>lt;sup>247</sup> Replies to questions 90 of questionnaire Q1 to CRO and laboratory service providers.

Replies to questions 94 of questionnaire Q1 to CRO and laboratory service providers. As explained in footnote 235 in more detail, the Commission received mixed feedback from one respondent in this regard. The respondent did not indicate concerns with respect to cell culture media, and its explanation on potential to switch would in any event form a minority opinion among respondents.

<sup>&</sup>lt;sup>249</sup> Replies to question 94.1 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>250</sup> Replies to question 93 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>251</sup> Replies to question 92 of questionnaire Q1 to CRO and laboratory service providers.

- (271) Particularly with respect to standard basal media, for which Thermo Fisher's market shares reach [50-60]% in an global market, but not at EEA-level, the Commission takes note of the Notifying Party's submission that PPD's profit associated with laboratory services that make use of this product was approximately EUR [...] globally, while Thermo Fisher's upstream profit from sales to PPD's competitors amounted to EUR [...]. Consequently, PPD would need to win significant additional business downstream to recoup upstream losses by Thermo Fisher. The Commission acknowledges that this scenario appears rather unlikely, given the fact that customers consider that they could switch away from Thermo Fisher. As for process liquids, where market shares reach equally [50-60]% at global level, [PPD purchase data]. [253]
- (272) Thirdly, the Transaction is unlikely to have an impact on the competitiveness of downstream companies competing with PPD or potential entrants into the downstream market with regard to the supply of cell culture media or any particular potential segment of the market. In the market investigation, no responding customers expressed concerns with regard to cell culture media or any type of media. 254 Similarly, the large majority of upstream competitors to Thermo Fisher indicated to have no concerns as regards to any type of media. 255
- (273) Furthermore, as set out Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider taking counter-measures in such event.
- (274) The Commission notes that potential concerns based on customer foreclosure, which were indicated by a small minority in the market investigation, <sup>256</sup> are likely not substantiated because of PPD's small downstream market shares in the market for laboratory services for clinical development both at global ([5-10]%) and EEA-wide ([0-5]%) level. Furthermore, cell culture media may not only be used for clinical development, but also in other areas of laboratory services, where PPD is not active.

# 6.4.7.4. Conclusion

(275) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for cell culture media or any potential segment of this market in an EEA-wide or global market.

<sup>&</sup>lt;sup>252</sup> Form CO, paragraph 336.

<sup>&</sup>lt;sup>253</sup> Form CO, paragraph 335.

<sup>&</sup>lt;sup>254</sup> Replies to questions 97 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>255</sup> Replies to questions 76 of questionnaire Q2 to Thermo Fisher competitors.

Replies to question 76.1 of questionnaire Q2 to Thermo Fisher competitors.

## 6.4.8. Plastics for magnetic bead-based instruments

#### 6.4.8.1. Market structure

(276) The below table shows the Notifying Party's market share estimates for plastics for magnetic bead-based instruments.

Table 15: 2020 value-based market shares for plastic for magnetic bead-based instruments.<sup>257</sup>

	Worldwide		EEA	
Competitor	Sales value (USD)	Share	Sales value (USD)	Share
Thermo Fisher	[]	[40-50]%	[]	[40-50]%
Corning	[]	[30-40]%	[]	[30-40]%
Greiner	[]	[10-20]%	[]	[10-20]%
Eppendorf	[]	[0-5]%	[]	[0-5]%
Others	[]	[10-20]%	[]	[5-10]%
Total	[]	100%	[]	100%

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

(277) The Notifying Party submits that Thermo Fisher's market share in the market for plastics for magnetic bead-based instruments grew disproportionately in 2020 given the frequent use of these plastics in Covid-19 PCR tests. The Notifying Party estimates it market share in 2018 and 2019 to be around [10-20]%. The Notifying Party expects its market share to return to this level in the future.

# 6.4.8.2. The Notifying Party's view

- (278) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure for the following reasons:<sup>258</sup>
  - (a) Thermo Fisher sells its plastics for magnetic bead-based instruments through distributors, which makes it difficult if not impossible to selectively foreclose PPD's competitors; and
  - (b) PPD's competitors could turn to competitive alternatives for magnetic beadbased plastics usable with Thermo Fisher's KingFisher instruments or to other magnetic bead-based instruments and their associated plastics.
- (279) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure for the following reasons:<sup>259</sup>
  - (a) Lost sales upstream would far outweigh any potential gains downstream. Stopping to supply PPD competitors would not lead to increased sales downstream as they have other options for both magnetic bead-based

<sup>257</sup> Thermo Fisher's 2020 worldwide volume market share estimate is slightly lower than its value share, at [30-40]%. The volume share estimates for the main competitors, as well as the volume shares for the EEA, are similar to the value shares.

<sup>&</sup>lt;sup>258</sup> Form CO, paragraph 422 et seq.

<sup>259</sup> Form CO, paragraph 425 et seq.

- instruments and plastics. Furthermore, many of the uses of these plastics relate to activities that PPD does not compete in; and
- (b) PPD competitors and their pharmaceutical and biotechnology clients source a wide variety of products from Thermo Fisher, and could retaliate in response to any attempt at input foreclosure.

#### 6.4.8.3. The Commission's assessment

- (280) The Commission notes that Thermo Fisher has a meaningful market share in the area of plastics for magnetic-bead based instruments in 2020, but that the market would not be affected on the basis of its market share in 2018 and 2019. Thermo Fisher faces competitors with significant market shares, such as Greiner and Corning.
- (281) The Notifying Party's position that third party suppliers are a competitive alternative for magnetic bead-based plastics usable with Thermo Fisher's KingFisher instruments is not consistent with the information on its website. On Thermo Fisher's website, it claims: "Use of KingFisher plastics ensures proper KingFisher instrument function and application performance and avoids costly repairs that may be caused by using third-party plastics, even if marketed as 'KingFisher compatible.' Use of third-party plastics may void instrument service contracts." <sup>260</sup> In the frequently asked questions section about the product, it answers the question "Can I use plates from other manufacturers with the KingFisher Flex Magnetic Particle Processor?" with "No, we strongly recommend that you use the MagMAX plates or KingFisher plates since they were specifically designed to be used with KingFisher Flex tip combs to attain maximal performance. Plates from other manufacturers may not be compatible with the KingFisher Flex heating blocks. They may also cause unexpected problems, such as cross-contamination, due to the divergent well volume and bottom height of the plate." <sup>261</sup>
- (282) CRO and laboratory service providers that responded to the Commission's market investigation gave inconclusive responses on whether they were able to use third party plastics with Thermo Fisher's devices, with some saying they can and others saying they cannot.<sup>262</sup> However, a significant amount of Thermo Fisher competitors indicates that they are able to supply plastics compatible with Thermo Fisher's magnetic bead-based devices.<sup>263</sup> [...].<sup>264</sup>
- (283) A large majority of CRO and laboratory service providers that replied to the Commission's market investigation indicated that they would be able to switch away

Thermo Fisher's website, <a href="https://www.thermofisher.com/lu/en/home/life-science/dna-rna-purification-analysis/automated-purification-extraction/kingfisher-systems/accessories.html">https://www.thermofisher.com/lu/en/home/life-science/dna-rna-purification-analysis/automated-purification-extraction/kingfisher-systems/accessories.html</a>. Accessed on 17 November 2021.

Thermo Fisher's website, <a href="https://www.thermofisher.com/search/results?query=5400610&persona=DocSupport&type=Product+FAQs">https://www.thermofisher.com/search/results?query=5400610&persona=DocSupport&type=Product+FAQs</a>. Accessed on 17 November 2021.

<sup>&</sup>lt;sup>262</sup> Replies to question 68 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>263</sup> Replies to question 52 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>264</sup> Form CO, paragraph 401.

from Thermo Fisher for both magnetic-bead based instruments as well as plastics for magnetic-bead based instruments, 265 showing that there are competitive alternatives.

- (284) Therefore, Thermo Fisher is unlikely to have the ability to engage in input foreclosure for plastics for magnetic bead-based instruments. Even if it were to do so, its incentive and the impact of such strategy would be very limited. PPD only purchased EUR [...] worth of these plastics globally in 2020 (none in the EEA), of which approximately EUR [...] from Thermo Fisher. They therefore clearly only make up a very small part of the cost base of CRO and laboratory service providers. Consistent with this, respondents to the Commission's market investigation do not expect Thermo Fisher's incentive to engage in foreclosure to change post-Transaction.<sup>266</sup>
- (285) In line with the above, the vast majority of respondents to the Commission's market investigation did not express any concerns with respect to plastics for magnetic bead-based instruments.<sup>267</sup>
- (286) Furthermore, as set out in Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider to take counter-measures in such event.

#### 6.4.8.4. Conclusion

(287) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for plastics for magnetic bead-based instruments globally and in the EEA.

#### 6.4.9. High-resolution accurate mass spectrometers

#### 6.4.9.1. Market structure

(288) Below table shows the Notifying Party's market share estimates for high-resolution accurate mass ('HRAM') spectrometers for the use with LC.

<sup>&</sup>lt;sup>265</sup> Replies to question 70 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>266</sup> Replies to question 74 of questionnaire Q1 to CRO and laboratory service providers and question 57 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>267</sup> Replies to question 76 of questionnaire Q1 to CRO and laboratory service providers and question 58 of questionnaire Q2 to Thermo Fisher competitors.

Table 16: 2020 value-based market shares for LC HRAM spectrometers.<sup>268</sup>

	Worldwide		EEA	
Competitor	Sales value (USD)	Share	Sales value (USD)	Share
Thermo Fisher	[]	[40-50]%	[]	[30-40]%
Bruker	[]	[10-20]%	[]	[20-30]%
Waters	[]	[10-20]%	[]	[10-20]%
Sciex	[]	[10-20]%	[]	[10-20]%
Agilent	[]	[5-10]%	[]	[0-5]%
Shimadzu	[]	[0-5]%	[]	[0-5]%
Others	[]	[5-10]%	[]	[5-10]%
Total	[]	100%	[]	100%

Source: Notifying Party, Annex 7.2-7.4 to the Form CO and response to RFI 13, paragraph 2.

(289) The Notifying Party explains that Thermo Fisher's sales for HRAM spectrometers used with GC are significantly lower, with USD [...] globally compared to USD [...] for LC HRAM spectrometers. Furthermore, Thermo Fisher's market shares for GC HRAM spectrometers would be lower, namely [20-30]% globally and [30-40]% at EEA-level, which would result in an affected market only under the latter geographic market definition. Consequently, market shares for a combined market for LC and GC HRAM spectrometers market would be slightly below those displayed in Table 16. However, the Commission notes the Notifying Party's submission that [PPD's operations]. The Notifying Party provides that no affected markets would arise for LC and GC mass spectrometers (not specifically HRAM) would arise.<sup>269</sup>

## 6.4.9.2. The Notifying Party's view

- (290) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure.<sup>270</sup> There are a number of other suppliers of HRAM spectrometer instruments and PPD competitors could switch to the HRAM instruments from these suppliers with relative ease. In addition, Thermo Fisher HRAMs are available from distributors and also on the secondary market.
- (291) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure.<sup>271</sup> Thermo Fisher's lost sales of mass spectrometry instruments to PPD's competitors would far outweigh any potential gains of PPD. Furthermore, CROs, laboratories, and their pharmaceutical and biotech clients have various possibilities to punish or pressure Thermo Fisher if it attempted to foreclose PPD's competitors' access to mass spectrometry instruments and if they were dissatisfied with Thermo Fisher's supply policy for HRAM instruments.

<sup>268</sup> Thermo Fisher's 2020 EEA volume market share estimate is slightly higher than its value share, at [40-50]%. The volume share estimates for the main competitors, as well as the worldwide shares, are similar to the value shares.

<sup>&</sup>lt;sup>269</sup> Response to RFI 13, paragraphs 3 et seq.

<sup>&</sup>lt;sup>270</sup> Form CO, paragraph 543 et seq.

<sup>&</sup>lt;sup>271</sup> Form CO, paragraph 545 et seq.

## 6.4.9.3. The Commission's assessment

- (292) Market shares of Thermo Fisher exceed 30% on the upstream market for LC HRAM and overall HRAM spectrometers both at global and EEA-wide level. A potential concern due to the Transaction is therefore input foreclosure of such spectrometers by Thermo Fisher. However, it is unlikely that Thermo Fisher would have the ability and the incentive to engage in input foreclosure, and such strategy would likely not have an impact on competition.
- (293) Firstly, Thermo Fisher would likely not have the ability to foreclose PPD's competitors of HRAM and LC HRAM spectrometers. Even though market shares are high, [30-40]% under any plausible geographic market definition, as shown in Table 16 above, alternatives with a significant market presence, namely at least Bruker, Waters and Sciex, are present in the market.<sup>272</sup> In the market investigation, responding customers confirm that products of those three manufacturers would be comparably suitable as Thermo Fisher HRAM spectrometers for the use of the company, with Shimadzu as a fifth supplier considered generally suitable.<sup>273</sup> The Commission notes that two customers submit that they would not be able to switch HRAM spectrometers in case Thermo Fisher were to increase prices or restrict access. The Commission understands, however, that one respondent is concerned for a particular assay, not the device. In any event, market feedback is inconclusive in this regard, as two other customers submit that they would be able to switch to other suppliers.<sup>274</sup> One customer explained for products including HRAM mass spectrometry: "There are multiple vendors for products that we currently source from Thermo Fisher such that any change in what Thermo Fisher sell or don't sell us has no material impact to our business."275 The Commission acknowledges that switching suppliers of HRAM products may entail significant costs, and may have an impact on ongoing clinical trials. On balance, however, based on the market shares level and the confirmation by other customers that other suppliers would be suitable alternatives, the Commission considers that Thermo Fisher would likely not have the ability to foreclose downstream competitors of HRAM mass spectrometers, including LC HRAM spectrometers, as customers would generally be able to source from other suppliers.
- (294) Secondly, because downstream competitors would have alternatives available to source HRAM mass spectrometers, including LC HRAM spectrometers from, as explained in paragraph (293) above, the merged entity would likely not be able to recoup upstream losses by additional gains downstream, and therefore would likely not have the incentive for input foreclosure. The Commission further notes that Thermo Fisher's gross margin on LC HRAM spectrometers upstream is [...], and therefore significantly higher than PPD's downstream margin of [...].<sup>276</sup> The merged entity would therefore need to win significant business downstream to make up for upstream sales losses, which appears unlikely given that other suppliers are available in the market.

<sup>&</sup>lt;sup>272</sup> Replies to question 57 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>273</sup> Replies to question 59 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>274</sup> Replies to questions 56 and 56.1 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>275</sup> Reply to question 61.1 of questionnaire Q1 to CRO and laboratory service providers.

<sup>276</sup> Reply to RFI 14, paragraph 5.

- (295) Thirdly, the Transaction is unlikely to have an impact on the competitiveness on downstream companies competing with PPD or potential entrants into the downstream market with regard to the supply of HRAM mass spectrometers and LC HRAM spectrometers. In the market investigation, the majority of responding customers did not raise concerns regarding HRAM spectrometers and did not indicate that their view would be different for LC HRAM spectrometers.<sup>277</sup> The Commission notes that two customers, however, showed concerns regarding the Transaction forming, however, the minority of respondents. Similarly, the clear majority of upstream competitors to Thermo Fisher did not raise concerns with regard to HRAM spectrometers, and no indication was made that concerns specifically for LC HRAM spectrometers would exist.<sup>278</sup>
- (296) Furthermore, as set out Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider taking counter-measures in such event.
- (297) The Commission notes that two competitors of Thermo Fisher raised concerns with regard to HRAM spectrometers in relation to potential customer foreclosure.<sup>279</sup> The Commission considers it highly unlikely that the merged entity will have the ability to impede effective competition by foreclosing upstream competitors from a significant part of its customer base. This is because PPD's market shares in the market for laboratory services for clinical development are small at both global ([5-10]%) and EEA-wide ([0-5]%) level. Further, HRAM spectrometers may not only used for clinical development, but also in other areas of laboratory services, where PPD is not active.

#### 6.4.9.4. Conclusion

(298) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for HRAM spectrometers and specifically LC HRAM spectrometers in an EEA-wide or global market.

# 6.4.10. Cryogenic storage tubes

### 6.4.10.1. Market structure

(299) The below table shows the Notifying Party's market share estimates for cryogenic storage tubes.

<sup>277</sup> Replies to questions 63 and 64 of questionnaire Q1 to CRO and laboratory service providers.

<sup>278</sup> Replies to questions 47, 47.1 and 48 of questionnaire Q2 to Thermo Fisher competitors.

<sup>&</sup>lt;sup>279</sup> Replies to question 47 and 47.1 of questionnaire Q2 to Thermo Fisher competitors.

Table 17: 2020 value-based market shares for cryogenic storage tubes.<sup>280</sup>

	Worldwide		EEA	
Competitor	Sales value (USD)	Share	Sales value (USD)	Share
Thermo Fisher	[]	[30-40]%	[]	[20-30]%
FluidX / Brooks	[]	[10-20]%	[]	[20-30]%
Corning ( Manual)	[]	[10-20]%	[]	[10-20]%
Micronic	[]	[10-20]%	[]	[10-20]%
Greiner	[]	[5-10]%	[]	[10-20]%
Others (Small	[]		[]	
importers from Korea, China, other EU)		[10-20]%		[10-20]%
Total	[]	100%	[]	100%

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

## 6.4.10.2. The Notifying Party's view

- (300) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure.<sup>281</sup> If Thermo Fisher attempted a foreclosure strategy, its cryogenic storage tubes customers could easily switch to another manufacturer's cryogenic storage tubes. Thermo Fisher faces strong competition and switching can be done with minimal disruption. The costs are relatively equal, the supplies are generally stable, and the quality within the market does not change materially. Such customers would also continue to be able to source Thermo Fisher cryogenic storage tubes through third-party distributors.
- (301) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure.<sup>282</sup> Thermo Fisher's lost sales of cryogenic storage tubes to PPD's competitors would likely outweigh any potential gains of PPD. Furthermore, CROs, laboratories, and their pharmaceutical and biotech clients have various possibilities to punish or pressure Thermo Fisher to supply cryogenic storage tubes to PPD competitors.

#### 6.4.10.3. The Commission's assessment

(302) Market shares of Thermo Fisher exceed 30% in a potential global upstream market for cryogenic storage tubes, but not in a potential EEA-wide upstream market. A potential concern arising from these market share levels is therefore input foreclosure of cryogenic storage tubes by Thermo Fisher. However, it is unlikely that Thermo Fisher would have the ability and the incentive to engage in input foreclosure, and such strategy would likely not have an impact on competition.

Market shares for 2018 and 2019 are similar to the ones shown here. The Notifying Party is unable to estimate volume based market share for all other global suppliers listed above, but Thermo Fisher's 2020 worldwide market share estimate is slightly lower than its value share, at [30-40]%.

<sup>&</sup>lt;sup>281</sup> Form CO, paragraph 721 et seq.

<sup>&</sup>lt;sup>282</sup> Form CO, paragraph 722 et seq.

- (303) Firstly, Thermo Fisher would likely not have the ability to foreclose PPD's competitors of cryogenic storage tubes. As presented in Table 17, market shares exceed 30%, but remain still moderate at [30-40]% at global level. Four significant competitors (FluidX / Brooks, Corning, Micronic and Greiner) would remain present in the market post-Transaction. All but one customer that expressed an opinion in the market investigation confirmed that they would be able to switch to alternative suppliers if Thermo Fisher were to increase prices or restrict access to cryogenic storage tubes.<sup>283</sup> Two companies noted that switching of storage tubes may have an impact of ongoing clinical trials, as it would require some time and would entail certain costs, as the replacing products would need to be assessed first as to their suitability.<sup>284</sup> The Commission notes that, these concerns mainly concern ongoing clinical trials, but not the companies' ability to compete for new business. Further, a majority of respondents did not raise such concerns. Lastly, the Commission notes that the merged entity would unlikely benefit directly from a foreclosure of ongoing clinical trials, as sponsors would not likely replace the existing CRO or laboratory service provider with PPD, which would likely constitute a more severe interruption of the ongoing trial than only replacing the type of storage tube used.
- (304) Secondly, because downstream competitors would have alternatives available to source cryogenic storage tubes from, as explained in paragraph (303) above, the merged entity would likely not be able to recoup upstream losses by additional gains downstream, especially by winning new clinical trials, and therefore would likely not have the incentive for input foreclosure.
- (305) Thirdly, the Transaction is unlikely to have an impact on the competitiveness on downstream companies competing with PPD or potential entrants into the downstream market with regard to the supply of cryogenic storage tubes. In the market investigation, all but one<sup>285</sup> responding customers expressed no concerns with regard to cryogenic storage tubes or any other form of storage tubes.<sup>286</sup> Similarly, no upstream competitors to Thermo Fisher raised concerns with regard to cryogenic storage tubes or any other form of storage tubes.<sup>287</sup>
- (306) Furthermore, as set out Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider to take counter-measures in such event.

<sup>&</sup>lt;sup>283</sup> Replies to questions 106 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>284</sup> Replies to question 106.1 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>285</sup> One respondent reiterated its concerns as discussed in paragraph (303) of this Decision.

<sup>&</sup>lt;sup>286</sup> Replies to questions 107 and 108 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>287</sup> Replies to questions 86 and 87 of questionnaire Q2 to Thermo Fisher competitors.

#### 6.4.10.4. Conclusion

(307) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for cryogenic storage tubes in an EEA-wide or global market.

# 6.4.11. General purpose benchtop centrifuges

### 6.4.11.1.Market structure

(308) Below table shows the Notifying Party's market share estimates for general purpose benchtop centrifuges.

Table 18: 2020 value-based market shares for general purpose benchtop centrifuges.<sup>288</sup>

	Worldwide		EEA	
Competitor	Sales value (USD)	Share	Sales value (USD)	Share
Thermo Fisher	[]	[30-40]%	[]	[20-30]%
Eppendorf	[]	[20-30]%	[]	[20-30]%
Hettich	[]	[10-20]%	[]	[20-30]%
Sigma	[]	[0-5]%	[]	[5-10]%
Danaher (Beckman Coulter)	[]	[10-20]%	[]	[0-5]%
Koki*	[]	[0-5]%	[]	[0-5]%
Others	[]	[10-20]%	[]	[10-20]%
Total	[]	100%	[]	100%

Source: Notifying Party, Table 46 of the Form CO. \* Now owned by Eppendorf.

## 6.4.11.2. The Notifying Party's view

(309) The Notifying Party submits that the merged entity would not have the <u>ability</u> or <u>incentive</u> to engage in input foreclosure. In the EEA, Thermo Fisher sells [...] of its general purpose benchtop centrifuges through VWR and other distributors, which makes it difficult if not impossible for Thermo Fisher to prevent PPD's competitors from procuring Thermo Fisher's general purpose benchtop centrifuges. Furthermore, Thermo Fisher's customers could easily switch to another manufacturer's general purpose benchtop centrifuges because there are low barriers to substitution across suppliers and Thermo Fisher faces strong competitors. <sup>289</sup>

(310) The Notifying Party submits that the Merged Entity would also not have the <u>incentive</u> to engage in input foreclosure, as Thermo Fisher's lost sales of general benchtop centrifuges to PPD's competitors would likely outweigh any potential gains of PPD. In addition, CROs, laboratories and their pharmaceutical and biotech clients have

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<sup>&</sup>lt;sup>288</sup> Volume-based market shares and market shares for 2018 and 2019 are similar to the ones shown here.

<sup>&</sup>lt;sup>289</sup> Form CO, paragraph 701 et seq.

various possibilities to punish or pressure Thermo Fisher to supply general purpose benchtop centrifuges to PPD competitors. <sup>290</sup>

### 6.4.11.3. The Commission's assessment

- (311) Market shares of Thermo Fisher exceed 30% in a potential global upstream market for general purpose benchtop centrifuges, but not in a potential EEA-wide upstream market. A potential concern arising from these market share levels is therefore input foreclosure of such centrifuges by Thermo Fisher. However, it is unlikely that Thermo Fisher would have the ability and the incentive to engage in input foreclosure, and such strategy would likely not have an impact on competition.
- (312) Firstly, Thermo Fisher would likely not have the ability to foreclose PPD's competitors of general purpose benchtop centrifuges. As presented in Table 18, market shares of Thermo Fisher [amount to 30-40%] at global level. At least two strong competitors (Hettich and Eppendorf) would remain present in the market post-Transaction, as well as a number of other competitors with non-negligible market shares. All but one customers responding to the market investigation confirmed that they would be able to switch to alternative suppliers if Thermo Fisher were to increase prices or restrict access to general purpose benchtop centrifuges. <sup>291</sup>
- (313) Secondly, because downstream competitors would have alternatives available to source general purpose benchtop centrifuges from, as explained in paragraph (312) above, the merged entity would likely not be able to recoup upstream losses by additional gains downstream, and therefore would likely not have the incentive for input foreclosure.
- (314) Thirdly, the Transaction is unlikely to have an impact on the competitiveness on downstream companies competing with PPD or potential entrants into the downstream market with regard to the supply of general purpose benchtop centrifuges. In the market investigation, no responding customers expressed concerns with regard to general purpose benchtop centrifuges or any other type of centrifuge.<sup>292</sup> Similarly no upstream competitor to Thermo Fisher raised concerns with regard to general purpose benchtop centrifuges or any other type of centrifuge.<sup>293</sup>
- (315) Furthermore, as set out Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider to take counter-measures in such event.

<sup>291</sup> Replies to questions 101 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>290</sup> Form CO, paragraph 702 et seq.

<sup>&</sup>lt;sup>292</sup> Replies to questions 102 and 103 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>293</sup> Replies to questions 81 and 82 of questionnaire Q2 to Thermo Fisher competitors.

#### 6.4.11.4. Conclusion

(316) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for general purpose benchtop centrifuges in an EEA-wide or global market.

## 6.4.12. Thermal cyclers

#### 6.4.12.1. Market structure

(317) The below table shows the Notifying Party's market share estimates for thermal cyclers.

Table 19: 2020 value-based market shares for thermal cyclers.<sup>294</sup>

	Worldwide		EEA	
Competitor	Sales value (USD)	Share	Sales value (USD)	Share
Thermo Fisher	[]	[30-40]%	[]	[20-30]%
Bio-Rad	[]	[20-30]%	[]	[30-40]%
Eppendorf	[]	[10-20]%	[]	[20-30]%
Takara Bio	[]	[5-10]%	[]	[5-10]%
Others	[]	[20-30]%	[]	[10-20]%
Total	[]	100%	[]	100%

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

## 6.4.12.2. The Notifying Party's view

- (318) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure for the following reasons:<sup>295</sup>
  - (a) Thermo Fisher faces strong competitors such as Bio-Rad and Eppendorf, as well as smaller competitors; and
  - (b) Switching thermal cyclers is easy and can be done at limited cost and disruption.
- (319) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure for the following reasons:<sup>296</sup>
  - (a) Lost sales upstream would far outweigh any potential gains downstream; and
  - (b) PPD competitors and their pharmaceutical and biotechnology clients source a wide variety of products from Thermo Fisher, and could retaliate in response to any attempt at input foreclosure.

<sup>&</sup>lt;sup>294</sup> Market shares for 2018 and 2019 are similar to the ones shown here. The Notifying Party is unable to estimate volume-based market share, but believes them to be similar to the value-based market shares.

<sup>&</sup>lt;sup>295</sup> Form CO, paragraph 764.

<sup>&</sup>lt;sup>296</sup> Form CO, paragraph 765.

#### 6.4.12.3. The Commission's assessment

- (320) The Commission notes that in the market for thermal cyclers, Thermo Fisher's market share is [...] above 30% globally, and under 30% in the EEA. Furthermore, Thermo Fisher faces competitors with significant market shares, such as Bio-Rad, which has a similar market share to Thermo Fisher, and Eppendorf. In view of this market structure, it is unlikely that Thermo Fisher has the ability to engage in input foreclosure.
- (321) Respondents to the Commission's market investigation indicated that they are able to switch away from Thermo Fisher in case it were to increase prices or restrict access to thermal cyclers post-Transaction.<sup>297</sup> Furthermore, respondents rated Bio-Rad and Eppendorf as strong competitors in the area of thermal cyclers.<sup>298</sup> The majority of Thermo Fisher's competitors that responded to the Commission's market investigation indicated that they are able to increase supply significantly in case of increased demand.<sup>299</sup>
- (322) In line with the above, respondents to the Commission's market investigation considered that Thermo Fisher's incentive to foreclose its customers in the market for thermal cyclers would not change as a result of the Transaction, and did not voice any concerns about the Transaction for the market for thermal cyclers.<sup>300</sup>
- (323) Furthermore, as set out Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider to take counter-measures in such event.

## 6.4.12.4. Conclusion

(324) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for thermal cyclers globally and in the EEA.

# 6.4.13. *Infrared spectrometers*

#### 6.4.13.1. Market structure

(325) The below table shows the Notifying Party's market share estimates for FT-IR spectrometers. As explained in the market definition Section 5.2.13, the Commission considers FT-IR spectrometers as a plausible segment of the IR spectrometer market. The Notifying Party submits market shares for FT-IR spectrometers, and notes that

<sup>&</sup>lt;sup>297</sup> Replies to question 82 of questionnaire Q1 to CRO and laboratory service providers.

 $<sup>^{298}</sup>$  Replies to question 83 of questionnaire Q1 to CRO and laboratory service providers.

Replies to question 62 of questionnaire Q2 to Thermo Fisher competitors.

Replies to questions 85 and 86 of questionnaire Q1 to CRO and laboratory service providers and questions 66 and 67 of questionnaire Q2 to Thermo Fisher competitors.

Thermo Fisher's market shares would be lower in a market comprising all IR spectrometers.<sup>301</sup>

Table 20: 2020 value-based market shares for FT-IR spectrometers.<sup>302</sup>

	Worldwide		EEA	
Competitor	Sales value (USD)	Share	Sales value (USD)	Share
Thermo Fisher <sup>303</sup>	[]	[20-30]%	[]	[30-40]%
Bruker	[]	[10-20]%	N/A	N/A
PerkinElmer	[]	[10-20]%	N/A	N/A
Shimadzu	[]	[5-10]%	N/A	N/A
Agilent	[]	[5-10]%	N/A	N/A
JASCO	[]	[5-10]%	N/A	N/A
FOSS	[]	[0-5]%	N/A	N/A
Others	[]	[10-20]%	N/A	N/A
Total	[]	100%	N/A	100%

Source: Notifying Party, Annex 7.2-7.4 to the Form CO.

## 6.4.13.2. The Notifying Party's view

- (326) The Notifying Party submits that the merged entity would not have the <u>ability</u> to engage in input foreclosure: if Thermo Fisher attempted a foreclosure strategy, its IR spectrometers customers could easily switch to another manufacturer's IR spectrometers. Thermo Fisher faces strong competition and switching would only require that a company decides to change the supplier which is done with minimal disruption. <sup>304</sup>
- (327) The Notifying Party submits that the merged entity would not have the <u>incentive</u> to engage in input foreclosure, because IR spectrometers are of limited (if any) relevance to the CRO/laboratory activities conducted by PPD and its competitors. Therefore, lost sales to IR spectrometer customers would likely outweigh any potential gains of PPD as a result. 305

# 6.4.13.3. The Commission's assessment

(328) Market shares of Thermo Fisher exceed 30% on the upstream market for FT-IR spectrometers, and would be lower — but potentially still exceeding 30% - in an overall market for IR spectrometers. A potential concern due to the Transaction is therefore input foreclosure of FT-IR or IR spectrometers by Thermo Fisher. However, it is unlikely that Thermo Fisher would have the ability and the incentive to engage in input foreclosure, and such strategy would likely not have an impact on competition.

<sup>301</sup> Form CO, paragraph 734.

Market shares for 2018 and 2019 are similar to the ones shown here. The Notifying Party is unable to provide an estimate of volume-based market shares.

<sup>303</sup> Market shares inclusive sales to other OEMs (original equipment manufacturers).

<sup>304</sup> Form CO, paragraph 743.

<sup>305</sup> Form CO, paragraph 744.

- (329) Firstly, Thermo Fisher would likely not have the ability to foreclose PPD's competitors of FT-IR and IR spectrometers. As presented in Table 20 above, market shares of Thermo Fisher do not exceed [30-40]% in the upstream market under any plausible market definition. At least two strong competitors (Bruker and PerkinElmer), as well as a number of other competitors with non-negligible market shares, would remain available to downstream competitors. While receiving limited feedback from customers with respect to the competitive strengths of alternative IR spectrometers providers, the Commission did not receive indication that any of those suppliers would not be a suitable provider of IR or FT-IR spectrometers. 306 Lastly, it is at least questionable to what extent IR and FT-IR spectrometers are important inputs for PPD's downstream business in the sense that it is a significant cost-factor, a critical component of a source for differentiation, in the light of the Notifying Party's submission that PPD bought [...] FT-IR instrument in the last [...] years, and [...] for operations in the EEA in the last [...] years. 307
- (330) Secondly, because downstream competitors would have alternatives available to source IR and FT-IR spectrometers from, as explained in paragraph (329) above, the merged entity would likely not be able to recoup upstream losses by additional gains downstream, and therefore would likely not have the incentive for input foreclosure.
- (331) Thirdly, the Transaction is unlikely to have an impact on the competitiveness on downstream companies competing with PPD or potential entrants into the downstream market with regard to the supply of IR or FT-IR spectrometers. In the market investigation, no responding customers expressed concerns with regard to IR spectrometers, and did not indicate that their view would differ for FT-IR spectrometers. Similarly, the majority of upstream competitors to Thermo Fisher did not raise concerns with regard to IR-spectrometers, and did not indicate that their view would differ for FT-IR spectrometers.
- (332) Furthermore, as set out Section 6.3 of this Decision, sponsors of clinical trials, *i.e.* pharmaceutical companies, indicated that that they do not consider Thermo Fisher products as essential for laboratory service providers to provide services for them. Neither would, in their view, Thermo Fisher have the incentive to engage in input foreclosure, nor would such strategy have an impact on the downstream market. Pharmaceutical companies pointed at potential reputational harm Thermo Fisher would suffer if it would foreclose PPD's downstream competitions, and indicated that they would consider to take counter-measures in such event.
- (333) The Commission notes that, during the market investigation, two competitors of Thermo Fisher raised concerns with regard to IR spectrometers. Both companies substantiated their concerns with the claim that post-Transaction, PPD may stop buying instruments by manufacturers other than Thermo Fisher, and thereby limiting the customer base for competitors.<sup>310</sup> While the potential loss of a theoretical or actual customer may be a commercial concern, the Commission considers it highly unlikely

<sup>&</sup>lt;sup>306</sup> Replies to question 57 of questionnaire Q1 to CRO and laboratory service providers.

<sup>307</sup> Form CO, paragraph 731.

<sup>&</sup>lt;sup>308</sup> Replies to questions 63 and 63.1 of questionnaire Q1 to CRO and laboratory service providers.

<sup>&</sup>lt;sup>309</sup> Replies to questions 47 and 47.1 of questionnaire Q2 to Thermo Fisher competitors.

<sup>310</sup> Replies to question 47 and 47.1 of questionnaire Q2 to Thermo Fisher competitors.

that the merged entity will have the ability to impede effective competition by engaging in customer foreclosure. This is because PPD's market shares in the market for laboratory services for clinical development are small at both global ([5-10]%) and EEA-wide ([0-5]%) level. It has to be noted that IR spectrometers may not only be used for clinical development, but also in other areas of laboratory services, where PPD is not active. The Notifying Party submits that in the past five years, PPD has only purchased [PPD purchase data].

(334) The Commission therefore concludes that PPD has no significant market power in the downstream market, and is not an important customer for IR spectrometers. Therefore, the Transaction is unlikely to lead to an impediment of effective competition due to customer foreclosure.

## 6.4.13.4. Conclusion

(335) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for IR or FT-IR spectrometers in an EEA-wide or global market.

# 6.5. Observations on the Transaction not related to specific markets

(336) This section covers additional feedback the Commission received in the course of its market investigation not related to specific product markets.

## 6.5.1. Concerns relating to information exchange

- (337) A few CRO and laboratory service providers that responded to the Commission's market investigation voiced the concern that the Thermo Fisher obtains competitively sensitive information, such as purchasing volumes, about their business through its supplier relationship. Post-Transaction, this information could constitute a competitive advantage for the merged entity when bidding for clinical trials, as it may have a view on the input cost of competitors.
- (338) Based on available information, the Commission does not consider that such eventual information exchange concern poses a competitive concern. The information that Thermo Fisher might obtain about PPD competitors as a supplier is limited and would likely not be a major competitive advantage. *First*, many of Thermo Fisher's products have a variety of use cases, and it is not visible to Thermo Fisher for what purpose a product is purchased. *Second*, for most products competitive alternatives to Thermo Fisher are available, which CRO and / or laboratory service providers will typically use for at least part of their products. Therefore, any information Thermo Fisher might receive would be incomplete. *Third*, the ultimately quoted price of clinical trial services is dependent on many factors, of which input cost are only a minor one. PPD submits that the largest elements of its cost base are employee costs and investigator grants (*i.e.* payments to third party clinical trial sites and physicians involved in the trial) and that inputs in which Thermo Fisher is active constitute less than [...] of the total price.<sup>311</sup>

<sup>311</sup> Reply to request for information 12, question 2.

- 6.5.2. Concerns relating to companion diagnostics
- (339) A small minority of CRO and laboratory service providers voiced concerns relating to companion diagnostics ("CDx"). CDx are tests developed for a specific drug, to test whether the drug will work for a patient and / or whether a patient is likely to suffer side effects from a pharmaceutical. Thermo Fisher is active in the development of CDx in collaboration with pharmaceutical companies, and today has one approved CDx product. PPD's activities in CDx are minimal: in the past [...], it was involved in the development of [...] CDx product as a CRO and laboratory service provider.
- (340) PPD's competitors that expressed some level of concern in the Commission's market investigation indicated that post-Transaction, the merged entity may (i) reduce other CROs' / labs' ability to bid competitively on companion diagnostic work for tests developed by Thermo Fisher and (ii) create the incentive to restrict selling certain products required for CDx development.
- (341) Based on available information, the Commission considers that the Transaction is unlikely to result in competitive concerns relation to CDx.
- (342) Regarding the concern that the Transaction may reduce other CRO or laboratory service providers' ability to bid competitively on companion diagnostic work for tests developed by Thermo Fisher, the Commission notes that Thermo Fisher only has one approved CDx product, and that the impact of such scenario would therefore be limited. Furthermore, there are various competitors active in CDx, such as Illumina, Roche, Myriad, Guardant health and others. Furthermore, it is unlikely that pharmaceutical companies for which CDx are developed would tolerate such restrictions on CDx testing.
- (343) Regarding the concern that the Transaction may create the incentive to restrict selling certain products required for CDx development, the Commission notes that it has investigated the products affected by the Transaction (see the sections above), including those that are used in CDx development (*e.g.* DNA sequencing instruments and consumables), and did not identify such foreclosure risk.
- (344) Furthermore, one of the main technologies used for CDx is next generation sequencing ("NGS"). Thermo Fisher's sole marketed CDx, the Oncomine Dx Target Test, is an NGS-based CDx. However, Thermo Fisher's market shares for NGS are low, an estimated [10-20]% in the EEA and [5-10]% globally. Illumina is the clear market leader within NGS. The large majority CRO and laboratory service providers that responded to the Commission's market investigation indicated that they are able to use Illumina's NGS devices instead of Thermo Fisher's devices for their purposes.<sup>312</sup> Therefore, input foreclosure with respect to NGS systems, either globally or in the EEA, cannot arise as a result of the Transaction.

# 7. CONCLUSION

(345) 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

Replies to question 11 of questionnaire Q1 to CRO and laboratory service providers.

EEA Agreement. This Decision is adopted in application of Article 6(1)(b) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission

(Signed)
Margrethe VESTAGER
Executive Vice-President