EUROPEAN COMMISSION

Brussels, 22.04.2021
C(2021) 2985 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 Where possible the information omitted has been replaced by ranges of figures or a general description.

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Subject: **Case M.10133 – Astorg/Nordic Capital/Novo/Bioclinica**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

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

2 OJ L 1, 3.1.1994, p. 3 (the "EEA Agreement").

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Dear Sir or Madam,

(1) On 16 March 2021, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which eResearchTechnology, Inc. ("ERT", US), jointly controlled by Astorg VII SLP (a fund managed by Astorg Asset Management S.à r.l ("Astorg", Luxembourg)), by affiliates of Nordic Capital IX Limited ("Nordic Capital", Jersey, Channel Islands), and by an affiliate of Novo Holdings A/S ("Novo", Denmark), acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of Bioclinica Holding I LP ("Bioclinica", US) (the "Transaction"). Astorg, Nordic Capital, and Novo are referred to as the "Notifying Parties" and, together with Bioclinica, the "Parties".

1. THE PARTIES AND THE OPERATION

(2) Astorg is a European private equity firm with activities focusing on Western Europe and North America.

(3) Nordic Capital is a European private equity firm with activities focusing on healthcare, technology & payments, financial services, and selectively, industrial & business services in Europe and globally.

(4) Novo is responsible for managing the assets of the Novo Nordisk Foundation through strategic investments in the life sciences and related areas.

(5) ERT is a provider of software-enabled clinical research solutions ("e-Clinical trial solutions").

(6) Bioclinica is a provider of e-Clinical trial solutions. Bioclinica is solely controlled by Cinven,[3] UK.

(7) On 7 December 2020, Astorg, Nordic Capital, Novo, ERT, and Bioclinica entered into an agreement pursuant to which ERT will acquire all of the issued and outstanding equity interests of Bioclinica.

(8) Currently, ERT is jointly controlled by Astorg, Nordic Capital and Novo.[4] Cinven will receive (cash and) ~[…]% of the share capital in the combined entity.[5] Cinven will also have the right to […].[6] Post-Transaction, each of Astorg and Nordic Capital will own ~[…]% of ERT. Novo will own ~[…]% of ERT. The rest of ERT's capital (~[…]%) will be owned by ERT's management.[7] Post-Transaction, Cinven will not (solely or jointly) control the combined entity. The combined entity's Board will consist of eleven members, of which, [Information about shareholder's rights to appoint certain board directors].[8] Each of Astorg, Nordic Capital and Novo will continue to have veto rights over several matters, including changes in the combined

3 Cinven means, depending on the context, any of or collectively, Cinven Partnership LLP, Cinven Holdings Guernsey Limited, Cinven (Luxco 1) S.A. and their respective "associates" (as defined in the Companies Act 2006) and/or funds managed and/or advised by any of the foregoing.

4 See Case COMP/ M.9633 – *Astorg/Nordic Capital/Novo/ERT*, decision of 20 March 2020, paragraph 1.

5 Form CO, paragraph 44.

6 Form CO, paragraph 44.

7 Form CO, paragraph 45 and table following.

8 Form CO, paragraph 49.

entity's strategy, business plan and annual budget.[9] On the contrary, Cinven will not obtain any veto rights over strategic commercial decisions of the combined entity. Cinven's veto rights will be limited, aiming only to protect its minority shareholding.[10] Against this background, the combined entity will continue to be jointly controlled by Astorg, Nordic Capital, and Novo.

2. EU DIMENSION

(9) The undertakings concerned[11,12] have a combined aggregate world-wide turnover of more than EUR 5 000 million[13]. Each of them has an EU-wide turnover in excess of EUR 250 million, but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State. The Transaction therefore has an EU dimension.

3. RELEVANT MARKETS

(10) Both ERT and Bioclinica are active in the provision of e-Clinical trial solutions. e-Clinical trial solutions are software solutions used in clinical trials to collect and organise data, and evaluate the trial's results. These solutions gather data on patients before, during and after a clinical trial, allowing researchers to monitor patients' biometric data and overall health. e-Clinical trial solutions facilitate overall clinical trial management by increasing the efficacy and accuracy of data collection, as well as enabling quick evaluation, analysis and reporting of collected data and trial outcomes.

(11) There are two types of e-Clinical trial solutions where the activities of ERT and Bioclinica overlap:

(a) *Cardiac safety services.* These services monitor the patients' cardiac parameters in the course of a clinical trial. They aim to assess the risk that the new treatment may have negative (side-)effects on the heart. Cardiac safety is monitored in approximately 70% of all clinical trials; and

(b) *Medical imaging solutions.* These solutions analyse medical images captured in clinical sites to assess drug safety and efficacy. Medical imaging is used in approximately one third of all clinical trials.

(12) Customers, typically pharmaceutical companies or contract research organisations ("CROs") carrying out clinical trials, often purchase e-Clinical trial solutions from third parties (like ERT or Bioclinica) but they may also organise the same data

9 Form CO, paragraph 49.

10 Form CO, paragraph 49.

11 Astorg, Nordic Capital, and Novo are considered as undertakings concerned by this Transaction given their "*significant involvement* […] *in the initiation, organisation and financing of the operation*" (see Consolidated Jurisdictional Notice, OJ 2008/C 95/01, paragraph 147 and in line with Case T-380/17, *HeidelbergCement and Schwenk Zement*, ECLI:EU:T:2020:471, paragraphs 97ff). Bioclinica (the target) is also an undertaking concerned by the Transaction.

12 The remainder of this decision focuses on ERT's and Bioclinica's activities. The activities of Astorg, Nordic Capital, and Novo do not give rise to any horizontal or vertical links with the activities of Bioclinica.

13 Turnover calculated in accordance with Article 5 of the Merger Regulation.

management processes in-house. When sourced from third parties, e-Clinical trial solutions are called "centralised". When sourced in-house, e-Clinical trial solutions are called "decentralised".

3.1. Market definition for e-Clinical trial solutions

3.1.1. Product market definition for e-Clinical trial solutions

3.1.1.1. The Commission's precedents

(13) The Commission has not considered in the past the product market definition for e-Clinical trial solutions.

3.1.1.2. The Notifying Parties' view

(14) The Notifying Parties suggest that there is one broad market including all e-Clinical trial solutions, in view of the strong supply-side substitutability between cardiac safety solutions, medical imaging services, and other business lines.[14] The Notifying Parties add that plausible markets for e-Clinical trial solutions or (more narrowly) for cardiac safety and medical imaging should include both centralised and decentralised services.[15] Yet, the Notifying Parties submit that the precise product market definition in this case can be left open.[16]

3.1.1.3. The Commission's assessment and conclusion

(15) The Commission's investigation provided indications that separate relevant markets exist for (i) cardiac safety services and (ii) medical imaging solutions within the broader space of e-Clinical trial solutions. In more detail:

(a) Third-party market reports analyse separately the competitive landscape in cardiac safety services[17] and in medical imaging solutions;[18]

(b) ERT internal documents report on ERT's and Bioclinica's activities separately for cardiac safety services and medical imaging solutions;[19]

(c) With the exception of ERT, Bioclinica, and BioTelemetry, different players are active in cardiac safety services and in medical imaging solutions;[20] and

(d) The vast majority of respondents to the market investigation suggested that cardiac safety services do not compete in the same relevant product market as medical imaging solutions.

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14 Form CO, paragraph 102.

15 Form CO, paragraph 114.

16 Form CO, paragraph 123.

17 E.g., reports by Orion Market Research, MarketsandMarkets, Transparency Market Research, Fiormarkets, and Reports And Data (see Form CO, paragraph 92).

18 E.g., Grand View Research, MarketsandMarkets, The Insight Partners, MarketWatch, and Data Bridge Market Research (see Form CO, paragraph 92).

19 Form CO, Annex 14-10, "[…]", 5 June 2020 and Form CO, Annex 14-13, "[…]", 5 June 2020.

20 See Tables 1 and 2.

(16) The Commission's investigation also provided indications that separate relevant markets exist including only centralised solutions for each of (i) cardiac safety services and (ii) medical imaging solutions. In more detail:

(a) [Internal documents][21],[22],[23] and

(b) During the market investigation, competitors submitted that only some (not all) customers can source decentralised services in-house.[24]

(17) In any event, for the purpose of assessing the Transaction, the exact scope of the product market definition can be left open since none of the above-mentioned plausible alternative product market definitions (namely, e-Clinical trial solutions (including centralised and decentralised solutions); e-Clinical trial solutions (including only centralised solutions); cardiac safety services (including centralised and decentralised solutions); cardiac safety services (including only centralised solutions); medical imaging solutions (including centralised and decentralised solutions); and medical imaging solutions (including only centralised solutions)) affects the outcome of the competitive assessment of the Transaction.

3.1.2. Geographic market definition

3.1.2.1. The Commission's precedents

(18) The Commission has not considered in the past the relevant geographic market for e-Clinical trial solutions or any of its sub-segments.

3.1.2.2. The Notifying Parties' view

(19) The Notifying Parties take the view that the market for e-Clinical trial solutions (and its sub-segmentations) are EEA-wide in scope.[25] The Notifying Parties recall that these solutions are often offered as part of the offering of a CRO and in the past, the Commission defined the market for CRO services as EEA-wide.[26] Yet, the Notifying Parties also acknowledge that the internal documents of ERT and Bioclinica often consider the relevant markets on a global basis.[27] In any event, the Notifying Parties submit that the precise geographic market definition in this case can be left open.[28]

3.1.2.3. The Commission's assessment and conclusion

(20) The Commission's market investigation provided indications that the market for e-Clinical trial solutions and all its plausible sub-segmentations (listed in paragraph (17) above) are worldwide in scope. As a competitor of ERT and Bioclinica put it for cardiac safety services, "*competition* [...] *takes place at worldwide level.* [Our company], *as one of the smallest players in the field, still offers cardiac safety*

21 Form CO, Annex 14-7, "[…]", 5 October 2020, page 19.
22 Form CO, Annex 14-7, "[…]", 5 October 2020, page 21.
23 Form CO, Annex 14-13, "[…]", 5 June 2020, page 2.
24 Minutes of conference call with competitor, 30 March 2021, paragraph 5; minutes of conference call with competitor, 25 March 2021, paragraph 7.
25 Form CO, paragraph 124.
26 Form CO, paragraph 126.
27 Form CO, paragraph 134.
28 Form CO, paragraph 133.

solutions to customers around the world [...]".[29] Competitors in medical imaging solutions also indicated that competition takes place on a worldwide level.[30]

(21) In any event, for the purpose of assessing the Transaction, the exact scope of the geographic market definition can be left open since under all above-mentioned plausible alternative geographic market definitions (namely, EEA-wide or worldwide), since these plausible alternative market definitions do not affect the outcome of the competitive assessment of the Transaction.

4. COMPETITIVE ASSESSMENT

(22) Both ERT and Bioclinica offer e-Clinical trial solutions, including cardiac safety solutions and medical imaging solutions.[31] The Transaction results in the following horizontally affected markets:[32]

(a) Worldwide market for cardiac safety services (including both centralised and decentralised services);

(b) (Worldwide or EEA-wide) market for cardiac safety services (including only centralised services);

(c) Worldwide market for medical imaging solutions (including both centralised and decentralised services); and

(d) (Worldwide or EEA-wide) market for medical imaging solutions (including only centralised services).

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29 Minutes of conference call with competitor, 25 March 2021, paragraph 8.

30 Minutes of conference call with competitor, 25 March 2021, paragraphs 3, 6, and 7; minutes of conference call with competitor, 26 March 2021, paragraphs 13-14.

31 The plausible relevant market for e-Clinical trial solutions (including both decentralised and centralised services) would not be affected worldwide or in the EEA as the combined market share of ERT and Bioclinica would be in both cases below 20% (see Form CO, paragraphs 136 and 209). The plausible relevant market for e-Clinical trial solutions (including only centralised services) would not be affected worldwide or in the EEA as the combined market share of ERT and Bioclinica would be in both cases below 20% (see Form CO, footnote 64). In addition, the potential EEA-wide market for cardiac safety services (including both centralised and decentralised services) would not be affected as the combined market share of ERT and Bioclinica would be below 20%. The potential EEA-wide market for medical imaging solutions (including both centralised and decentralised services) would not be affected as the combined market share of ERT and Bioclinica would be below 20%.

32 ERT is jointly controlled (among others) by Novo, which also controls pharmaceutical companies Novo Nordisk, Stargazer, and Spruce Bio. Each of these companies purchased centralised e-Clinical trial solutions (including cardiac safety services and medical imaging solutions). However, these purchases do not give rise to a meaningful vertical relationship between Novo and Bioclinica because e-Clinical trial solutions (including cardiac safety services and medical imaging solutions) do not constitute an "*important input*" for the markets of finished pharmaceutical products where Novo's portfolio entities are active within the meaning of paragraph 34 of the Commission's Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings ("Non-Horizontal Merger Guidelines"), OJ C 265, 18.10.2008. This is because (i) e-Clinical trial solutions do not represent a significant cost factor related to the price of the development of a pharmaceutical product ([…]% according to Novo Nordisk's estimates); (ii) they are not a critical component to perform and complete the clinical trial (or for the market success of the finished pharmaceutical product); (iii) they do not represent a significant source of differentiation for finished pharmaceutical products; and (iv) customers can switch to alternative providers in the context of subsequent tenders.

4.1. Legal framework for the Commission's assessment of horizontal non-coordinated effects

(23) 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.

(24) The Commission Guidelines on the assessment of horizontal mergers under the Merger Regulation (the "Horizontal Merger Guidelines")[33] distinguish between two main ways in which mergers between actual or potential competitors on the same relevant market may significantly impede effective competition, namely non-coordinated effects and coordinated effects.

(25) Non-coordinated effects may significantly impede effective competition by eliminating the competitive constraint imposed by each merging party on the other, as a result of which the merged entity would have increased market power without resorting to coordinated behaviour. According to recital (25) of the Merger Regulation, a significant impediment to effective competition can result from the anticompetitive effects of a concentration even if the merged entity would not have a dominant position on the market concerned. In this regard, the Horizontal Merger Guidelines consider not only the direct loss of competition between the merging firms, but also the reduction in competitive pressure on non-merging firms in the same market that could be brought about by the merger.[34]

(26) The Horizontal Merger Guidelines list a number of factors which may influence whether or not significant non-coordinated effects are likely to result from a merger, such as the large market shares of the merging firms, the fact that the merging firms are close competitors, the limited possibilities for customers to switch suppliers, or the fact that the merger would eliminate an important competitive force. Not all of these factors need to be present for significant non-coordinated effects to be likely. The list of factors, each of which is not necessarily decisive in its own right, is also not an exhaustive list.[35]

33 OJ C 31, 05.02.2004, p. 5.

34 Horizontal Merger Guidelines, paragraphs 24 and 25.

35 Horizontal Merger Guidelines, paragraphs 26-38.

4.2. Cardiac safety services

(27) Both ERT and Bioclinica are active in the provision of cardiac safety services. Set forth below are the market shares of ERT, Bioclinica, and their competitors in the market for cardiac safety services worldwide and in the EEA (including only centralised services).[36]

Table 1: Market share estimates for the provision of cardiac safety services, 2019 (based on revenue)[37]

Supplier	Including decentralised and centralised services	Centralised services only	
	Worldwide	Worldwide	EEA
ERT	[20-30]%	**[40-50]%**	**[20-30]%**
Bioclinica	[0-5]%	**[0-5]%**	**[0-5]%**
Combined	*[20-30]%*	*[40-50]%*	*[20-30]%*
IQVIA	[10-20]%	[20-30]%	[10-20]%
Banook	[0-5]%	[5-10]%	[10-20]%
BioTelemetry	[5-10]%	[10-20]%	[0-5]%
Nabios	[0-5]%	[0-5]%	[0-5]%
Richmond	[0-5]%	[0-5]%	[0-5]%
Decentralised services	*[50-60]%*	*N/A*	*N/A*
Others	*[0-5]%*	*[5-10]%*	*[30-40]%*
Total	**100%**	**100%**	**100%**

Source: Form CO

4.2.1. The Notifying Parties' views

(28) The Notifying Parties submit that (i) Bioclinica is an insignificant player in the cardiac safety space, so that the Transaction will not result in anything but a negligible change in the market structure;[38] (ii) the combined entity will continue to face strong competition from a large number of established players, such as IQVIA, Banook, BioTelemetry, Nabios, Richmond, Medpace, Celerion, Spaulding clinical, Clinilabs, Vitalograph, CardioLabs, Compleware, and well as CROs such as Worldwide Clinical Trials, Phar-Olam and Parexel;[39] (iii) the combined entity will continue to face the competitive pressure of the decentralised model, with pharmaceutical companies always retaining the ability to source the relevant cardiac safety services in-house instead of out-sourcing them to external providers, and having the ability to switch between centralised solutions and a decentralised option after each clinical trial, or even between phases of a single clinical trial;[40] (iv) the lack of closeness of competition between ERT's and Bioclinica's cardiac safety activities is reflected in the fact that among their respective 15 largest cardiac safety

36 The potential EEA-wide market for cardiac safety services (including both centralised and decentralised services) would not be horizontally affected.

37 The Notifying Parties have also provided market share estimates, based on the number of clinical trials worldwide in 2019. In a plausible worldwide market for cardiac safety services including both centralised and decentralised services, in 2019, ERT held a [10-20]% share and Bioclinica held [0-5]% (by volume). In a plausible worldwide market for cardiac safety services including only centralised services, in 2019, ERT held a [30-40]% share and Bioclinica held [0-5]% (by volume). See Notifying Parties' Submission of 7 April 2021, footnote 1.

38 Form CO, paragraph 139.

39 Form CO, paragraphs 140-158.

40 Form CO, paragraphs 159-171.

customers, there are only […] customers in common;[41] and that (v) ERT's database of opportunities for customers in the EEA for the years 2016-2020 shows that the competitors that ERT lost most often to in cardiac safety were […], while Bioclinica is only placed […].[42]

4.2.2. The Commission's assessment

4.2.2.1. Cardiac safety services (including centralised and decentralised services)

(29) In the potential worldwide market for cardiac safety services (including both centralised and decentralised services), the combined share of ERT and Bioclinica would be [20-30]% (with a share increment of [0-5]% contributed by Bioclinica). As such, the Transaction will only bring a negligible increment to ERT's already modest market share, and the HHI delta would remain well below 150.[43] As a result, the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the potential worldwide market for cardiac safety services (including both centralised and decentralised services).

4.2.2.2. Cardiac safety services (including only centralised services)

(30) In the potential worldwide and EEA-wide markets for cardiac safety services (including only centralised services), the Transaction does not raise serious doubts as to its compatibility with the internal market for the following reasons:

(31) *First*, while the combined market share of ERT and Bioclinica would be significant at a worldwide level ([40-50]%), the share increment contributed by Bioclinica is limited at [0-5]%.[44] As a result, the HHI increment would be equal to [200-300] (below [200-300] without rounding in the market shares), in a market where the post-merger HHI would be ~[2000-3000]. This suggests that the Transaction would not change meaningfully the competitive landscape in this market. As a customer put it, the Transaction would give rise to *"very little overlap"* between the activities of

41 Form CO, paragraph 173.

42 Form CO, paragraph 173.

43 Based on the Horizontal Merger Guidelines (paragraph 20), the Commission is unlikely to identify horizontal competition concerns in a merger concerning relevant markets with an HHI delta below 150 (subject to certain caveat factors). In the markets that are relevant to this decision, none of these caveat factors apply.

44 The Commission sought to confirm that the market share estimates provided by the Notifying Parties were reliable. The Notifying Parties submitted that ERT's and Bioclinica's market shares have been estimated by using (i) ERT's and Bioclinica's actual sales in 2019 and (ii) a total market size based on a model of the total sales of cardiac safety services created by LEK Consulting (Form CO, Annex 15.b, "[…]"). The Notifying Parties submitted that ERT has commissioned this report since […] and uses it in the ordinary course of business (see email of outside counsel of the Notifying Parties to the case team dated 1 April 2021). On the basis of this report, the Notifying Parties estimated that the total size of a plausible worldwide market for cardiac safety services (including only centralised services) in 2019 is USD [200-300] million (approximately EUR [200-300] million). This is in line with ERT internal documents (see Form CO, Annex 14-3, "[…]", 2020, page 4). In the market investigation, several competitors estimated the total size of a plausible worldwide market for cardiac safety services (including only centralised services) at USD 450 million (approximately EUR 378 million) or more (see minutes of conference call with competitor, 30 March 2021, paragraph 13; minutes of conference call with competitor, 26 March 2021, paragraph 12; minutes of conference call with competitor, 8 April 2021, paragraph 15). This suggests that if anything, the market share data provided for the Parties in Table 1 above underestimate the total size of a plausible worldwide market for cardiac safety services (including only centralised services). Thus, the Commission can rely to the market share estimates provided by the Notifying Parties in the competitive assessment of the Transaction in cardiac safety services (including only centralised services).

ERT and Bioclinica in cardiac safety services.[45] This is even more the case in the possible market for centralised only cardiac safety services in the EEA, where the combined market share of ERT and Bioclinica is lower ([20-30]%), and Bioclinica holds only a negligible market share ([0-5]%). In this market, the Transaction would result in an HHI delta below 150.

(32) *Second*, post-Transaction, the combined entity will continue facing competitive constraints by several players who each hold a share higher than the increment brought by Bioclinica. These include IQVIA ([20-30]% share globally and [10-20]% in the EEA); BioTelemetry ([10-20]% globally and [0-5]% in the EEA); Banook ([5-10]% globally and [10-20]% in the EEA); Nabios ([0-5]% globally and [0-5]% in the EEA); and Richmonds ([0-5]% globally and [0-5]% in the EEA). During the market investigation, a competitor estimated that there are 5-10 players in the worldwide market for cardiac safety services (including only centralised services).[46]

(33) *Third*, ERT and Bioclinica are not the closest competitors in this market (worldwide and in the EEA). An internal document of ERT dated 5 June 2020 states that "*ERT is seen as the top provider for cardiac safety monitoring solutions, followed closely by […]*". The same document identifies […] as the closest competitor to ERT in terms of reputation and […] as the closest competitor to ERT in terms of product offering strength.[47] In 2016-2020, Bioclinica won only […] out of the […] cardiac safety opportunities that ERT lost in the EEA to other providers of centralised solutions.

(34) *Fourth*, even if they are not part of a plausible market for cardiac safety services including only centralised solutions, decentralised cardiac safety services also exert competitive constraints on the combined entity. Both in the EEA and worldwide, between 2016 and 2020, when ERT lost in a tender, in most cases […].[48] There are several examples of a clinical trial sponsor switching from a centralised to a decentralised solution for cardiac safety services even in the context of one and the same clinical trial (i.e., from one phase to the next). These examples cover pharmaceutical companies of all sizes, including […].[49]

(35) *Fifth*, during the market investigation, all customer respondents agreed that the Transaction does not raise competition concerns in the plausible worldwide or EEA-wide markets for cardiac safety services (including only centralised services).[50] One customer recognised that the Transaction could also result in an increased choice of products and lower prices.[51]

(36) By contrast, several competitors submitted that the Transaction does raise competition concerns in these plausible markets.[52] In particular, competitors argued that the Transaction would reinforce ERT's already strong position in the worldwide or EEA-wide markets for centralised cardiac safety services, giving to the combined

45 Response of a customer of the Parties to question 3 of Q1 – Questions to customers.
46 Minutes of conference call with competitor, 25 March 2021, paragraph 9.
47 Form CO, Annex 14-10, "[…]", 5 June 2020, pages 4 and 6.
48 Form CO, paragraphs 167 and 211 and RFI 3 reply, question 3, paragraph 5.
49 Form CO, paragraph 170.
50 Responses to questions 1.c and 1.d of Q1 – Questions to customers.
51 Response of a customer of the Parties to question 4 of Q1 – Questions to customers.
52 Responses to questions 1.c and 1.d of Q2 – Questions to competitors.

entity pricing power and the ability to impose its scientific methodology for cardiac safety services on customers.[53]

(37) However, these claims are not sufficiently cogent and substantiated to outweigh the body of evidence illustrated above and to cast doubt as to the Transaction's compatibility with the internal market in cardiac safety services. This is so for the following reasons:

(a) In the market investigation, some of the competitors referred to ERT's already strong position in the worldwide and EEA-wide markets for centralised cardiac safety solutions but without substantiating merger-specific concerns. The Commission notes that Bioclinica's position in cardiac safety services remains limited (with a share of [0-5]% or less in 2019). One competitor raising concerns acknowledged that "*Bioclinica alone currently* [does not] *represent*[] *an important competitive force in the provision of cardiac safety solutions*".[54] Another competitor raising concerns regarding the prevalence of ERT's scientific methodology indicated that "*it does not have proof* [...] *that there is anything special in Bioclinica's scientific approach*".[55]

(b) Despite its significant market share in the worldwide and EEA-wide markets for centralised cardiac safety services, the combined entity would likely face competitive pressure post-Transaction from its customers.[56] Each of ERT and Bioclinica sell to a concentrated group of customers. ERT's 15 largest customers represent […]% of its revenues in the worldwide market for cardiac safety services. Bioclinica's 15 largest customers represent […]% of its revenues in the worldwide market for cardiac safety services. The customers of cardiac safety services are typically repeat customers and they purchase services through tenders where several rivals can be invited to bid. The fact that no customer raised concerns regarding the Transaction also suggests that the combined entity faces competitive constraints from customers in cardiac safety services.

(38) In light of the above, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the market for cardiac safety services (including only centralised services) worldwide or in the EEA.

4.3. Medical imaging solutions

(39) Both ERT and Bioclinica are active in the provision of medical imaging solutions. Set forth below are the market shares of ERT, Bioclinica, and their competitors in

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53 Minutes of conference call with competitor, 25 March 2021, paragraphs 12ff and minutes of conference call with competitor, 26 March 2021, paragraphs 9ff.

54 Minutes of conference call with competitor, 30 March 2021, paragraph 12.

55 Minutes of conference call with competitor, 25 March 2021, paragraph 13.

56 See Horizontal Merger Guidelines, paragraph 64, which reads: "[e]*ven firms with very high market shares may not be in a position, post-merger, to significantly impede effective competition, in particular by acting to an appreciable extent independently of their customers, if the latter possess countervailing buyer power*".

the market for medical imaging solutions worldwide and in the EEA (including only centralised services).[57]

Table 2: Market share estimates for the provision of medical imaging solutions, 2019

Supplier	Including decentralised and centralised services	Centralised services only	
	Worldwide	Worldwide	EEA
Bioclinica	[10-20]%	**[30-40]%**	**[20-30]%**
ERT	[0-5]%	**[0-5]%**	**[0-5]%**
Combined	[20-30]%	***[30-40]%***	***[20-30]%***
Parexel	[10-20]%	[20-30]%	[20-30]%
ICON	[10-20]%	[10-20]%	[10-20]%
BioTelemetry	[0-5]%	[5-10]%	[5-10]%
Median	[0-5]%	[0-5]%	[5-10]%
Invicro	[0-5]%	[0-5]%	[0-5]%
Ixico	[0-5]%	[0-5]%	[0-5]%
Imaging Endpoints	[0-5]%	[0-5]%	[0-5]%
AG (Mednet)	[0-5]%	[0-5]%	[0-5]%
Decentralised services	*[30-40]%*	-	-
Others	*[0-5]%*	*[0-5]%*	*[5-10]%*
Total	**100%**	**100%**	**100%**

Source: Form CO

4.3.1. The Notifying Parties' views

(40) The Notifying Parties submit that (i) ERT is an insignificant player in the medical imaging space, so that the Transaction will not result in anything but a negligible change in the market structure,[58] (ii) the combined entity will continue to face strong competition from a large number of established players, such as Parexel, Calyx, ICON, BioTelemetry, Median Technologies, Invicro, Ixico, Imaging Endpoint and AG Mednet,[59] (iii) the combined entity will continue to face the competitive pressure of the decentralised models, with pharmaceutical companies always retaining the ability to source the relevant medical imaging solutions in-house instead of out-sourcing them to external providers, and having the ability to switch between centralised solutions and a decentralised option after each clinical trial, or even between phases of a single clinical trial,[60] (iv) Bioclinica participated globally in around […] times as many medical imaging opportunities as ERT, so that, even if every ERT opportunity was also bid for by Bioclinica, ERT would be a competitor in at most […] % of Bioclinica's opportunities,[61] (v) the lack of closeness of competition between ERT's and Bioclinica's respective medical imaging activities is reflected in the fact that among their respective 15 largest customers for medical imaging, there are only […] customers in common,[62] (vi) ERT's and Bioclinica's customers are strong and sophisticated pharmaceutical companies, who can switch supplier with no efforts and possess significant bargaining power,[63] and that (vii)

57 The potential EEA-wide market for medical imaging solutions (including both centralised and decentralised services) would not be horizontally affected.

58 Form CO, paragraph 176.

59 Form CO, paragraphs 177-194.

60 Form CO, paragraphs 195-199.

61 Form CO, paragraph 205.

62 Form CO, paragraphs 200-203.

63 Form CO, paragraphs 200-203.

ERT and Bioclinica have different focuses in medical imaging, with Bioclinica – along with its other major competitors – focusing particularly on oncology studies (which is the largest therapeutic area requiring medical imaging services), while ERT generates most of its medical imaging revenue from […], with less than […] % of its medical imaging revenues coming from oncology.[64]

4.3.2. The Commission's assessment

4.3.2.1. Medical imaging solutions (including centralised and decentralised services)

(41) In the potential worldwide market for medical imaging solutions (including both centralised and decentralised services), the combined share of ERT and Bioclinica would be [20-30]% (with a share increment of [0-5]% contributed by ERT). As such, the Transaction will only bring a small increment to Bioclinica's already modest market share, and the HHI delta would remain well below 150. As a result, the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the potential worldwide market for medical imaging solutions (including both centralised and decentralised services).

4.3.2.2. Medical imaging solutions (including only centralised services)

(42) In the potential worldwide and EEA-wide markets for medical imaging solutions (including only centralised services), the Transaction does not raise serious doubts as to its compatibility with the internal market for the following reasons:

(43) *First*, while the combined market share of ERT and Bioclinica would be moderate at a worldwide level ([30-40]%), the share increment contributed by ERT is limited at [0-5]%.[65] As a result, the HHI increment would be [200-300], where the post-merger HHI would be ~[2000-3000] which is above, but not far from, [2000-3000] (<2500). This suggests that the Transaction would not change meaningfully the competitive landscape in this market. The same holds in the market for medical imaging solutions including only centralised services in the EEA, where the combined market share of ERT and Bioclinica is even lower ([20-30]%). As a result, the Transaction would bring about an HHI delta of 168 in a market where the post-Transaction HHI would be below [2000-3000].[66] During the market investigation, a competitor stated

64 Form CO, paragraphs 200-203.

65 The Commission sought to confirm that the market share estimates provided by the Notifying Parties were reliable. The Notifying Parties submitted that ERT's and Bioclinica's market share have been estimated by using (i) ERT's and Bioclinica's actual sales in 2019 and (ii) a total market size based on a model of the total sales of cardiac safety services created by LEK Consulting (Form CO, Annex 15.b, "[…]"). The Notifying Parties submitted that ERT has commissioned this report since […] and uses it in the ordinary course of business (see email of outside counsel of the Notifying Parties to the case team dated 1 April 2021). On the basis of this report, the Notifying Parties estimated that the total size of a plausible worldwide market for medical imaging solutions (including only centralised services) is USD [500-600] million (approximately EUR [400-500] million). In the market investigation, several competitors estimated the total size of a plausible worldwide market for medical imaging solutions (including only centralised services) at USD 480-550 million or more (approximately EUR 404-463 million or more) (see minutes of conference call with competitor, 30 March 2021, paragraph 15, minutes of conference call with competitor, 8 April 2021, paragraph 11). This suggests that the market share data provided for the Parties in Table 2 above are generally reliable.

66 Based on the Horizontal Merger Guidelines (paragraph 20), the Commission is unlikely to identify horizontal competition concerns in a merger with a post-merger HHI between 1 000 and 2 000 and a delta below 250 (subject to certain caveat factors). In the EEA-wide market for medical imaging solutions (including only centralised services), none of these caveat factors apply.

that it "*does not view ERT as a significant player in the [medical imaging] market. Thus, the Transaction would only marginally affect the competitive dynamics in the market".*[67] A customer added that the Transaction would give rise to *"very little overlap"* between the activities of ERT and Bioclinica in medical imaging solutions.[68]

(44) *Second*, post-Transaction, the combined entity will continue facing competitive constraints by several players who each hold a share higher than the increment brought by ERT. These include Parexel ([20-30]% share globally and [20-30]% in the EEA), ICON ([10-20]% globally and 17% in the EEA), and BioTelemetry ([5-10]% globally and [5-10]% in the EEA).

(45) *Third*, Bioclinica and ERT are not close competitors in these markets. According to the Notifying Parties, between 2017 and 2020, Bioclinica participated globally in around […] times as many medical imaging opportunities as ERT, which implies that, even if every ERT opportunity was also bid for by Bioclinica, ERT would be a competitor in at most […] of Bioclinica's opportunities.[69] There is also limited overlap among the top customers of Bioclinica and ERT for medical imaging solutions worldwide. There are only […] overlapping customers among the top 15 medical imaging customers of Bioclinica and the top 15 medical imaging customers of ERT.[70]

(46) The market investigation confirmed that ERT and Bioclinica do not compete closely in medical imaging solutions. Rather, Bioclinica competes most closely with […]. An internal document […] for Astorg and Nordic Capital identifies Bioclinica and […] as the two Tier 1 players in this market while ERT features as a "[…]".[71] The same document explains: "[…]".[72] In the same vein, an internal document of ERT dated […] refers to […] as closer competitors to Bioclinica ([…]) both in terms of reputation and strength of product offering.[73]

(47) *Fourth*, during the market investigation, all customer respondents agreed that the Transaction does not raise competition concerns in the plausible worldwide or EEA-wide markets for medical imaging solutions (including only centralised services).[74]

(48) By contrast, several competitors submitted that the Transaction does raise competition concerns in these plausible markets. Specifically, competitors argued that post-Transaction, the combined entity would be able to compete aggressively on price until it forces rivals out of the market.[75, 76]

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67 Minutes of conference call with competitor, 26 March 2021, paragraph 14.

68 Response of a customer of the Parties to question 3 of Q1 – Questions to customers.

69 Form CO, paragraph 205.

70 Namely, […]. See Form CO, paragraph 201.

71 Form CO, Annex 14-6, "Project Bright", page 5.

72 Form CO, Annex 14-6, "Project Bright", page 8.

73 Form CO, Annex 14-13, "[…]", 5 June 2020, page 6.

74 Responses to questions 1.a and 1.b of Q1 – Questions to customers.

75 Responses to questions 1.a and 1.b of Q2 – Questions to competitors.

76 In the market investigation, one competitor respondent also claimed that post-Transaction, ERT and Bioclinica would be able to combine their respective offerings in cardiac safety services and medical imaging solutions and thus obtain "*preferred provider*" status from customers. According to this competitor, this would reduce the opportunities in medical imaging solutions for which rivals of the combined entity can bid (minutes of conference call with competitor, 9 April 2021, paragraphs 12ff).

(49) However, these claims are not sufficiently cogent and substantiated to outweigh the body of evidence illustrated above and to cast doubt as to the Transaction's compatibility with the internal market in medical imaging solutions. This is so for the following reasons:

(a) Some of the competitors referred to Bioclinica's already strong position in the worldwide and EEA-wide markets for centralised medical imaging solutions but without substantiating any merger-specific concerns. None of the competitor respondents raising concerns identified ERT as a significant competitive constraint to Bioclinica in medical imaging solutions. In any event, the Transaction does not materially change the incentives of the combined entity to adopt a hypothetical strategy of aggressively reducing prices to exclude competitors. If Bioclinica considered such a strategy to be profitable and viable, it is likely that it would have already implemented it irrespective of the Transaction. None of the competitor respondents provided evidence to that effect. Rather, an internal document […] for Astorg and Nordic Capital states for medical imaging solutions: "[…]".[77]

(b) Despite its meaningful market share in the worldwide and EEA-wide markets for medical imaging solutions, the combined entity would likely face competitive pressure post-Transaction from its customers. Both ERT and Bioclinica sell to a concentrated group of customers. ERT's 15 largest customers represent […]% of its revenues in the worldwide market for medical imaging solutions. Bioclinica's 15 largest customers represent […]% of its revenues in the worldwide market for medical imaging solutions. The customers of medical imaging solutions are typically repeat customers and they purchase services through tenders where several rivals can be invited to bid. An internal document […] for Astorg and Nordic Capital confirms this: "[…]".[78] The fact that no customer raised concerns regarding the Transaction also suggests that the combined entity faces competitive constraints from customers in medical imaging solutions.

(50) In light of the above, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the market for medical imaging solutions (including only centralised services) worldwide or in the EEA.

These claims are however not sufficiently substantiated to raise serious doubts as to the Transaction's compatibility with the internal market in medical imaging solutions. The Commission considers that post-Transaction, rivals will be able to continue competing against the combined entity for the vast majority of opportunities involving medical imaging solutions. This is for the following reasons. *First*, the competitor respondent raising concerns acknowledged that a customer can grant "*preferred provider*" status for one type of service only (e.g., medical imaging solutions) and not always for a combination of services. *Second*, the same competitor recognised that even after granting "*preferred provider*" status the customer can still source some of the services required from third parties e.g., if the preferred provider is unable to offer them. *Third*, the same competitor submitted that it sometimes bids itself "*together with other companies offering its specialized services as part of a combined proposal in selection processes for preferred providers*" (minutes of conference call with competitor, 9 April 2021, paragraphs 13ff).

77 Form CO, Annex 14-6, "Project Bright", page 29.

78 Form CO, Annex 14-6, "Project Bright", page 104.

5. CONCLUSION

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

For the Commission

(Signed)
Margrethe VESTAGER
Executive Vice-President