EUROPEAN COMMISSION
DG Competition

Case M.10238 - NORDIC CAPITAL / LEO FOUNDATION / LEO PHARMA

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 23/06/2021

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EUROPEAN COMMISSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

Nordic Capital X Limited
26 Esplanade
JE2 3QA St. Helier
Jersey

LEO Foundation
Lautrupsgade 7, 5.
2100 Copenhagen
Denmark

Subject: **Case M.10238 – NORDIC CAPITAL / LEO FOUNDATION / LEO PHARMA**
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]

Dear Sir or Madam,

(1) On 21 May 2021, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which Nordic

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').

Capital Fund X ("Nordic Capital", Jersey) and Leo Foundation ("Leo Foundation", Denmark) acquire within the meaning of Articles 3(1)(b) and 3(4), joint control of the whole of Leo Pharma A/S ("Leo Pharma", Denmark) by way of purchase of shares ("the Transaction")[3]. Nordic Capital and Leo Foundation are referred to hereinafter as the "Notifying Parties" or the "Parties".

1. THE PARTIES

(2) Nordic Capital is a group of private equity funds focusing on investments primarily in the Nordic region of Europe and selected Northern European sectors. Nordic Capital invests across a wide range of industries but has a particular focus on healthcare, technology and payments, financial services, industrial and business services and consumer products.

(3) LEO Foundation is a private foundation established under Danish law, which, apart from LEO Pharma, does not control any other operating undertakings and which is itself not controlled by any other entities. LEO Foundation's financial assets are held in LEO Holding, where the investments activities of the LEO Foundation are carried out.

(4) LEO Pharma is headquartered in Denmark and develops, manufactures and markets pharmaceutical products to be used predominantly for treatment of dermatological and thrombotic diseases.

2. THE TRANSACTION

(5) Pursuant to an Investment Agreement dated 16 March 2021, Nordic Capital will acquire […]% of the shares and LEO Foundation will retain […]% of the shares of LEO Pharma.

(6) In addition, the Parties will enter into a Shareholder Agreement according to which a number of "reserved matters" will require the prior consent of both Parties. The reserved matters include (i) material amendments to the business plan, (ii) material amendments to and adoption of the annual budget, and (iii) the appointment and removal of each member of the executive management.[4] Post-Transaction, LEO Foundation and Nordic Capital will therefore jointly control LEO Pharma.

(7) LEO Pharma is an existing company, with management and staff dedicated to its day-to-day operations and access to sufficient resources (including finance and assets) to conduct its business on a lasting basis. Moreover, LEO Pharma has its own market presence. This will not change post-Transaction. It can therefore be concluded that LEO Pharma will be a full-functional JV.

(8) The Transaction is therefore a concentration within the meaning of Article 3(1)(b) and 3(4) of the Merger Regulation.

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3 Publication in the Official Journal of the European Union No C 207, 1.6.2021, p. 6.

4 […].

3. UNION DIMENSION

(9) The undertakings concerned have a combined aggregate worldwide turnover of more than EUR 5 000 million.[5] Each of them has a Union-wide turnover in excess of EUR 250 million, but they do not achieve more than two-thirds of their aggregate Union-wide turnover within one and the same Member State. The notified Transaction therefore has a Union dimension by virtue of Article 1(2) of the Merger Regulation.

4. RELEVANT MARKETS

(10) The Transaction concerns the pharmaceutical sector, where both Leo Pharma and some of Nordic Capital's portfolio companies are active.

(11) Leo Pharma is active in the provision of pharmaceutical contract manufacturing organisation ("CMO") services, as well as in the distribution of finished dose pharmaceuticals ("FDPs") globally.

(12) Two of Nordic Capital's portfolio companies are involved in these markets, namely Advanz Pharma Corp. Limited, ("Advanz", Jersey) in FDPs and Acino International AG ("Acino", Switzerland) in FDPs and CMO services.

(13) Limited horizontal overlaps arise in the market for the distribution of FDPs between Leo Pharma and Advanz in two ATC3 categories (see paragraph (15)). These are D6A (topical antibacterials) in Italy where the Parties have a combined market share of [10-20]%, and J1X (other antibacterials) in France where the Parties have a combined market share of [0-5]% and in Italy with a combined market share of [0-5]%. Moreover, limited horizontal overlaps also arise between Leo Pharma and Acino in the market for CMO services. The Notifying Parties confirm that the combined market shares of LEO Pharma and Acino are well below 5% under any plausible product and geographic market definition. As these do not result in affected markets, they will not be discussed in the present decision.

(14) Moreover, the Transaction results in a vertical relationship between the activities of Leo Pharma in the upstream market CMO services in the EEA and Advanz in the downstream market for the distribution of FDPs for ophthalmological anti-infectives (ATC3 class S1A) in Sweden. This vertical relationship is further discussed in the present decision.

4.1. Finished Dose Pharmaceuticals - Ophthalmological anti-infectives (ATC3 class S1A)

4.1.1. Product market definition

(15) In previous decisions concerning finished dose pharmaceutical products, the Commission has followed the approach of dividing the products into therapeutic classes by reference to the ATC (Anatomical Therapeutic Chemical) classification devised by EphMRA (European Pharmaceutical Market Research Association).[6]

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

6 See e.g. Cases M.8889 – Teva/Pgt Otc Assets, Decision of 29 June 2018, paragraphs 16 – 18; M.7919 - Sanofi/Boehringer Ingelheim Consumer healthcare Business, Decision of 4 August 2016, paragraphs 9 –

More specifically, the Commission referred to the ATC3 level, where pharmaceuticals are grouped in terms of their therapeutic indications, as the starting point for defining the relevant product market, but it also recognized that it may be appropriate to depart from it if the circumstances of the case show that competitive constraints are situated at another level (i.e. by using the more detailed ATC4 level or based on active ingredients or other therapeutic criteria).[7]

(16) The ATC3 class relevant for this Transaction is S1A (Ophthalmological anti-infectives).

(17) In previous decisions, the Commission considered that the appropriate level for market definition of ophthalmological anti-infectives (S1A) is ATC3, but ultimately left the product market definition open.[8]

(18) According to the EphMRA classification, class S1A is not further subdivided at ATC4. Nevertheless, the Commission has also considered in the past an alternative market definition, namely the combination of ATC3 class S1A and ATC4 class S1C1 (ophthalmological anti-inflammatory and anti-infective combinations containing corticosteroids), but ultimately left the market definition open.[9] The combination of classes S1A and S1C1 is not relevant for this Transaction as the Parties are not active in the S1C1 class.

(19) In the present case, the exact market definition can be left open since the transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement under any plausible product market definition.

4.1.2. Geographic market definition

(20) According to previous Commission decisions, the relevant geographic market for FDPs is national in scope.[10] The Commission does not find any reason to depart from this approach in the present case.

4.2. Contract manufacturing organisation services

4.2.1. Product market definition

(21) CMO services is an arrangement under which a manufacturer provides upstream manufacturing services of FDPs under contract on behalf of a third party.

(22) In previous decisions, the Commission has left open the market definition for contract manufacturing. Specifically, the Commission has left open whether the CMO services market should be defined as an overall market, or whether it could be

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12; M.6969 - Valeant Pharmaceuticals International/Bausch & Lomb Holdings, Decision of 5 August 2013, paragraph 10.

7 See Case M.9995 Permira Holdings Limited/ Neuraxpharm Midco S.C.A, Decision of 4 December 2020 paragraphs 7 – 8.

8 See e.g. Cases M.6969 – Valeant Pharmaceuticals International/Bausch & Lomb Holdings, Decision of 5 August 2013, paragraph 28; M.5778 – Novartis/Alcon, Decision of 9 August 2010, paragraph 35.

9 See e.g. Cases M.6969 – Valeant Pharmaceuticals International/Bausch & Lomb Holdings, Decision of 5 August 2013, paragraphs 22 - 28; M.5778 – Novartis/Alcon, Decision of 9 August 2010, paragraph 34.

10 See e.g. Cases M.8889 – Teva/Pgt Otc Assets, Decision of 29 June 2018, paragraph 29; M.8675, CVC/Teva's Women's Health Business, Decision of 20 December 2017, paragraph 20.

further segmented into four product markets, namely contract manufacturing of: (i) solid dose and powder pharmaceuticals, (ii) liquids and semi-solid pharmaceuticals, (iii) sterile liquid pharmaceuticals, and (iv) medicated confectionary pharmaceuticals.[11]

(23) For the purpose of the assessment of the transaction, the relevant segment of the upstream CMO services product market is the one of sterile liquid pharmaceuticals, as Leo Pharma produces anti-infective eye drops.

(24) In any event, for the purposes of this Decision, it is not necessary to conclude on the exact product market definition for CMO services as, regardless of the market definition considered, the transaction does not give rise to serious doubts as to its compatibility with the internal market and the functioning of the EEA Agreement.

4.2.2. Geographic market definition

(25) In previous decisions, the Commission found that the relevant geographic market for CMO services is worldwide or at least EEA-wide, as CMO services are generally procured anywhere in the world, regardless of the country where the pharmaceutical products are subsequently marketed.[12] Neither of the plausible alternative geographic market definitions (worldwide or EEA-wide) affects the outcome of the competitive assessment of the Transaction as to its compatibility with the internal market or the functioning of the EEA Agreement.

5. COMPETITIVE ASSESSMENT

5.1. Analytical framework

(26) Under Articles 2(2) and 2(3) of the Merger Regulation, the Commission must assess whether a proposed concentration would significantly impede effective competition in the internal market or in a substantial part of it, in particular through the creation or strengthening of a dominant position.

(27) A concentration can entail horizontal effects. When the Commission analyses such cases it does so in line with the Commission Guidelines on the assessment of horizontal mergers under the Merger Regulation.[13]

(28) Furthermore, a concentration can entail vertical and/or conglomerate effects. The Commission Guidelines on the assessment of non-horizontal mergers under the Merger Regulation[14] (the "Non-Horizontal Merger Guidelines") distinguish between two main ways in which non-horizontal mergers may significantly impede effective competition: (a) when they give rise to input and/or customer foreclosure (non-

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11 See e.g. Cases M.9962 – Mylan/Aspen's EU Thrombosis Business, Decision of 15 October 2020, paragraphs 14-15; M.5953- Reckitt Benckister/SSL, Decision of 25 October 2010, paragraphs 58 – 59 and 63.

12 See e.g. Cases M.5953- Reckitt Benckiser/SSL, Decision of 25 October 2010, paragraph 64; M.6613- Watson/Actavis, Decision of 5 October 2012, paragraph 34.

13 Commission Guidelines on the assessment of horizontal mergers under the Merger Regulation (OJ C 31, 5.2.2004, p. 5).

14 Commission Guidelines on the assessment of non-horizontal mergers under the Merger Regulation (OJ C 265, 18.10.2008, p. 6).

coordinated effects); and (b) when the merger changes the nature of competition in such a way that firms that previously were not coordinating their behaviour, are now more likely to coordinate to raise prices or otherwise harm effective competition (coordinated effects).[15] The Non-Horizontal Merger Guidelines distinguish two types of foreclosure: (a) where the merger is likely to raise the costs of downstream rivals by restricting their access to an important input (input foreclosure) and (b) where the merger is likely to foreclose upstream rivals by restricting their access to a sufficient customer base (customer foreclosure)[16].

(29) In assessing the likelihood of an anticompetitive input foreclosure strategy, the Commission has to examine whether (i) the merged entity would have the ability to substantially foreclose access to inputs; (ii) whether it would have the incentive to do so; and (iii) whether a foreclosure strategy would have a significant detrimental effect on competition downstream.[17] In assessing the likelihood of an anticompetitive customer foreclosure strategy, the Commission has to examine whether (i) the merged entity would have the ability to foreclose access to downstream markets by reducing its purchases from upstream rivals; (ii) whether it would have the incentive to do so; and (iii) whether a foreclosure strategy would have a significant detrimental effect on consumers in the downstream market.[18] According to the Non-Horizontal Merger Guidelines, the Commission is unlikely to find concern in non-horizontal mergers, where the market share post-merger of the new entity in each of the markets concerned is below 30%.[19]

(30) The Non-Horizontal Merger Guidelines define conglomerate mergers as mergers between firms that are in a relationship which is neither horizontal (as competitors in the same relevant market) nor vertical (as suppliers or customers).[20]

(31) As the Transaction only gives rise to vertically affected markets, this Section addresses only input and customer foreclosure concerns.

5.2. Vertically affected market: CMO services in the EEA (for sterile liquid pharmaceuticals) (upstream) – ATC3 class S1A in Sweden (downstream)

(32) Both Parties are active upstream in the provision of CMO services in the EEA, with a combined market share well below [5-10]%.[21] Moreover, the Notifying Parties submit that Leo Pharma provides CMO services to Advanz for one product […] in the ATC3 class S1A. Leo Pharma's market share in the EEA market for CMO services is [0-5]%.[22] World-wide market shares are not higher under any plausible market definition.

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15 Non-horizontal Merger Guidelines, paragraphs 17-19.
16 Non-horizontal Merger Guidelines, paragraph 30.
17 Non-horizontal Merger Guidelines, paragraph 32.
18 Non-horizontal Merger Guidelines, paragraph 59.
19 Non-horizontal Merger Guidelines, paragraph 25.
20 Non-horizontal Merger Guidelines, paragraph 5.
21 See Form CO, paragraph 143. The market share is a combined market share of Leo Pharma and Acino in the overall CMO market in the EEA. […].
22 See Reply to RFI 6, of 1 June 2021.

(33) With regards to the downstream market for ophthalmological anti-infectives, Advanz only distributes […] in ATC3 class S1A. The only Member State where its market share exceeds 30% is Sweden, where Advanz holds a market share [of 30-40]%.[23]

(34) Therefore, on the basis of the Parties' activities and the market definitions discussed in Section 4, the following two vertical relationships result in affected markets:

(a) The provision of CMO services in the EEA (upstream) and the distribution of ophthalmological anti-infectives (ATC3 class S1A) in Sweden (downstream).

(b) The provision of CMO services for sterile liquid pharmaceuticals in the EEA (upstream) and the distribution of ophthalmological anti-infectives (ATC3 class S1A) in Sweden (downstream).

(35) The following sections address input foreclosure and customer foreclosure concerns in all of the vertically affected markets.

5.2.1. Input foreclosure

(36) The Transaction is unlikely to give rise to input foreclosure concerns. The combined entity would not have the ability to foreclose its downstream competitors in the distribution of ophthalmological anti-infectives (ATC3 class S1A) in Sweden for the following reasons:

(a) For input foreclosure to be a concern, the combined entity must have a significant degree of power in the upstream market.[24] However, the Parties have a very limited position in the CMO services market. Both in the overall CMO services market and in the CMO services market for sterile liquid pharmaceuticals in the EEA and worldwide ([…]) the Parties' combined market share is [5-10]%. Furthermore, many alternative CMO services' suppliers would remain available to the downstream competitors, if Leo Pharma were to stop providing CMO services to Advanz's competitors in the downstream market for ATC3 class S1A.

(b) The combined entity would not have the ability to restrict access to CMO services by downstream competitors, as it cannot negatively affect the overall availability of inputs for the downstream market.[25] […].

(37) As the Commission found that the combined entity would have no ability to restrict access to CMO services by its downstream competitors in the distribution of ophthalmological anti-infectives (ATC3 class S1A) in Sweden, it is not necessary to assess in detail the incentives of the combined entity to do so or the overall impact of such an input foreclosure strategy.

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23 See Annex 1, Reply to RFI 4, of 26 May 2021.

24 Non-horizontal Merger Guidelines, paragraph 35.

25 Non-horizontal Merger Guidelines, paragraph 36.

5.2.2. Customer foreclosure

(38) The Transaction is unlikely to lead to customer foreclosure concerns due to the combined entity's lack of ability to foreclose its upstream competitors for the following reasons:

(a) For customer foreclosure to be a concern, the combined entity must be an important customer with a significant degree of market power in the downstream market.[26] However, Advanz only has a modest position in ATC3 class S1A in Sweden, with a market share [of 30-40]%.[27] Therefore, downstream customers will remain available to Leo Pharma's competitors providing CMO services within the ATC3 class S1A in Sweden.

(b) Moreover, when assessing customer foreclosure, the Commission takes into account the existence of different uses for the upstream product. These can ensure that a sufficiently large customer base remains for that product post-Transaction.[28] In the present case, distributors of all liquid pharmaceuticals in the EEA (of which ATC3 class S1A distributors in Sweden present only a small proportion) purchase CMO services for sterile liquid pharmaceuticals. The Parties estimate that turnover related to ATC3 category S1A represents [less than 10]% of the total turnover related to CMO services for sterile liquid pharmaceuticals in the EEA.[29]

(c) Customer foreclosure is less likely when the combined entity is not an important customer for the upstream product.[30] This is the case here, as […].[31]

(39) As the Commission found that the combined entity would have no ability to restrict access to customers by its upstream competitors in the CMO services' market in the EEA, it is not necessary to assess in detail the incentives of the combined entity to do so or the overall impact of such a customer foreclosure strategy.

5.3. Conclusion

(40) In light of the above considerations, the Commission concludes that the transaction does not raise serious doubts as to its compatibility with the internal market and the functioning of the EEA agreement as a result of either input or customer foreclosure on the markets for CMO services in the EEA (for sterile liquid pharmaceuticals) (upstream) and the distribution of ophthalmological anti-infective (ATC3 class S1A) in Sweden (downstream).

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26 Non-horizontal Merger Guidelines, paragraph 61.
27 See Reply to RFI 6, of 1 June 2021.
28 Non-Horizontal Merger Guidelines, paragraphs 61 and 66.
29 See Reply to RFI 6, of 1 June 2021.
30 Non-horizontal Merger Guidelines, paragraph 61.
31 See Reply to RFI 6, of 1 June 2021.

6. CONCLUSION

(41) For the above reasons, the European Commission has decided not to oppose the notified concentration 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