



EUROPEAN COMMISSION
DG Competition

Case M.7982 - ABBOTT LABORATORIES / ALERE

Only the English text is available and authentic.

REGULATION (EC) No 139/2004

MERGER PROCEDURE

Decision on the implementation of remedies - Art. 6(1)(b) in
conjunction with 6(2) - Purchaser approval

Date: 29.9.2017



EUROPEAN COMMISSION

Brussels, 29.9.2017
C(2017) 6720 final

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

To the notifying party:

Subject: Case M.7982 – Abbott/Alere

Approval of Quidel as purchaser of the Triage Divestment Business and the BC Commercialisation Divestment Business following your Reasoned Proposal of 28 July 2017 and the Trustee's Reasoned Opinion of 25 September 2017

Dear Sir/Madam,

I. FACTS AND PROCEDURE

1. By decision of 25 January 2017 (the "Decision") based on Article 6(1)(b) and Article 6(2) of Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "Merger Regulation"), the Commission declared the operation by which Abbott Laboratories ("Abbott", USA), acquired within the meaning of Article 3(1)(b) of the Council Regulation control of the whole of Alere Inc. ("Alere", USA) compatible with the internal market and the EEA Agreement, subject to conditions and obligations (the "Commitments").
2. In its Decision, the Commission concluded that the acquisition of Alere by Abbott raised serious doubts as to its compatibility with the internal market, in the EEA in general and in several EEA countries in particular, in relation to (i) markets for *in vitro* diagnostics (IVD) point-of-care (POC) blood gas systems for tests in human

and animal health,¹ where Abbott's i-Stat and Alere's EPOC portable blood gas systems were closely competing in the overall market for IVD POC blood gas systems and the only two systems to be handheld; (ii) markets for IVD POC cardiac markers systems,² where Abbott's i-Stat and Alere's Triage were closely competing systems; and (iii) markets for IVD laboratory immunochemistry testing,³ where Abbott's takeover of the pre-existing manufacturing agreement between Alere and Danaher Corporation ("Danaher"), a competitor of Abbott in this market, could result in foreclosure effects that could allow the merged entity to profitably increase the price charged to consumers in a number of Member States and in the EEA

3. The Commitments provide that the following Alere businesses shall be divested on a worldwide basis: (i) Alere's EPOC business (the "EPOC Divestment Business"); (ii) Alere's Triage business (the "Triage Divestment Business"); and Alere's commercialisation of B-type natriuretic ("BNP") Assays (the "BC Commercialisation Divestment Business");⁴ together referred to as the "Divestment Businesses".
4. The present decision is limited to the proposal for the acquisition of the Triage Divestment Business and the BC Commercialisation Divestment Business by Quidel Corporation ("Quidel", USA) and is adopted in parallel to the decision limited to the proposal for the acquisition of the EPOC Divestment Business by Siemens AG ("Siemens", Germany).

A. Content of the Commitments

5. Under Section B of the Commitments, Abbott commits to divest, or procure the divestiture of the Divestment Businesses within [...] from the adoption of the Decision ("First Divestiture Period") to one or more purchasers fulfilling the criteria set out in Section D of the Commitments, namely a) independence from Abbott; b) established presence, including distribution and sales capabilities, in the IVD sector in the EEA with a geographic footprint comparable to Alere prior to the Concentration; c) financial resources, proven expertise and incentive to maintain and develop the Divestment Businesses as a viable and active competitive force; d) absence of *prima facie* competition concerns; and on terms of sale approved by the Commission in accordance with the procedure described in paragraphs 19 and 20 of the Commitments.
6. Paragraph 19 of the Commitments provides that the proposed concentration (i.e. Abbott's acquisition of control over Alere) shall not be implemented before Abbott has entered into a final binding sale and purchase agreement for the sale of the

¹ Blood gases are vital parameters (such as pH, pO₂ and pCO₂) found in blood that must be closely monitored for patients admitted into critical care, undergoing prolonged anaesthesia or when a patient is on oxygen.

² Cardiac markers are biomarkers measured to evaluate heart functions, that is to either diagnose a cardiac event or to evaluate the risk of cardiac event occurring.

³ Immunochemistry testing involves the use of targeted antibodies to identify and test enzymes, drugs, hormones and other substances found in relatively small concentrations in samples in order to diagnose a variety of medical problems such as cancer, HIV and thyroid problems.

⁴ BNP helps to detect heart failure, so as to be able to evaluate cardiac event risks.

Divestment Businesses and the Commission has approved the purchasers and the terms of sale (a so-called upfront buyer clause).

7. Paragraph 20 of the Commitments provide that, in case Abbott does not propose to divest all Divestment Businesses to a single purchaser, the Commission will take the decision approving the proposed purchasers only after having assessed the complete information related to the proposed purchasers of the EPOC Divestment Business, the Triage Divestment Business and the BC Commercialisation Divestment Business, and all agreements concluded in relation to those divestments.
8. The Commitments also provide for a Monitoring Trustee to monitor the implementation of the Commitments. On 17 February 2017 Abbott proposed ING Bank N.V. London Branch ("the Trustee"), which has been approved by the Commission as a suitable Monitoring Trustee on 20 February 2017.

1. Triage Divestment Business

9. The Triage Divestment Business, described in more detail in Schedule B of the Commitments, consists of the Triage System at global level, which is primarily manufactured at Alere's facility in San Diego, California.
10. More specifically, the Triage Divestment Business includes the manufacturing, development and commercialisation of:
 - the Triage MeterPro System analyser including all related pipeline products;
 - the Triage System tests (including all related pipeline products) as follows:
 - i. Triage B-type Natriuretic peptide (BNP);
 - ii. Triage NT-Pro-BNP;
 - iii. Triage Troponin I;
 - iv. Triage Cardiac Panel (CK-MB, Myoglobin, and TnI);
 - v. Triage Cardio3 Panel (CK-MB, TnI, BNP);
 - vi. Triage Cardio2 Panel (TnI, BNP);
 - vii. Triage Profiler SOB Panel (Myoglobin, CK-MB, TnI, BNP, D-Dimer);
 - viii. Triage Cardiorenal Panel (NGAL, BNP) (which is not commercialised currently);
 - ix. Triage PLGF (which is not commercialised currently); and
 - x. Triage TOX Drug Screen.

The marketed and pipeline products listed above comprise all analysers and reagents sold (or in development) belonging to the Triage System.

11. The Triage Divestment Business also includes:

- The manufacturing and supplying to Danaher of the antibodies used in the manufacture by Danaher of the BNP Assays (the "BC Manufacturing Activities");
- the tangible assets used for the production and development of Triage and in the BC Manufacturing Activities, in particular the Triage manufacturing and R&D facility and equipment used exclusively or predominantly for Triage or the BC Manufacturing Activities:
 - i. Dedicated Triage equipment, namely Triage automation, Triage manual lines and front and back end assembly equipment;
 - ii. Main tangible assets, namely other Triage machinery, improvement and tooling, lab equipment and improvements, R&D equipment and improvements and inventories – raw material, work in progress, pre-paid and inspection;
 - iii. all four buildings and plant land of Alere's San Diego facility;
 - iv. Cell lines and calibration materials used for the manufacturing of BNP antibodies.
- the following main intangible assets:
 - i. all patents exclusively or predominantly relating to the Triage Divestment Business;
 - ii. a non-exclusive perpetual, irrevocable, sub-licensable, royalty free license under other patents owned by Alere to the extent such patents include a claim that is practiced by Triage Divestment Business;
 - iii. full assignment of all relevant licenses and rights used exclusively or predominantly in the Triage Divestment Business (subject to obtaining all relevant third party consents, recognising that the Parties will use their reasonable best efforts to obtain such consents and it being understood that, pursuant to Section D, third parties' consent of critical intellectual property rights holders for the transfer of the relevant licenses and/or use of the relevant other intellectual property ("IP") rights is a pre-condition for the approval of the purchaser);
 - iv. assignment of, or other non-exclusive, irrevocable, sub-licensable, royalty free right or license to or under, any other relevant licenses to the extent related to the Triage Divestment Business (subject to obtaining all relevant third party consents, recognising that the Parties will use their reasonable best efforts to obtain such consents and it being understood that, pursuant to Section D, third parties' consent of critical intellectual property rights holders for the transfer of the relevant licenses and/or use of the relevant other IP rights is a pre-condition for the approval of the purchaser);

- v. all rights held by Alere under the Scios license for the manufacturing, development and commercialisation of Triage products and for the BC Manufacturing Activities (subject to obtaining relevant third party consents, recognising that the Parties will use their reasonable best efforts to obtain such consents and it being understood that, pursuant to Section D, Scios' consent for the transfer of the relevant licenses and/or use of the relevant other IP rights is a pre-condition for the approval of the purchaser);
 - vi. all trademarks relating to the Triage Divestment Business, except "Alere" for which a license and/or right to use the trademark will be granted for a reasonable term to avoid supply disruption to the Triage Divestment Business;
 - vii. all trade secrets, confidential know-how, confidential customer data, or other confidential information and certain other intellectual property used exclusively or predominantly in the Triage Divestment Business;
 - viii. co-ownership of an undivided interest (with Alere and its Affiliated Undertakings) in trade secrets, confidential know-how, confidential customer data, or other confidential information and other certain intellectual property used both in the Triage Divestment Business and in other businesses of Alere and its Affiliated Undertakings, to the extent used in the Triage Divestment Business;
- to the extent they can transfer by law, all necessary regulatory clearances and authorisations used exclusively or predominantly in the distribution, marketing, promotion, selling or offering for sale of the Triage System;
 - all inventories, including raw materials, works in process, semi-finished and finished products, stores, replacement and spare parts, packaging and labelling materials, operating supplies and inventory on consignment, in transit or deposited in a warehouse, in each case to the extent used in the Triage Divestment Business;
 - all advertising, marketing, training and promotional materials, books, records, files, tax records, customers lists, information and history used exclusively in the Triage Divestment Business, and co-ownership of an undivided interest of all other books, records, files, tax records, customers lists, information and history to the extent related to the Triage Divestment Business;
 - all supply contracts, distribution agreements, manufacturing and packaging agreements, all independent contractor contracts and customer contracts, including the OEM Agreement to the extent it relates to the supply of BNP antibodies;

- personnel necessary for the continued viability and competitiveness of the Triage Divestment Business including, but not necessarily limited to, quality assurance/regulatory affairs, technical services, R&D, operations, general and administrative, software and marketing personnel, as listed in Table 5 of Schedule B;
 - transfer of all pipeline products predominantly related to the Triage Divestment Business and right to access other pipeline products which are intended to be used in relation to the Triage Divestment Business if any.
12. The Commitments provide that if there is any asset or personnel which is not covered by Schedule B of the Commitments but which is both used (exclusively or not) in the Triage Divestment Business and necessary for the continued viability and competitiveness of the Triage Divestment Business, that asset, or personnel, or adequate substitute will be offered to the purchaser.
13. In addition, the Triage Divestment Business includes the benefit, for a transitional period of up to two years after Closing and on terms and conditions equivalent to those at present afforded to the Triage Divestment Business, of all current arrangements under which Alere or its Affiliated Undertakings supply products or services to the Triage Divestment Business, as detailed in Schedule B, unless otherwise agreed with the Purchaser.
14. The Commitments also provide that strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from such supply arrangements (e.g. product roadmaps) will not be shared with, or passed on to, anyone outside the Triage Divestment Business operations.

2. BC Commercialisation Divestment Business

15. The BC Commercialisation Divestment Business, described in more detail in Schedule C of the Commitments, consists of the commercialisation of BNP Assays to customers of Danaher for use on the Beckman Analysers, and also includes the personnel required for such commercialisation. The BC Commercialisation Divestment Business does not, however, include the antibody generation and reagent formulation and manufacturing operations at the San Diego site since these are part of the Triage Divestment Business.
16. The BC Commercialisation Divestment Business includes, but is not limited to:
- the following main intangible assets:
 - i. licenses and rights in intellectual property arising under contracts to which Alere is a party for commercialising BNP Assays;
 - ii. all rights held by Alere under the Scios license for the commercialisation of BNP Assays;
 - iii. all trademarks relating to the BC Commercialisation Business, except "Alere" for which a license and/or right to use the trademarks will be granted for a reasonable term to avoid supply disruption to the BC Commercialisation Divestment Business;

- iv. all trade secrets, confidential know-how, confidential customer data, or other confidential information and other intellectual property used exclusively or predominantly in the BC Commercialisation Divestment Business which shall include, without limitation, supporting documentation (including marketing and customer service procedures) and pricing and volume history with customers;
- v. co-ownership of an undivided interest (with Alere and its Affiliated Undertakings and their respective successors and assigns) in the trade secrets, confidential know-how, confidential customer data, or other confidential information and certain other intellectual property used both in the BC Commercialisation Divestment Business (but not predominantly) and in other businesses of Alere and its Affiliated Undertakings, to the extent used in the BC Commercialisation Divestment Business;

- to the extent they can transfer by law, all necessary regulatory clearances, registrations and authorisations used exclusively or predominantly in the distribution, marketing, promotion, selling or offering for sale of the BNP Assays;
- all inventories, including raw materials, works in process, semi-finished and finished products, stores, replacement and spare parts, packaging and labelling materials, operating supplies and inventory on consignment, in transit or deposited in a warehouse, in each case to the extent used in the BC Commercialisation Divestment Business, and other than those used in the BC Manufacturing Activities;
- all advertising, marketing, training and promotional materials, books, records, files, tax records, customers lists, information and history used exclusively in the BC Commercialisation Divestment Business, and co-ownership of an undivided interest of all other books, records, files, tax records, customers lists, information and history to the extent related to the BC Commercialisation Divestment Business;
- all of the following contracts to the extent related to the BC Commercialisation Divestment Business, namely all supply contracts, including the OEM Agreement to the extent it relates to the supply of BNP Assays, all distribution agreements; and customer contracts.
- At the option of the Purchaser, personnel providing customer services, distribution or sales and marketing services for the BC Commercialisation Divestment Business.

17. The Commitments provide that if there is any asset or personnel which is not covered by Schedule C of the Commitments but which is both used (exclusively or not) in the BC Commercialisation Divestment Business and necessary for the continued viability and competitiveness of the BC Commercialisation Divestment Business, that asset, or personnel, or adequate substitute will be offered to the purchaser.

18. In addition, the BC Commercialisation Divestment Business includes the benefit, for a transitional period of up to two years after Closing and on terms and conditions equivalent to those at present afforded to the BC Commercialisation Divestment Business, of all current arrangements under which Alere or its Affiliated Undertakings supply products or services to the BC Commercialisation Divestment Business, as detailed in Schedule C, unless otherwise agreed with the Purchaser.
19. The Commitments also provide that strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from such supply arrangements (e.g. product roadmaps) will not be shared with, or passed on to, anyone outside the BC Commercialisation Divestment Business operations.

B. Reasoned Proposal

20. Abbott signed a Sale and Purchase Agreement with Quidel in respect of the sale and divestiture of the Triage Divestment Business and the BC Commercialisation Divestment Business and a Sale and Purchase Agreement with Siemens in respect to the sale and divestiture of the EPOC Divestment Business on 15 and 21 July 2017 respectively. As indicated above, the present decision is limited to the assessment of Quidel as a suitable purchaser of both the Triage Divestment Business and the BC Commercialisation Divestment Business.
21. In its reasoned proposal of 28 July 2017 (the "First Reasoned Proposal"), Abbott proposed Quidel as the purchaser of the Triage Divestment Business and the BC Commercialisation Divestment Business for approval by the Commission, on the basis of the submitted signed Sale and Purchase Agreements as well as other related agreements (the "First Proposed Agreements").
22. Following a preliminary review of the First Reasoned Proposal and the First Proposed Agreements, the Commission services indicated to Abbott that certain aspects of the First Proposed Agreements appeared not to be in line with the Commitments and raised questions as to Quidel's ability to maintain and develop the Triage Divestment Business and the BC Commercialisation Divestment Business.
23. Danaher, the other party to the OEM Agreement to be divested as part of the BC Commercialisation Divestment Business, contacted the Commission services and the Trustee on 20 July and 18 August, expressing its opposition to Quidel as purchaser of the BC Commercialisation Divestment Business. Following the divestment of the BC Commercialisation Divestment Business, Danaher will manufacture the BNP Assays using antibodies that it will source from the purchaser of the Triage Divestment Business and will sell the BNP Assays it manufactures to the purchaser of the BC Commercialisation Divestment Business that will then commercialise them worldwide for use on the Beckman Analysers. Therefore, Danaher has a particular interest in ensuring that the purchaser of the BC Commercialisation Divestment Business has the financial resources, expertise and incentive to maintain and develop the divestment business. Danaher's primary concerns were that the Parties would retain material influence over the BC Commercialisation Divestment Business and that Quidel was not a suitable

purchaser, capable and with sufficient incentives to effectively operate the BC Commercialisation Divestment Business.⁵

24. Abbott submitted revised sale and purchase agreements and other related agreements (the "Revised Proposed Agreements") on 15 September 2017 as well as a revised reasoned proposal (the "Revised Reasoned Proposal") on 12 September 2017, in order to ensure compliance with the Commitments.
25. On 25 September 2017, the Trustee submitted a reasoned opinion (the "Reasoned Opinion") with an assessment of Quidel's suitability as a purchaser of the Triage Divestment Business and the BC Commercialisation Divestment Business and confirmed that Quidel fulfils the purchaser requirements set out in section D of the Commitments. In its assessment, the Trustee also indicated that, on the basis of the Revised Proposed Agreements, the Triage Divestment Business and the BC Commercialisation Divestment Business would be sold in a manner consistent with the Commitments.

II. ASSESSMENT OF THE PROPOSAL

A. Description of the purchaser

26. Quidel is a US company, commenced operations in 1979 and launched its first products in 1984. Headquartered in San Diego, California, the company is listed on the NASDAQ stock exchange with a market capitalisation of USD 1.48 billion as of 19 September 2017. The company reported net revenues of USD 192 million and a net loss of USD 14 million in 2016. As of June 2017, Quidel employed a total of 622 employees, with a presence in the Americas, Europe and Asia.
27. Quidel develops, manufactures and markets rapid test systems and POC diagnostic testing systems, which are sold directly to end users and distributors for professional use in physician offices, hospitals, clinical laboratories, laboratories, universities, clinics and screening centres. Quidel's products are categorised in four areas, namely (i) immunoassays; (ii) molecular assays; (iii) virology; and (iv) specialty products.
28. More concretely, Quidel manufactures POC analysers for immunoassay (Sofia, and its next generation Sofia 2) and molecular (Solana and the upcoming Savanna) testing, as well as associated assays that are run on these analysers. Quidel also produces non-instrumented molecular testing devices and has developed IT solutions that enable access to the Quidel ecosystem and to testing data in near real-time (Virena Connectivity). Quidel is extensively engaged in research and development ("R&D") in the area of POC diagnostics.
29. Quidel has submitted that it currently has one operating location in the EEA – a multi-purpose facility in Kornwestheim, Germany, which engages in manufacturing, R&D, sales & marketing, and distribution, and which was acquired as part of Quidel's acquisition of the company AnDiaTec GmbH in 2013. Quidel

⁵ Non-confidential version of Danaher's supplementary submission opposing Proposed Quidel Divestment of 18 August 2017, p.6-7; it should be noted that Danaher relied on information publicly available after the conclusion of the First Proposed Agreements in its submissions to the Commission and the Trustee.

currently has [number of employees] employees at this facility, [number of employees] dedicated to sales and marketing roles, [number of employees] focused on R&D activities, and [number of employees] employed as a general and administrative employee. In addition to these employees, Quidel's sales director for the Europe/Africa region is based in [EEA country]. As such, Quidel currently employs [number of employees] personnel in commercial roles in the EEA.

30. Quidel made sales of USD [...] million in the EEA in 2016 ([important proportion] are related to immunoassay products), at an operating margin of [...].% The majority of this revenue was derived in [EEA country] ([...].%) and [EEA country] ([...].%). Remaining EEA revenues were generated in [EEA country] ([...].%), [EEA country] ([...].%), [EEA country] ([...].%), [EEA country] ([...].%), [EEA country] ([...].%) and [...].% in other EEA countries.

B. Purchaser criteria

31. In order to be approved by the Commission, the Purchaser must fulfil the following criteria⁶:

- a) be independent of and unconnected to the Parties and their Affiliated Undertakings, this being assessed having regard to the situation following the divestiture;
- b) have an established presence, including distribution and sales capabilities, in the IVD sector in the EEA with a geographic footprint comparable to Alere prior to the concentration;
- c) have the financial resources, proven expertise and incentive to maintain and develop the Triage Divestment Business and the BC Commercialisation Divestment Business as a viable and active competitive force in competition with the Parties and other competitors;
- d) The acquisition of the Triage Divestment Business and of the BC Commercialisation Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Triage Divestment Business and the BC Commercialisation Divestment Business. In addition, the Purchaser must show to the Commission satisfactory evidence that it has obtained the consents of Scios and any other critical intellectual property rights holders for the transfer of the relevant licenses and/or use of the relevant other IP rights.

a. Independence from the Parties

32. In its Reasoned Opinion, the Trustee analysed information provided by Quidel and the Parties and submitted that there are no equity interests, cross-shareholdings, corporate links and common board directorships currently in place between each of Abbott and Alere and Quidel (or *vice versa*).

⁶ Commitments, paragraph 18.

33. The Commission and the Trustee originally identified the creation of four economic links through the First Proposed Agreements between Quidel and the Parties, intended to continue post-closing:

- the framework transitional services arrangements between Alere and Quidel (both ways);
- the distribution agreement concluded between Quidel and Abbott, whereby Abbott would act as Quidel's [confidential aspect on the arrangements with Quidel] distributor of BNP Assays outside the EEA;
- the payment arrangement, whereby Quidel pays Abbott the consideration for the BC Commercialisation Divestment Business in instalments over a 5-year period is directly linked to the performance of the BC Divestment Business;
- the leasing agreements for the benefit of the Parties on the San Diego site for a period of up to [more than 20] years.

34. The last three out of these future economic links between Quidel and the Parties were seen as creating a number of serious concerns regarding Quidel's independence after the completion of the proposed divestments of the Triage Divestment Business and the BC Commercialisation Divestment Business. In the Revised Proposed Agreements, Abbott aimed at addressing these concerns, as described under Sections (ii) – (iv) below.

i) Transitional services and supply arrangements between Alere and Quidel

35. A framework Transition Services Agreement was entered into by Abbott and Quidel for the Triage Divestment Business as part of the First Proposed Agreements. According to this agreement, Abbott shall provide to Quidel access to facilities, commercial, financial, regulatory and administrative support, research and development, IT-services, infrastructure, procurement, manufacturing and supply chain arrangements, as well as knowledge transfer for up to [...]. Quidel shall provide Abbott with reverse transitional services consisting in facilities access, knowledge transfer, IT applications support and manufacturing and supply chain arrangements for the same period of time.

36. A framework Transition Services Agreement was entered into by Abbott and Quidel for the BC Commercialisation Divestment Business as part of the First Proposed Agreements. According to this agreement, Abbott shall provide Quidel with commercial, financial, regulatory and administrative support, IT infrastructure, manufacture, supply chain arrangements and knowledge transfer for up to [...].

37. No material concerns have been identified by the Trustee in its Reasoned Opinion regarding the proposed transitional services and supply arrangements between Quidel and the Parties.⁷ In particular, the Trustee suggested that the scope and term of the agreed transitional arrangements appropriately reflect the transitional needs of the Triage Divestment Business and the BC Commercialisation Divestment Business that the duration of the transitional arrangements is in line with the

⁷ See Trustee Comments in Sections 7.5 and 8.5 of the Trustee's Reasoned Opinion.

Commitments. Indeed, the duration of the transitional period during which Quidel can chose to depend on Abbott is [...], which can be regarded as normal in the industry.

38. In light of all available information and particularly the scope and duration of the transitional services agreements and also having regard to the Trustee's Reasoned Opinion, the Commission finds that the transitional arrangements proposed by Abbott are in line with the Commitments

ii) The distribution agreement concluded between Quidel and Abbott for the BC Commercialisation Divestment Business

39. According to the First Proposed Agreements, Quidel would purchase the BC Commercialisation Divestment Business and consequently replace Alere in the OEM Agreement. As a result, Quidel would take over the relationship with Danaher, whereby Danaher manufactures BNP Assays on behalf and based on orders received by Quidel and, upon delivery, Quidel commercialises the BNP assays.

40. However, Quidel also concluded, as part of the First Proposed Agreements, a distribution agreement with Abbott for all countries outside the EEA. According to this [confidential aspect of the initial arrangement with Quidel] distribution agreement, Quidel would sell the BNP Assays to Abbott [confidential aspect of the initial arrangement with Quidel] and Abbott would then retain [confidential aspect of the initial arrangement with Quidel] powers regarding the commercialisation of the products of the BC Commercialisation Divestment Business in all non-EEA territories, such as [example of retained power 1], [example of retained power 2], [example of retained power 3], [example of retained power 4], [example of retained power 5], etc. This distribution agreement would be in place for [duration] years and Quidel would have [confidential aspect of the initial arrangement with Quidel].⁸ Moreover, the distribution agreement also limited Quidel's ability to [confidential aspect of the initial arrangement with Quidel] without Abbott's consent.⁹

41. The appointment of Abbott as the [confidential aspect of the initial arrangement with Quidel] distributor of the BC Commercialisation Divestment Business for the non-EEA countries in the First Reasoned Proposal was identified as incompatible with the Commitments, both by the Trustee¹⁰ and the Commission and was flagged to the Parties as such.¹¹

42. First, the scope of the BC Commercialisation Divestment Business is global, as evidenced by the fact that (i) the Decision clearly states in paragraph 257 that "[...] *The Divestment Businesses are worldwide in scope [...]*" and that "[...] *The BC*

⁸ Clause 11 of the Distribution Agreement, Exhibit C to the Purchase Agreement between Alere, Quidel and Abbott of 15 July 2017 regarding the BC Commercialisation Divestment Business.

⁹ Clause 5.8 of the Distribution Agreement, Exhibit C to the Purchase Agreement between Alere, Quidel and Abbott of 15 July 2017 regarding the BC Commercialisation Divestment Business.

¹⁰ See Section 8.7 of the Trustee's Reasoned Opinion.

¹¹ Additional information were requested from the Parties on 19 July 2017, following their initial presentation of the proposed divestment structure on 13 July 2017 and the incompatibility of the distribution agreement with the Commitments discussed in meetings held on [date] with the Parties, on [date] with Quidel and on [date] with the Parties and Quidel, as well as in several calls in the period prior to the submission of the Revised Reasoned Proposal.

Commercialisation Divestment Business also covers the worldwide commercialisation of BNP reagents for BCIS to customers of Danaher"; (ii) there is no geographic delimitation spelled out in the definition of the BC Commercialisation Divestment Business in the Commitments;¹² (iii) the Commitments' Schedule C and the Form RM and its annexes for the BC Commercialisation Divestment Business include financial data relating to the BC Commercialisation Divestment Business's worldwide revenues and profits and the top 20 customers worldwide, thus acknowledging that there is no delimitation of the geographic scope of the BC Commercialisation Divestment Business;¹³ and (iv) following the Decision Abbott's financial advisor, [...].¹⁴

43. Second, the appointment of Abbott as [confidential aspect of the initial arrangement with Quidel] distributor of the BC Commercialisation Divestment Business appears to be in breach of paragraph 18a of the Commitments which provide that the proposed buyer of the divestment business must be "[...]independent of and unconnected to the Parties[...]" and of paragraph 5 of the Commitments, whereby Abbott commits that it "[...]shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence over the whole or part of the Divestment Business [...]".
44. According to the proposed distribution agreement, Abbott, by virtue of its appointment as [confidential aspect of the initial arrangement with Quidel] distributor would be [confidential aspect of the initial arrangement with Quidel] regarding the BC Commercialisation Business outside the EEA. More concretely, [example of retained power 1], [example of retained power 2], [example of retained power], [example of retained power 4], [example of retained power 5], etc. would be [confidential aspect of the initial arrangement with Quidel], and Quidel, despite being the purchaser of the BC Commercialisation Business, would be [confidential aspect of the initial arrangement with Quidel] in such matters. Quidel's [...] involvement with the commercialisation of BNP Assays outside the EEA would appear to be limited to [confidential aspect of the initial arrangement with Quidel].
45. Third, Abbott would have access to information on the BC Commercialisation Divestment Business, while being a direct competitor of Danaher in the commercialisation of IVD laboratory immunochemistry testing.¹⁵
46. Taking into account that the non-EEA countries represent around [important propotion] of the global turnover of the BC Commercialisation Business, Abbott would have continued to retain decisive influence on [...] distribution related issues in relation to the BC Commercialisation Business in all of the non-EEA countries and be in the position of indirectly impact Quidel's and Danaher's sales in the EEA,

¹² See in particular paragraph 6 of the Commitments and paragraph 2 of Annex C of the Commitments stating that "*The BC Commercialization Divestment Business consists of the commercialization of BNP Assays to customers of Danaher for use on the Beckman Analyzers, and also includes the personnel required for such commercialization*".

¹³ Annexes C2 and C3 to the Form RM.

¹⁴ [...].

¹⁵ According to Danaher, the distribution agreement with Quidel for outside the EEA would allow Abbott "*to disparage the quality and reliability of [Danaher] systems including inside the EEA*". Non-confidential version of Danaher's supplementary submission opposing Proposed Quidel Divestment of 18 August 2017, p.6-7.

e.g. by increasing the cost per unit or by compromising BNP Assays' reliability and reputation.

47. In the Revised Reasoned Proposal, Abbott addressed all of the above issues. No distribution agreement is concluded between Quidel and Abbott and Quidel intends to commercialise the BNP Assays outside the EEA through distribution agreements with third parties (unrelated to Abbott), as Alere currently does. Moreover, the limitations previously included in the distribution agreement as to Quidel's ability to [confidential aspect of the initial arrangement with Quidel] without Abbott's consent are not replicated in the Revised Proposed Agreements.
48. The Trustee notes in his Reasoned Proposal that according to the Final Proposed Agreements, Quidel will be the sole entity commercialising, marketing and distributing the BNP Assays within and outside the EEA and that the Parties will have no ability to impact the sale of BNP Assays or the placement of Beckman Analysers after the divestment. Moreover, the Trustee considers that the current divestment structure also addresses the concerns raised by Danaher in relation to the distribution agreement.
49. Following the removal of the distribution agreement between Quidel and Abbott and the exclusion of any clause likely to limit Quidel's ability to [confidential aspect of the initial arrangement with Quidel] with Danaher, the Commission concludes that the proposed structure of the divestment of the BC Commercialisation Divestment Business is in line with the Commitments.

iii) The payment arrangement for the BC Commercialisation Divestment Business

50. Abbott's First Reasoned Proposal provided for a contingent payment structure for the BC Commercialisation Divestment Business, whereby Quidel would pay Abbott in five annual instalments of USD 8 million each. The First Proposed Agreements also provided that Quidel could stop paying if (i) a competing BNP test compatible with Danaher's analysers were launched and (ii) BC Commercialisation Divestment Business' sales in the EEA fell below certain threshold in the EEA, which amounted to approximately [important proportion] of the EEA sales in the twelve months leading to the entry of the competitor.
51. Abbott and Quidel argued that this agreement was put in place in order to protect Quidel from the possible entry of a competitor to the BC Commercialisation Divestment Business, by mitigating Quidel's financial risk in case its revenues were materially reduced following a competitor's entry.
52. The payment structure of the BC Commercialisation Divestment Business in the First Reasoned Proposal has been identified as incompatible with the Commitments, both by the Trustee¹⁶ and the Commission, and has been brought to the Parties' attention.
53. First, the fact that the instalment payments are conditional on the sales of the BC Commercialisation Divestment Business following its acquisition by Quidel is likely to compromise Quidel's incentives to "maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties

¹⁶ See Trustee Comments in Section 8.8.1 of the Trustee's Reasoned Opinion.

and other competitors".¹⁷ Indeed, if following the entry of a competing product a reduction in sales would relieve Quidel from one or more outstanding payments of USD 8 million, its incentives to compete on the market may diminish. As a result, any payment structure, whereby the amount of the payment for the BC Commercialisation Divestment Business depends on or is in anyway linked to the performance of that divestment business, would not be compatible with the Commitments.

54. Second, the mere fact that Abbott and Quidel agreed on that payment structure for the BC Commercialisation Divestment Business in the First Reasoned Proposal, puts into question Quidel's ability and willingness to operate the divestment business as a competitive force competing with the Parties and other competitors, as required by the Commitments.¹⁸ Indeed, Quidel has agreed on reduced payments for the divestment business if another competitor enters the market and there is a drop in its sales, thus appearing unwilling to take over the business risk of competing on the market. The fact that Quidel would pay a lower purchase price if its sales drop, would instead appear as reducing its incentives to compete and increase its sales.
55. Third, any sharing between Abbott and Quidel of the BC Commercialisation Divestment Business' commercial risk of having to face a new competitor, in case a competing BNP test compatible with Danaher's analysers is launched by Danaher itself, or another company, would be incompatible with the obligation for the purchaser to remain independent and unconnected to Abbott included in the Commitments.¹⁹
56. In its submission, Danaher also views the payment structure and total purchase price agreed for the BC Commercialisation Divestment Business in the Original Reasoned Proposal as evidence of Quidel's lack of interest in taking over the operation of the business and undertaking any related commercial risk. In particular, Danaher also points out that Quidel may be better off if sales decline, as its obligation to pay is linked to the sales it achieves.²⁰
57. In the Revised Reasoned Proposal, Abbott addressed all of the above issues. A payment schedule has been agreed upon between Abbott and Quidel, whereby Quidel will pay USD 8 million in five annual instalments for the EEA commercialisation of the BNP Assays and USD 240 million in six annual instalments for the commercialisation of BNP Assays in outside the EEA. In case a competing BNP Assay (compatible with Danaher's analysers) is launched by Danaher or any other competitor and that competing product generates material sales in [designated countries], the instalment payments for the EEA commercialisation of the BNP Assays will be reduced.²¹

¹⁷ Clause 18c of the Commitments.

¹⁸ Clause 18c of the Commitments.

¹⁹ Clause 18.a of the Commitments.

²⁰ Non-confidential version of Danaher's supplementary submission opposing Proposed Quidel Divestment of 18 August 2017, p.6.

²¹ The agreed reductions of the instalment payments differ, depending on the moment in time in which a competing BNP Assay (compatible with Danaher's analysers) of Danaher or any other competitor will enter the EEA market. The total payment for the EEA commercialisation of the BNP Assays over five years thus ranges between USD 16 million (if a competitor enters before the initial payment date) and USD 40 million (if a competitor enters after the 2022 payment date).

58. The payment provided for in the Revised Reasoned Proposal is no longer conditional on the commercial behaviour of the purchaser or in any way contingent upon circumstances under the control of the Parties or Quidel.²² Therefore, the payment structure in the Revised Reasoned Proposal is not liable to influence Quidel's incentives to compete on the market. Moreover, the overall payment is materially higher than in the First Proposed Agreements, thus demonstrating Quidel's willingness to invest into the BC Commercialisation Divestment Business.²³
59. The Monitoring Trustee in its Reasoned Opinion also suggested that the final payment structure should be seen as acceptable under the Commitments.²⁴
60. Following the removal of the clause conditioning the payment to the sales generated by the BC Commercialisation Divestment Business, the Commission concludes that the proposed payment structure for the BC Commercialisation Divestment Business is in line with the Commitments.

iv) The rental agreements for the San Diego site

61. Under the First Proposed Agreements,²⁵ Abbott and Quidel entered into a sell and lease-back agreement for part of the San Diego facility, in which the manufacturing of the Triage, the anti-bodies used in the BNP Assays, as well as the development and manufacturing of products retained by the Parties take place.
62. More concretely, the sell and lease-back provided that following the sale of the entire site to Quidel, Quidel would concentrate its activities to two of the four buildings of the San Diego facility (Buildings C and D) and lease the other two (Buildings A and B) to Abbott. The lease period of Building A would be [...] years, with a possibility to renew [...] for [...] additional periods. The lease period of Building B would be for [...] years, with the possibility to renew up to [...] times for additional [...] -year periods.
63. Abbott argued that the lease-back agreement would allow it to continue occupying portions of the San Diego property until [...] and that Quidel does not need all four buildings to be viable.²⁶
64. The sell and lease-back agreement regarding part of the San Diego facility in the First Reasoned Proposal was identified as incompatible with the Commitments, both by the Trustee²⁷ and the Commission and was flagged to the Parties as such.
65. First, Abbott committed to transfer all its activities out of and exit the San Diego facility. This is reflected in the Decision, which reports that the initial commitment proposal consisting in the divestiture of only part of the San Diego plant received

²² In particular, in the event of a competing product launch, Quidel will save a capital cost, but this will impact neither the variable or marginal costs of the commercialisation of the BNP Assays, nor the margin Quidel will obtain from their commercialisation.

²³ The higher payment also reflects the fact that Quidel will be effectively in charge of the worldwide commercialisation of the BNP Assays, and will be able to reap the full benefits from this business.

²⁴ See Section 9.4 of the Trustee's Reasoned Opinion.

²⁵ Triage Purchase Agreement, Exhibit E.

²⁶ Abbott's position paper of [date].

²⁷ See Trustee Comments in Section 7.5 of the Trustee's Reasoned Opinion.

negative feedback from the market test, and that in response to this result Abbott submitted revised commitments, explicitly providing for the divestment of the entire San Diego plant.²⁸ The Commitments text also refers to the full divestment of the San Diego facility, by providing that "[...]the retained Alere activities will be transferred out of the San Diego facility[...]"²⁹

66. Second, the sharing of the same facility on a long-term basis could compromise Abbott's compliance with the Commitments, to the extent that Abbott committed to ensure that strong firewall procedures would be in place regarding any potentially commercial sensitive information of the Divestment Businesses, as well as to not re-acquire influence over the Divestment Businesses.³⁰
67. Under the Revised Proposed Agreements, the Parties ultimately agreed that Abbott would only transitionally occupy these two buildings, until [...]. For Building A, Abbott agreed to leave within [x] years from the closing of the divestment of the Triage Divestment Business (except for one dedicated room), while, for Building B, the dedicated room in Building A and defined shared spaces at the San Diego facility, Abbott agreed to leave within [y] years from Closing. The [y]-year transitional period may be renewed for one additional period of [...] years, subject to [confidential aspect of the initial arrangement with Quidel].
68. The Trustee notes in his Reasoned Opinion that, as Abbott has now agreed to only occupy Buildings A and B transitionally until all activities for Alere's retained business can be transferred out and Quidel does not require the entirety of the facility to operate the Triage Divestment Business and the BC Commercialisation Divestment Business, the proposed rental agreement between Abbott and Quidel should be considered acceptable under the Commitments.³¹ The Trustee, however, also considers that appropriate and continued hold-separate and ring-fencing of the divested and retained business activities and respective personnel and information need to be maintained by Abbott and Alere.³²
69. The Commission finds that the revised lease agreement for part of the San Diego facility is in line with the Commitments, as it now only covers the transitional period required for Abbott to transfer out its retained activities, that are unrelated to the divested activities and currently conducted in that facility. The Trustee will monitor the transfer so as to ensure that the two businesses are held and operated separately from one another. In particular, the Parties will cooperate with the Trustee so as to ensure that the sharing of the San Diego facility during the lease period does not result in coordination with or decisive influence exercised by

²⁸ See in conjunction paragraph 225 on the initial set of Commitments: "*The Triage Divestment Business consists in parts of the manufacturing and R&D facility located in San Diego (United States), where the Triage system is currently manufactured (two buildings out of the four buildings of the plant, together with the personnel and inventories in these buildings).*"; paragraph 240 on the market tests results: "*In that respect, several respondents, firstly identified the San Diego plant sharing, transitional services and also the envisaged leasing of part of one building by the merged entity, as creating complexities and entanglements for the Purchaser, affecting the viability of the divestment.*"; and paragraph 246 of the Commitments: "*First, the Final Commitments include in the Triage Divestment Business the entire San Diego manufacturing facility and provide for a reverse carve-out for the manufacturing businesses of the other, unrelated Alere products, currently in that site.*"

²⁹ Commitments, Schedule B, paragraph 6.a.i.

³⁰ Clauses 5 and 7 of the Commitments.

³¹ See Trustee Comments in Sections 7.5 of the Trustee's Reasoned Opinion.

³² See Trustee Comments in Section 7.5 and 7.8 of the Trustee's Reasoned Opinion.

Abbott over the Triage Divestment Business and BC Commercialisation Divestment Business.

Conclusion

70. The Trustee suggests in its Reasoned Opinion that it has not identified any current or through the Revised Proposed Agreements established material links between the Parties and Quidel that would give rise to concerns from an independence perspective.³³
71. Based on all available information and also having regard to the Trustee Reasoned Opinion the Commission establishes that Quidel is independent of and unconnected to Abbott and Alere.

b. Established presence in the IVD sector in the EEA

72. It is recalled that the Commitments of 19 January 2017 stipulate that the acquirer(s) of the Triage Divestment Business and BC Commercialisation Divestment Business "*shall have an established presence, including distribution and sales capabilities, in the In Vitro Diagnostics (IVD) sector in the EEA with a geographic footprint comparable to Alere prior to the Concentration*".³⁴
73. Moreover, based on publicly available information following the First Proposed Agreements, Danaher submitted to the Commission its concern that, in light of its size, resources, geographic focus and experience, Quidel would not be capable to effectively operate the BC Commercialisation Divestment Business. Danaher was also concerned that Quidel would cooperate in the EEA with distributors likely not having the incentives to actively promote the BNP Assays.³⁵
74. In its Reasoned Opinion, the Trustee analysed information provided by Quidel and the Parties and submitted that, in the EEA, Quidel is active in the IVD sector on markets which are similar or adjacent to those of the Triage Divestment Business and BC Commercialisation Divestment Business. Quidel, however is not active in the IVD laboratory market, to which the BNP Assays of the BC Commercialisation Divestment Business belong.
75. The Trustee also found that Quidel has a direct presence in the EEA since 2013 and sells its products (either directly or through distributors) in 19 countries in the EEA.³⁶ Quidel currently employs [number of employees] individuals in the EEA, of which, [number of employees] are in sales and marketing roles. In 2016, Quidel achieved revenues of USD [...] million in the EEA.³⁷
76. Having analysed Alere's and Quidel's current presence in the EEA, as well as Quidel's business plans in relation to the Triage Divestment Business and the BC Commercialisation Divestment Business submitted as part of the Revised Reasoned

³³ See Section 9.5 of the Trustee's Reasoned Opinion.

³⁴ Commitments, paragraph 18b.

³⁵ Non-confidential version of Danaher's supplementary submission opposing Proposed Quidel Divestment of 18 August 2017, p.5-6.

³⁶ Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden and the United Kingdom

³⁷ See Section 3.3 of the Trustee's Reasoned Opinion.

Proposal and the Trustee's Reasoned Opinion, the Commission establishes that Quidel has an established presence in the IVD sector in the EEA that allows it to effectively operate the two divestment businesses, for the following reasons:

77. First, Quidel already generates sales in [...] countries in which the Triage Divestment Business recorded sales in 2016 and [...] countries in which the BC Commercialisation Divestment Business recorded sales in 2016.
78. Second, based on the information received from Quidel and the Parties, the Trustee notes that even if Alere's total sales and distribution footprint in the EEA is larger than Quidel's, the personnel dealing with the Triage Divestment Business and the BC Commercialisation Divestment Business in the EEA is equivalent to [number of employees] full time employees ([number of employees] in [EEA country], [number of employees] in [EEA country] and [number of employees] in [EEA country]).³⁸
79. In addition to its existing [number of employees] sales and distribution personnel in the EEA, Quidel will offer employment to [number of employees] Alere sales and distribution personnel in the EEA ([number of employees] in [EEA country], [number of employees] in [EEA country] and [number of employees] in [EEA country]), as part of the acquisition of the Triage Divestment Business and BC Commercialisation Divestment Business. The Hold Separate Manager ("HSM") confirmed that the individuals identified by Quidel among Alere's employees have extensive experience to train others. In order to incentivise Alere's employees to join Quidel, Quidel intends to offer them a sign-on/retention bonus. Should any employees not accept that opportunity, Quidel expects and the Parties confirmed to the Trustee that Quidel will be permitted to approach other individuals identified by the Parties. Therefore, Quidel will have [number of employees] sales and marketing personnel in the EEA after the completion of the proposed acquisitions, of which [number of employees] in [EEA country], [number of employees] in [EEA country], [number of employees] in [EEA country], [number of employees] in [EEA country] and [number of employees] in [EEA country]. In addition, Quidel will also have [number of employees] sales and marketing personnel in [...].
80. In the rest of the EEA, Quidel intends to cooperate with distributors for the sale of Triage products and BNP Assays. Quidel currently generates revenues for its own products in some EEA countries by sales through distributors. Similarly, Alere's current sales of Triage systems and BNP Assays are also generated in some EEA countries through distributors.
81. Following the Revised Proposed Agreements, Quidel will be able to decide in all independence on all aspects of the running of the BC Commercialisation Divestment Business, including on matters concerning the choice of its distributors. As analysed in more detail in section c below, Quidel has strong incentives to increase BNP Assays' sales in order to recoup its material investment in the BC Commercialisation Divestment Business, further increase revenues and benefit from the associated important gross margins. In order to achieve that, Quidel is reinforcing its EEA presence in order to sell directly in the EEA countries where

³⁸ See Section 3.3 of the Trustee's Reasoned Opinion.

most of the BNP Assays' sales³⁹ occur and will ensure that the distributors it cooperates with in the rest of the EEA will effectively promote BNP Assays.

82. Third, in cooperation with the Parties and Quidel, the Trustee analysed whether the EEA sales force that Quidel will have in the EEA after the proposed acquisitions will enable it to make the necessary sales calls in each EEA jurisdiction to the level that Alere does today. The Trustee submits that the sales calls estimates of Quidel exceed by [...] % those achieved by Alere, thus providing additional comfort that, even if this forecast were to be somewhat overestimated, Quidel would have a sales presence in the EEA comparable to that of Alere.
83. Finally, Quidel has informed the Trustee that it intends to hire [number of employees] to [number of employees] additional commercial employees in the EEA within [duration] years of Closing, in order to (i) develop regional headquarters in Europe, (ii) centralise its customer service functions for Europe, (iii) further improve its ability to deal with customers' technical issues and complaints and (iv) to also open a distribution centre in Europe.
84. Based on all available information and also having regard to the Trustee Reasoned Opinion, the Commission concludes that Quidel has an established presence, including distribution and sales capabilities in the IVD sector in the EEA with a geographic footprint comparable to Alere.

c. Financial resources, proven expertise and incentive to maintain and develop the Triage Divestment Business and the BC Divestment Business as a viable and active competitor

85. It is recalled that paragraph 18c of the Commitments stipulates that the purchaser "*shall have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors*".

Financial resources

86. In its Reasoned Opinion, the Trustee analysed information provided by Quidel and the Parties and submitted that, in 2016, Quidel generated USD 192 million of revenues, increased from USD 175 million in 2013 by CAGR of 3.0%.⁴⁰ Gross margin achieved by Quidel have been fairly constant over the 2013-2016 period at an average level of 62%.⁴¹ While Quidel made a net loss in each of 2014, 2015 and 2016, which the Trustee understands to be largely driven by high operating costs, the Trustee observes that operating cash flows as well as EBITDA⁴² have been consistently positive in each of these years, respectively reaching USD [...] million and USD [...] million in 2016, and with an average EBITDA margin of

³⁹ Quidel will have a direct presence in [EEA countries], where approximately [...] % of the BNP Assays' sales occur in the EEA, Section 7.4.7 of the Trustee's Reasoned Opinion.

⁴⁰ By comparison, the revenues of the Triage Divestment Business on a *pro forma* basis for 2016 were USD 146 million, or approximately 76% of Quidel's revenues.

⁴¹ By comparison, the gross margin of the Triage Divestment [...] and the gross margin of the BC Divestment Business was [...] in 2016.

⁴² Earnings Before Interest, Taxes, Depreciation and Amortisation.

approximately [5-10]-[20-30]% over the period. Operating expenses are driven by high sales and marketing costs and high R&D expenditures, at an average level of [20-30]% and [20-30]% of revenues, respectively.

87. As of June 2017, Quidel employs [number of] personnel in its R&D division, representing [...]% of its overall workforce. When compared to revenues, Quidel's level of R&D investment is materially higher than for its peer competitors as assessed by the Trustee, namely Abbott, Alere, Danaher, Thermo Fisher, Becton Dickinson and Meridian Bioscience. The Trustee understands that this reflects Quidel's efforts and strategy to grow its product portfolio and customer base while having products in (relatively) early stages.
88. Excluding the impact of the proposed acquisitions of the Triage Divestment Business and the BC Commercialisation Divestment Business, Quidel forecasts its EBITDA margin to increase to [...]% in 2017, driven by both revenue growth and an improved operating margin.
89. As far as the proposed acquisition of the Triage Divestment Business is concerned, Quidel has agreed to pay USD 400 million. It intends to fund this acquisition as well as associated costs of USD [...] million, through USD [...] million of cash⁴³, and the proceeds of the issuance of a committed USD 245 million senior secured term loan. In addition, Quidel has agreed a USD 25 million revolving credit facility with the same banks providing it with the secured term loan. Quidel is permitted to use this facility for general corporate purposes.
90. Concerning the proposed acquisition of the BC Commercialisation Divestment Business, Quidel has agreed to pay USD 280 million, of which USD 40 million in contingent consideration, payable in instalments of USD 8 million over 5 years (EEA business) and USD 240 million payable in instalments of USD 40 million over 6 years (non-EEA business). The financial model provided to the Trustee by Quidel indicates that it will be able to fund these instalments through cash on hand or committed credit facilities at the time of payments. [Business secrets relating to Quidel's financial situation].
91. Based on the available information, the Trustee considers that Quidel is in a strong solvency position, with significant cash holdings and a net cash position (i.e. no net debt) prior to the proposed acquisitions of the Triage Divestment Business and the BC Commercialisation Divestment Business. In the context of the proposed acquisitions, the Trustee notes the ability of Quidel, as a publicly listed company, to secure material borrowing from top tier lenders and observes that reactions of both research analysts and the stock market to the announcement of the proposed acquisitions are also positive. The Trustee further notes that the projected financial performance of Quidel includes material deleveraging of its balance sheet and that Quidel should be able to repay its debts as and when they fall due.
92. Based on all available information and also having regard to the Trustee Reasoned Opinion, the Commission concludes that Quidel has the financial resources necessary to maintain and develop both the Triage Divestment Business and the BC Commercialisation Divestment Business as viable and active competitive forces.

⁴³ As of 30 June 2017, Quidel had cash holdings of USD 175 million.

Proven expertise

93. Since 2010, inorganic growth has been a significant component of Quidel's strategy and has provided Quidel with repeated experience in integrating companies within the IVD sector. Significant acquisitions have been:
- Diagnostics Hybrids Inc., a privately owned business based in the USA that develops, manufactures and markets cellular and molecular IVD kits, which enabled Quidel to broaden its portfolio in non-seasonal infectious and autoimmune diseases (February 2010, USD 131 million);
 - BioHelix Inc., a molecular diagnostics company based in the USA and which enabled Quidel to accelerate the development of its AmpliVue isothermal assays (May 2013, USD 19 million);
 - Assets of AnDiaTec GmbH, a German based developer and manufacturer of molecular assays, which enabled Quidel to broaden its molecular IVD expertise, accelerate its molecular assay development as well as provide Quidel with a direct presence in the EEA through AndiaTec's facility in Kornwestheim, Germany (May 2013, USD 7 million);
 - Immutopics, Inc., a life science research company based in the USA and incorporated into Quidel's MicroVue brand (March 2016, USD 5 million);
 - Two diagnostics businesses (InflammaDry and AdenoPlus) from RPS Diagnostics, a developer and manufacturer of rapid POC tests for eye health and primary care markets (May 2017, USD 14 million).
94. Quidel has relevant experience and competencies in designing, marketing and selling products in markets which are similar or adjacent to those of the Triage Divestment Business and the BC Commercialisation Divestment Business, in particular through its Sofia product, for which it develops and sells immunoassay testing devices as well as the assays to be used on this product. Over the 2014-2016 period, Quidel's revenues derived from its activities in immunoassay products represented [...] % of its yearly revenues.
95. From the financial information available, Quidel appears to show a commitment to invest in R&D and received, since 2009, 25 clearances from the US Food and Drug Administration and has launched the AmpliVue, Lyra, Sofia, Solana and Sofia 2 products on the IVD market.
96. The Trustee further notes that several board members of Quidel including its Chairman, who was a co-founder of the business that developed the Triage system, have experience in the IVD sector.
97. In view of the above considerations and in line with the Reasoned Opinion of the Trustee, the Commission finds that Quidel has the proven expertise in the IVD sector necessary to maintain and develop both the Triage Divestment Business and the BC Commercialisation Divestment Business as viable and active competitive forces.

Incentives to maintain and develop the Triage Divestment Business as an active and viable competitor

98. Quidel's rationale for acquiring the Triage Divestment Business is (i) to enter the cardiology and toxicology markets, (ii) to reduce its exposure to the seasonality of its existing markets and (iii) to achieve synergies of USD [...] million per year following the integration of the Triage Divestment Business. Quidel furthermore notes that it is located very near to the Triage Divestment Business' manufacturing operations in San Diego.
99. [Business secrets relating to Quidel's R&D and business plans].
100. While the growth forecasts provided by Quidel are higher than the recent (negative) growth performance of the Triage Divestment Business, the Trustee observes that Quidel's business plan is based on a more conservative forecast than that outlined by Abbott to potential purchasers and notes that the hold separate manager ("HSM") for the Triage Divestment Business considers Quidel's growth forecasts to be relatively conservative and reasonable.
101. According to the Trustee, Quidel's business plan for the Triage Divestment Business appears to be consistent with the objective of creating a viable and active competitive force in the market, with revenue and EBITDA expected to grow throughout the forecast period.
102. Based on all available information and also having regard to the Trustee Reasoned Opinion, the Commission concludes that Quidel has incentives to maintain and develop the Triage Divestment Business as an active and viable competitive force.

Incentives to maintain and develop the BC Commercialisation Divestment Business as an active and viable competitor

103. [Business secrets relating to Quidel's financial forecast plans].
104. Quidel's rationale for the acquisition of the BC Commercialisation Divestment Business is (i) to take advantage of the natural fit with the Triage Divestment Business (given that the Triage Divestment Business manufactures the antibodies used in the production of the BNP Assays), (ii) to benefit from the fact that revenues of the BC Commercialisation Divestment Business are linked to the large existing installed base of Beckman Analysers and (iii) to further reduce Quidel's exposure to the seasonality of certain of its existing products.
105. According to the Trustee, Quidel's business plan for the BC Commercialisation Divestment Business, which provides a material revenue and EBITDA contribution to Quidel, appears to be consistent with the objective of creating a viable and active competitive force in the market.
106. Danaher raised concerns as to Quidel's incentives to operate the BC Commercialisation Divestment Business efficiently and with a view to compete on the market. Danaher, in light of publicly available information on the First Proposed Agreements, considered that Quidel was mainly interested in the acquisition of the Triage Divestment Business and had no intention to invest in the BC

Commercialisation Divestment Business.⁴⁴ According to Danaher, such lack of incentives could result in a material reduction of sales and eventually impact Danaher's position on the IVD markets in the EEA.

107. Following the Revised Reasoned Proposal, however, it becomes clear that the acquisition of the BC Commercialisation Divestment Business is a material investment for Quidel, which it seriously plans to recoup by through substantial sales of BNP Assays. Moreover, the BC Commercialisation Divestment Business achieves significant gross margins ([...] % in 2016), Quidel thus has strong incentives to increase its sales in order to further increase revenues and benefit from the associated important gross margins.

108. The Trustee notes that Quidel appears to be highly incentivised to continue working with Danaher in order to benefit from the attractive returns generated under this business model, given the high-margin nature of the BC Commercialisation Divestment Business and its strong interdependence with Danaher under the existing OEM Agreement.

109. Similarly, the HSM confirmed that Quidel has incentives to work closely with Danaher as it is in both players' interests to have the best forecasting information available as a mechanism to avoid rushed production requirements that could lead to a supply interruption either creating a problem for Danaher by Quidel not having antibodies or samples that Danaher needs, or by Danaher not being able to meet extra demand for Danaher kits that could result from successful marketing efforts.

110. Based on all available information and also having regard to the Trustee Reasoned Opinion, the Commission concludes that Quidel has incentives to maintain and develop the BC Commercialisation Divestment Business as an active and viable competitive force.

C. Absence of prima facie competition concerns

Horizontal overlaps and vertical relationships

111. Given the specificities of the IVD areas in which Quidel is active on the one hand and to which the Triage Divestment Business and the BC Commercialisation Divestment Business belong on the other hand, the proposed acquisitions of the Triage Divestment Business and the BC Divestment Business by Quidel do not give rise to horizontally affected markets or vertically affected ones.

112. More specifically, the Triage Divestment Business and the BC Commercialisation Divestment Business relate to the fields of cardiac and toxicology diagnostics, fields in which Quidel is not active since its IVD testing solutions primarily address infectious diseases, women's health, gastrointestinal diseases, autoimmune diseases, bone health and thyroid diseases. In all of those markets Quidel's market shares are well below 30% under any plausible geographic market delineation, namely EEA-wide or national.

⁴⁴ Non-confidential version of Danaher's supplementary submission opposing Proposed Quidel Divestment of 18 August 2017, p.6.

113. In terms of vertical concerns, Quidel, as Alere prior to the concentration, has no incentive to foreclose Danaher from the supply of antibodies for the manufacture of BNP Assays and for the commercialisation and distribution of these assays for use on the Beckman Analysers as Quidel (like Alere prior to the concentration) is not active in the downstream market for laboratory IVD analysers that would compete with Danaher's laboratory devices. In countries where Quidel has no direct presence, Quidel will have strong incentives to select distributors that are similarly not active in the market for laboratory IVD analysers.

114. In its Reasoned Opinion, the Trustee notes that it has not identified any material *prima facie* competition concerns in respect to the proposed acquisitions of the Triage Divestment Business and the BC Commercialisation Divestment Business, as Quidel (i) is not currently present in the specific markets in which these two divestment businesses operate and (ii) has an incentive to continue working with Danaher in order to ensure the continued operation and development of the BC Commercialisation Divestment Business along the lines of the existing antibodies supply and assay purchasing/commercialising arrangement given the high-margin nature of the business and attractive returns to be generated by Quidel.

115. In view of the above considerations and in line with the Reasoned Opinion of the Trustee, the Commission concludes that the proposed acquisitions of the Triage Divestment Business and the BC Commercialisation Divestment Business by Quidel are unlikely to give rise to *prima facie* competition concerns.

116. As further explained below, based on the information submitted by Abbott and Quidel, the acquisition of the Triage Divestment Business and the BC Divestment Business by Quidel does not result into a notifiable concentration in the EEA.

117. This *prima facie* assessment is based on the information available to the Commission for the purpose of this buyer approval and does not prejudice the possible competition assessment of the acquisition of the Divestment Business by Quidel by a competent competition authority under applicable merger control rules.

Consents of Scios and of any other critical IP rights holders for the transfer of the relevant licences

118. The IP rights used in the Triage Divestment Business consist primarily of patents and know-how owned by Alere, none of which is subject to third-party consent requirements.

119. According to the Commitments,⁴⁵ Abbott committed to assign to Quidel all relevant rights held by Alere under the Scios license for the manufacturing, development and commercialisation of Triage products and for the BC Manufacturing Activities at Closing. The Trustee reviewed a letter dated [date] signed by Scios whereby it formally consents to such assignment.

120. With respect to in-licensed IP (besides Scios), consent is required to assign the IP rights under agreements with [several licensors]. The Trustee submits that it is not aware of any material issues in this respect, as consent by [a particular licensor] was obtained on [date] and the Parties are finalising the requisite documentation with

⁴⁵ See paragraph 6(b)(v) of Schedule B of the Commitments.

[remaining licensors]. At Closing, the license agreements will be assigned to Quidel, unless the consent of the counterparty is required to effect such assignment and such consent is not received prior to Closing. Abbott confirmed in this respect that, if any license agreement is not assigned at Closing, then, under the Revised Proposed Agreements, Abbott and Quidel would continue to seek such consent post-Closing and, in the interim, would implement alternative arrangements to provide Quidel with the rights and benefits of such agreements. The Commission will continue monitoring the transfer of all required IP rights, with the help of the Trustee and the cooperation of Abbott and Quidel.

121. In view of the above considerations and in line with the Reasoned Opinion of the Trustee, the Commission concludes that there is satisfactory evidence that Quidel will obtain consents of Scios and other IP rights holders for the transfer of the relevant licenses and/or use of the relevant IP rights necessary for the viability of both the Triage Divestment Business and the BC Commercialisation Divestment Business.

Other jurisdictions where the acquisitions of the Triage Divestment Business and the BC Commercialisation Divestment Business are notifiable

122. Given the magnitude and location of the revenues of Quidel, the Triage Divestment Business and the BC Commercialisation Divestment Business, only the acquisition of the BC Commercialisation Divestment Business by Quidel is subject to notification in the US pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR"). Quidel and Alere submitted their HSR filings on 19 September 2017 and Abbott expects the BC Commercialisation Divestment Business to be cleared by the Federal Trade Commission shortly.

III. ASSESSMENT OF THE PROPOSED AGREEMENTS

123. The Revised Proposed Agreements between Abbott and Quidel were signed on 15 September 2017 and set forth Quidel's irrevocable commitment to purchase the Triage Divestment Business and the BC Commercialisation Divestment Business on the terms and conditions as set forth in the corresponding Sale and Purchase Agreements.

124. The Revised Agreements are fully in line with the scope of the Triage Divestment Business and the BC Commercialisation Divestment Business as defined in the Commitments. The Commitments also contain elements that are at the option of the purchaser and that have been required by Quidel. These include the transfer of additional sales personnel.

125. The Trustee has reviewed and provided an assessment of the Revised Proposed Agreements and submitted that these fulfil the requirements of the Commitments and that the Triage Divestment Business and the BC Commercialisation Divestment Business are sold in a manner consistent with the Commitments.

126. Based on all available information and also having regard to the Trustee Opinion, the Commission concludes that the Triage Divestment Business and the BC Commercialisation Divestment Business are sold in a manner that is consistent with the Commitments.

IV. CONCLUSION

127. On the basis of the above assessment, the Commission approves Quidel as a suitable purchaser for the above-mentioned reasons.
128. Moreover, on the basis of the Revised Proposed Agreements, the Commission further concludes that the Triage Divestment Business and of the BC Commercialisation Divestment Business are being sold in a manner consistent with the Commitments.
129. This decision only constitutes approval of the proposed purchaser identified herein and of the Revised Proposed Agreements. This decision does not constitute a confirmation that Abbott has complied with their Commitments.
130. This decision is based on paragraph 19 of the Commitments attached to the Commission Decision.

For the Commission

(signed)

Johannes LAITENBERGER

Director-General