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 Where possible the information omitted has been replaced by ranges of figures or a general description.

To the notifying parties

Subject: **Case M.9315 – Chr. Hansen/Lonza/JV**
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 11 June 2019, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which Chr. Hansen Holding A/S ("Chr. Hansen", Denmark) and Lonza Ltd ("Lonza", Switzerland), controlled by Lonza Group Ltd (Switzerland), acquire within the meaning of Article 3(1)(b) and 3(4) of the Merger Regulation joint control over a newly created undertaking (the "JV", Switzerland) by way of purchase of shares (the "Transaction").[3] In this decision, Chr. Hansen and Lonza are collectively designated as the "Notifying Parties", while Chr. Hansen, Lonza and the JV are referred to as the "Parties".

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").

3 Publication in the Official Journal of the European Union No C 208, 19.06.2019, p. 6.

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1. THE PARTIES

(2) Chr. Hansen is a global bioscience company that mainly develops natural solutions for the food, nutritional, and agricultural industries. Chr. Hansen develops and produces cultures, enzymes, probiotics and natural colours for a rich variety of foods, confectionery, beverages, dietary supplements and animal feed.

(3) Lonza is active in the supply of various services in the pharmaceutical, consumer health and nutrition industries. It notably provides contract development and manufacturing organisation ("CDMO") services for active pharmaceutical ingredients ("API") and finished dose pharmaceuticals ("FDP") under current Good Manufacturing Practice ("cGMP") and offers, since 2017[4], delivery mechanisms technology.

(4) The JV will provide cGMP-certified CDMO services to pharmaceutical companies active in the microbiome space[5] and exclusively in relation to the development and manufacture of live biotherapeutics[6] and bacteriophages[7] (together referred to as "LBP"). Contrary to existing CDMO players in this specific field, the JV will be active across the whole CDMO value chain, from the initial development of manufacturing processes for the production of LBP-based APIs to the final commercial-scale manufacturing of LBP-based FDP.

2. THE TRANSACTION

(5) On 2 April 2019, Chr. Hansen and Lonza entered into a joint venture agreement relating to the establishment of the JV as a full-functional joint venture. The Transaction consists in the acquisition of joint control by Chr. Hansen and Lonza over the JV by way of purchase of shares.

2.1. Joint control

(6) Post-Transaction, Chr. Hansen and Lonza will each hold 50% of the shares in the JV.

(7) In terms of governance, the JV will be run by a board of eight directors, half of which will be appointed by Chr. Hansen and Lonza respectively. The board will take key strategic decisions such as the approval of the JV's annual budget, business plan, major investments, and the appointment of top management positions. The adoption

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4 Following Lonza's acquisition of Capsugel SA (Luxembourg). Case COMP/M. 8362 – *Lonza Group/Capsugel*, decision of 21 April 2017.

5 The microbiome space is a nascent research area in the biopharmaceutical industry involving microorganisms that reside in an environmental niche such as humans, animals or plants. For instance, the human microbiome includes communities of bacteria, fungi, archaea and viruses, the majority of which live in the guts. In recent years, research on the human microbiome has significantly intensified and is currently perceived as very promising for the treatment of human health and diseases in the coming 5 to 10 years.

6 LBPs are biological products made of living organisms (such as bacteria), that are suitable for the prevention, treatment and/or cure of a human diseases and that are not vaccines. LBPs are not filterable viruses or products intended as gene therapy. Contrary to vaccines, LBPs are not administered by injection but rather by oral, rectal, vaginal or topical delivery mechanisms.

7 Bacteriophages, also called "phages" or "bacterial viruses", refer to any viruses that infect and ultimately kill bacteria.

of these key strategic decisions will require the affirmative votes of all directors present with the obligation that at least one director nominated by each of Chr. Hansen and Lonza is present. Thus, the approval of key strategic decisions will require joint action from both Notifying Parties and neither Chr. Hansen nor Lonza will benefit from *de facto* sole control on these matters. Pursuant to the joint venture agreement, all other decisions will be taken on a simple majority basis, with the express approval of at least one director nominated by each of Chr. Hansen and Lonza. Consequently, the JV will be jointly controlled by Chr. Hansen and Lonza.

2.2. Full functionality

(8) The JV will operate by performing the functions normally carried out by undertakings active on the same markets, independently from its parents.[8] The JV will also have sufficient resources to operate independently, including its own staff dedicated to its day-to-day management. The JV's activities will go beyond one specific function performed by the parents, as the JV will provide new services to third-party pharmaceutical companies that are not currently offered by either of its parents. Although the JV will have several contractual agreements with its respective parents in relation to IP licensing, leasing or transitional service and supplies, these commercial arrangements will be entered into on an arm's length basis and at market price. Neither Lonza nor Chr. Hansen are expected to become future clients of the JV. Conversely, the JV may potentially enter into supply agreements with Lonza with respect to the procurement of solid oral dosage delivery (SODDM) mechanisms. However, the Notifying Parties indicated that the choice of SODDM provider will ultimately remain with the JV's final customer. Finally, the JV will operate on a lasting basis.

(9) The Transaction will therefore lead to the creation of a full-functional joint venture.

2.3. Conclusion

(10) In view of the above, the Transaction constitutes a concentration within the meaning of Article 3(1)(b) and 3(4) of the Merger Regulation.

3. EU DIMENSION

(11) The undertakings concerned have a combined aggregate worldwide turnover of more than EUR 5 000 million[9] (Chr. Hansen: EUR 1 097 million; Lonza: EUR 4 792 million). Each of them has an EU-wide turnover in excess of EUR 250 million (Chr. Hansen: EUR […] million; Lonza: EUR […] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State.

(12) The Transaction therefore has an EU dimension pursuant to Article 1(2) of the Merger Regulation.

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8 Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings, OJ C 95, 16.4.2008, recital 94 (the "Notice").

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

4. RELEVANT MARKETS

(13) The Transaction reflects the Notifying Parties' intention to expand their activities into the microbiome space. To that end, the JV will combine Lonza's biopharmaceutical cGMP CDMO capabilities (that are not suitable for the development and manufacture of LBPs) and delivery mechanisms technology, with Chr. Hansen's experience with bacterial strains (microbial physiology, fermentation and freeze drying science).[10]

(14) The JV is said to become the first player to offer a complete range of cGMP CDMO services for pharmaceutical products in the LBP space. More specifically, the JV will provide the following services to pharmaceutical companies:

- CDMO services in relation to LBP-based API, i.e. contract development organisation services at the API level ("API CDO" services) and contract manufacturing organisation services at the API level ("API CMO" services) of LBP-based API; and

- CDMO services in relation to LBP-based FDP, i.e. the supply of dosage-related technology and development solution services ("FDP CDO" services) for LBP-based pharmaceutical products and the commercial-scale manufacturing ("FDP CMO" services) of FDP based on LBP-API.[11]

(15) The JV will be involved in the evaluation of strains selected by its customer to determine whether these can be scaled-up safely and whether production is feasible on a commercial basis, as part of the supply of API CDO services, but it will not be active within the area of drug discovery. Thus, the identification and establishment of the clinical benefit of the bacterial strains, as well as the clinical trial and commercialisation of the FDP, will be undertaken by the JV's customers.

4.1. Market definitions

4.1.1. Supply of CDMO services to pharmaceutical companies

4.1.1.1. Product market definition

(16) The Notifying Parties submit that the relevant product market should be defined as encompassing all CDMO services to pharmaceutical companies, without any further segmentation.

(17) In previous decisions, the Commission considered the existence of a market for the supply of CDMO services for API distinct from the market for the supply of contract manufacturing for FDP.[12] The results of the market investigation confirmed the relevance of such a distinction. First, from a demand-side perspective, the respective CDMO services for API and FDP address separate needs. On the one hand, CDMO

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10 In fact, Chr. Hansen essentially is a contract manufacturer with experience in bacterial strains for the food and nutrition industry [confidential details in relation to the business strategy of Chr. Hansen].

11 Importantly, neither Chr. Hansen nor Lonza are currently active in this specific business segment, as Chr. Hansen [confidential details relating to business strategy of Chr. Hansen] while Lonza does not have [confidential details relating to the business strategy of Lonza].

12 Cases COMP/M. 8362 – *Lonza Group/Capsugel*, decision of 21 April 2017 and COMP/M.8541 – *Thermo Fisher Scientific/Patheon*, decision of 23 August 2017

services at the API level involve the evaluation, characterisation, development of production and scaling-up processes in relation to the manufacture of API. On the other hand, CDMO services at the FDP level mainly pertain to the development of an appropriate dosage formulation and the large-scale manufacture of the final drug products. Second, from a supply-side perspective, CDMO services at the API and FDP levels do not involve the same equipment and require specific know-how and expertise. In fact, multiple CDMO players do not have the capability to be active throughout the CDMO value chain and several respondents to the market investigation indicated to be exclusively active either at the API level or at the FDP level.[13]

(18) *Within the market for the supply of CDMO services at the API level*, the Commission previously considered a separate product market for biopharmaceutical CDMO services (as opposed to CDMO services in relation to chemically-synthesised drugs). The Commission also envisaged, but ultimately left open, the question of whether the product market for biopharmaceutical CDMO services should be further segmented (i) based on the host system used in the manufacturing process (*i.e.* mammalian cell cultures or microbial fermentation processes) and (ii) between process development and large-scale manufacturing of biopharmaceuticals.[14]

(19) The results of the market investigation confirmed the relevance of a distinction between the supply of CDMO services for biopharmaceuticals and chemically-synthesised API, as the production processes require different equipment and expertise.[15] Market participants further explained that, within the segment for biopharmaceutical CDMO services, (i) the development and manufacturing of LBPs usually requires dedicated equipment[16] because of the risks of cross-contamination with other products,[17] and (ii) a distinction could be made between the supply of CDO services (i.e. process development) and the provision of CMO services (i.e. large-scale commercial production). Indeed, certain pharmaceutical companies observe that certain CDO service providers in relation to biopharmaceuticals do not have sufficient capacity to ensure a large-scale CMO activity.[18] Conversely, other respondents further explained that they generally procure CDO services in-house and outsource CMO services only.[19]

(20) *Within the market for the supply of CDMO services at the FDP level*, the Commission previously considered the existence of a separate market for the supply of contract manufacturing services (CMO) but left open the question of whether this market should be further segmented according to: (i) the pharmaceutical form (solid dose and powder pharmaceuticals, liquid and semi-solid pharmaceuticals, sterile

13 Responses to questionnaire Q1 to CDMO competitors, question 2.

14 Case COMP/M.5479 – *Lonza/Teva/JV*, decision of 14 May 2005.

15 Responses to questionnaire Q3 to potential customers of the JV, question 5 and responses to questionnaire Q1 to CDMO competitors, question 5.

16 Responses to questionnaire Q1 to CDMO competitors, question 5.

17 Responses to questionnaire Q3 to potential customers of the JV, question 6. In the Form CO, the Notifying Parties also explain: "*LBP-APIs are different in nature* [from other API] *because the APIs are not the molecules expressed during the reproduction process, but rather the entire bacteria. Other differences also exist in the manufacturing process as well, such as the fact that the manufacturing of LBP-APIs requires larger tanks*".

18 Responses to questionnaire Q3 to potential customers of the JV, question 9.

19 Responses to questionnaire Q3 to potential customers of the JV, question 8 and non-confidential version of the minutes of a call with a pharmaceutical company held on 6 June 2019.

liquid pharmaceuticals, and medicated confectionary pharmaceuticals);[20] (ii) the conditions of manufacture (toxicity, sterile environment, the nature of the technology/know-how needed to produce the FDP);[21] and (iii) the type of API used.

(21) In addition, in its recent *Lonza Group/Capsugel* decision,[22] the Commission considered a market for dosage formulation and development services (CDO) but left open whether this market is part of a broader market for the supply of CDMO services (i.e. comprising both CMO and CDO services for FDP) or whether CDO should be considered separately and potentially further segmented by technology.[23]

(22) The Commission's market investigation confirmed that several relevant segmentations could be envisaged for the market for the supply of CDMO services at the FDP level,[24] based on (i) the type of API used (chemically-synthesised and biopharmaceutical API) and (ii) the delivery mechanism used, but also (iii) between the supply of CDO and CMO services.

(23) In any event, for the purpose of the present decision, the Commission considers that the exact product market definition for the supply of CDMO services to pharmaceutical companies can be left open since the Transaction does not raise serious doubts as to its compatibility with the internal market irrespective of whether the market is defined as encompassing all CDMO services or is segmented by type of services.[25]

4.1.1.2. Geographic market definition

(24) The Notifying Parties submit that the market for CDMO services to pharmaceutical companies is at least EEA-wide in scope, if not global.

(25) The Commission previously left open the question of whether the respective markets for CDMO services at the API and FDP levels and their possible segmentations are worldwide or EEA-wide in scope.[26]

(26) The results of the market investigation confirmed that the geographic market for CDMO services to pharmaceutical companies, and its potential segments, is likely to be global in scope and, in any event, at least EEA-wide.[27]

(27) For the purpose of this decision, the question of whether the market for CDMO services to pharmaceutical companies and its potential segments is at least EEA-

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20 Cases COMP/M.8541 – *Thermo Fisher Scientific/Patheon*, decision of 23 August 2017; COMP/M.5253 – *Sanofi-Aventis/Zentica*, decision of 4 February 2009; and COMP/M.5953 – *Reckitt Benckiser/SLL*, decision of 25 October 2010.

21 Cases COMP/M.5253 – *Sanofi-Aventis/Zentica*, decision of 4 February 2009 and COMP/M.5555 – *Novartis/Ebewe*, decision of 22 September 2009.

22 Case COMP/M. 8362 – *Lonza Group/Capsugel*, decision of 21 April 2017.

23 Case COMP/M. 8362 – *Lonza Group/Capsugel*, decision of 21 April 2017.

24 Responses to questionnaire Q3 to potential customers of the JV, questions 5, 6 and 10 and responses to questionnaire Q1 to CDMO competitors, questions 5, 6, 11 and 13.

25 See recitals 41 and 42, as well as sections 5.1, 5.2.1 (in particular recital 54) and 5.2.2. (in particular recitals 61 and 63).

26 Cases COMP/M. 8362 – *Lonza Group/Capsugel*, decision of 21 April 2017 and COMP/M.8541 – *Thermo Fisher Scientific/Patheon*, decision of 23 August 2017.

27 Responses to questionnaire Q3 to potential customers of the JV, question 14 and responses to questionnaire Q1 to CDMO competitors, question 15.

wide or global in scope can be left open since the Transaction does not raise serious doubts as to its compatibility with the internal market under any of the alternative definitions.[28]

4.1.2. Manufacture and supply of SODDM

4.1.2.1. Product market definition

(28) The Notifying Parties submit that the relevant product market should include all types of SODDM, without any further segmentation.[29]

(29) In previous decisions, the Commission considered a market for the manufacturing and supply of SODDM to the pharmaceutical/over-the-counter and nutrition industries that could be segmented into the following categories: (i) hard gelatine capsules; (ii) soft gelatine capsules; (ii) liquid filled hard capsules; and (iv) alternative polymer capsules. However, the Commission left open the exact product market definition.[30]

(30) Lonza is also developing a new technology of hard capsules designed for enteric delivery. These enteric delivery capsules are currently used only in clinical trials by a limited number of customers.[31] The Notifying Party considers that enteric delivery capsules do not constitute a separate market since, from a technical perspective, the same delivery mechanism can be achieved by coating normal hard capsules in latex. The results of the market investigation confirmed the Notifying Parties' claim.[32]

(31) In any event, for the purpose of this decision, the product market definition can be left open, since the Transaction does not lead to serious doubts as to its compatibility with the internal market irrespective of whether the market for the manufacture and supply of SODDM is defined as encompassing all SODDM or is segmented by type of capsules (hard gelatine, soft gelatine, alternative polymer and liquid filled).[33]

4.1.2.2. Geographic market definition

(32) The Notifying Parties submit that the relevant geographic market for the manufacture and supply of SODDM is at least EEA-wide in scope, if not global.

(33) In previous decisions, the Commission left open the question of whether the manufacture and supply of SODDM and its possible segments are EEA-wide or worldwide in scope.[34] The market investigation confirmed that the geographic markets would be either EEA-wide or worldwide in scope.

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28 See recitals 41 and 42, as well as sections 5.1, 5.2.1 (in particular recital 54) and 5.2.2. (in particular recital 63).

29 In particular, the Notifying Parties consider that even enteric capsules can be used interchangeably with hard capsules dipped into latex (in order to offer similar properties in terms of gastric acid resistance).

30 Case COMP/M. 8362 – *Lonza Group/Capsugel*, decision of 21 April 2017.

31 Currently, Lonza's enteric delivery capsules are [confidential] sold to [confidential] customers who use them for drugs in clinical trials, namely [confidential details relating to customer sales].

32 Responses to questionnaire Q1 to CDMO competitors, question 28, and to questionnaire Q3 to potential customers of the JV, question 25.

33 See section 5.2.1 (in particular recitals 52, 53, 56, 57 and 58).

34 Case COMP/M. 8362 – *Lonza Group/Capsugel*, decision of 21 April 2017.

(34) In any event, for the purpose of this decision, the question of whether the market for the manufacture and supply of SODDM and its potential segments is EEA-wide or global in scope can be left open since the Transaction does not lead to serious doubts as to its compatibility with the internal market under any of the alternative definitions.[35]

4.1.3. Bacterial strains

4.1.3.1. Product market definition

(35) The Notifying Parties consider that the relevant product market for bacterial strains encompasses all possible bacterial strains without a need for any segmentation.

(36) The Commission did not previously assess the market for bacterial strains. In the context of the present case, the market investigation envisaged five alternative approaches to segment the market for bacterial strains based on their scientific classification, their end-use application, their technical characteristics, their property of occurring naturally or being genetically modified, or, finally, the types of related services offered by the bacterial strain provider. However, the results of the market investigation did not reveal any evidence suggesting that the market for bacterial strains should be segmented into narrower relevant product markets.[36]

(37) For the purpose of the present decision, the Commission therefore considers that the exact product market definition for bacterial strains can be left open since the Transaction does not lead to serious doubts as to its compatibility with the internal market irrespective of the alternative product market definition considered.[37]

4.1.3.2. Geographic market definition

(38) The Notifying Parties submit that the geographic market for bacterial strains is worldwide in scope or at least EEA-wide.

(39) The Commission did not previously assess the market for bacterial strains. The results of the market investigation carried out in the context of the present case did not reveal any evidence suggesting that the geographic market for bacterial strains or any of its hypothetical segments would be narrower than the EEA.[38]

(40) For the purpose of the present case, the geographic market definition for bacterial strains and its potential segments can be left open since the Transaction does not lead to serious doubts as to its compatibility with the internal market irrespective of the alternative geographic definitions considered.[39]

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35 See section 5.2.1 (in particular recitals 52, 53 and 57).

36 Responses to questionnaire Q1 to CDMO competitors, question 23; responses to questionnaire Q3 to potential customers of the JV, questions 19 and 20, and responses to questionnaire Q4 to bacterial strain service providers, questions 4 and 5.

37 See section 5.2.2 (in particular recitals 61 and 62).

38 Responses to questionnaire Q4 to bacterial strain service providers, questions 1 and 7.

39 See section 5.2.2 (in particular recital 62).

5. COMPETITIVE ASSESSMENT

(41) The JV does not currently commercialise any products but is set up to supply CDMO services in relation to API and FDP, including small-scale manufacturing to pharmaceutical companies engaged in pre-clinical and phase I / phase II clinical trials from 2019 onwards. Consequently, there is presently no horizontal overlap between the JV's activities and Lonza's activities on the markets for the supply of CDMO services. Still, the Transaction leads to affected markets in some of the possible relevant markets where Lonza is active and the JV will be active (i.e. supply of (i) biopharmaceutical CDMO services at the API level (including LBP and non LBP-based API), and (ii) biopharmaceutical CMO services at the API level (including LBP and non LBP-based API).

(42) The Transaction also leads to two vertically affected relationships between:

- Lonza's supply of hard gelatine capsules (upstream), where Lonza holds EEA and global market shares in excess of 30%, and the JV's future activities in CDMO services at the FDP level (downstream); and

- Chr. Hansen's activities in relation to bacterial strains (upstream) and Lonza's and the JV's activities in the supply of biopharmaceutical CDMO services at the API level (downstream), where Lonza's and the JV's combined market share would be in excess of 30%.

(43) For the avoidance of doubt, the present decision and the below competitive assessment remain without prejudice to the legal obligation of the JV and its parents to comply with Articles 101 and 102 TFEU.

5.1. Horizontal non-coordinated effects

(44) The JV will supply a complete range of CDMO services in relation to LBPs to pharmaceutical companies, both at the API and FDP levels. Neither the activities of Lonza (who supplies CDMO services for chemical and non-LBP biological products) nor the activities of Chr. Hansen's (who supplies CDMO services, including for LBPs, exclusively to the health and nutrition industries and not to pharmaceutical companies[40]) will specifically overlap with the JV's activities. The Transaction therefore does not lead to any horizontal overlap between the JV and its parents on the hypothetical segment for the supply of CDMO services for LBPs at the API and/or FDP levels.

(45) Nevertheless, horizontally affected markets arise when considering the broader hypothetical markets, at global level[41], for the supply of (i) biopharmaceutical CDMO services at the API level (including both LBP-based and non-LBP-based API), and (ii) biopharmaceutical CMO services at the API level (including both

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40 Internal documents assessing the creation of the JV show that Chr. Hansen [confidential details relating to the sales strategy and the business and marketing plan of Chr. Hansen] (Annex 5.4.6 of the Form CO). An additional internal analysis undertaken by Chr. Hansen concludes that [confidential details relating to the sales strategy and the business and marketing plan of Chr. Hansen] (Annex 1 to the Notifying Parties' response to RFI6).

41 Under the alternative on an EEA-wide geographic market definition, the markets for the supply of biopharmaceutical CDMO services at the API level and for biopharmaceutical CMO services at the API level are not affected by the Transaction.

LBP-based and non-LBP-based API) due to Lonza's market share on each of these markets (i.e. [30-40]% on the market for CDMO services at the API level worldwide and [30-40]% on the market for CMO services at the API level worldwide).

(46) On each of these markets, the JV's market share is expected to remain fairly limited (up to [0-5]%) over the […] year period following the start of its activities. This is due to the fact that the LBP space currently constitutes a niche area of the market for the provision of biopharmaceutical CDMO and CMO services to pharmaceutical companies worldwide.[42]

(47) Post-Transaction, Lonza and the JV would continue to face numerous other large suppliers of biopharmaceutical CDMO services at the API level, including Boehringer Ingelheim ([10-20]% on the markets for CDMO and CMO services at the API level worldwide), Samsung Biologics ([10-20]% on the markets for CDMO and CMO services at the API level worldwide), Wuxi Biologics ([5-10]% on the market for CDMO and CMO services at the API level worldwide), and other smaller players such as, among others, Fujifilm Diosynth, Luina Bio, SynCo Wacker and Biose.

(48) Moreover, Lonza and the JV would not be close competitors, as they would offer biopharmaceutical CDMO and CMO services in relation to different types of API (LBP-based API for the JV as opposed to chemical and non-LBP biological API for Lonza). Multiple alternative biopharmaceutical cGMP CDMO players such as Luina Bio, SynCo Wacker or Biose will directly compete with the JV on the hypothetical markets for the supply of biopharmaceutical CDMO and CMO services in relation to LBP-based API, where the Transaction aims to create a new player on the market.[43]

(49) Eventually, the vast majority of market participants consider the impact of the Transaction to be neutral on the overall market for CDMO and CMO services in relation to biopharmaceutical products. More specifically, no customer expects any negative impact of the Transaction on these broad markets and some even expect the Transaction to have a positive impact on their activities.[44] While some competitors pointed out that the JV would become the first player active throughout the whole production chain in the nascent LPB space and therefore expect it to rapidly acquire a strong position on this hypothetical market, the creation of the JV would also entail additional production capacity (in particular, commercial manufacturing capacity).[45]

(50) In view of the above and all the information obtained over the course of the market investigation, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to its horizontal

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42 Market shares are expressed in terms of sales (value). Considering Lonza's production capacity and the JV's (future production capacity), their combined market share would remain below 20% under all plausible market definitions.

43 In the context of the present case, merger-specific horizontal coordinated effects are unlikely to arise since the supply of biopharmaceutical CDMO services at the API level and its potential segment for biopharmaceutical CMO services at the API level involve multiple players of various sizes, non-homogeneous products (services addressing specific customer needs) and are characterised by a dynamic environment driven by research and innovation (as evidenced by the expected emergence of CDMO services in relation to LBP). Therefore, the Transaction is unlikely to enable or facilitate market players in the supply of biopharmaceutical CDMO services at the API level to reach common terms of coordination.

44 Responses to questionnaire Q3 to potential customers of the JV, question 27.1.

45 Responses to questionnaire Q1 to CDMO competitors, question 31.4.

non-coordinated effects in the supply of CDMO services and its potential relevant segments.

5.2. Vertical effects

5.2.1. Vertical relation between Lonza's supply of hard gelatine capsules (upstream) and the JV's supply of CDMO services at the FDP level (downstream)

(51) Lonza manufactures and supplies SODDM that are used in the production of FDP, including LBP-based drugs.

(52) The Transaction gives rise to one vertically affected relationship involving the hypothetical upstream market for hard gelatine capsules, where Lonza held relatively high market shares in 2018 both in the EEA and globally (see Table 1).

Table 1 – Worldwide and EEA-wide market shares (based on 2018 sales and volume) in the market for hard gelatine capsules

	Global		**EEA**	
Market player	**volume**	**value**	**volume**	**value**
JV	*0%*	*0%*	*0%*	*0%*
Chr. Hansen	*0%*	*0%*	*0%*	*0%*
Lonza	[20-30]%	[40-50]%	[50-60]%	[50-60]%
ACG	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Qualicaps	[5-10]%	[10-20]%	[10-20]%	[10-20]%
GS Capsule	[0-5]%	[0-5]%	(incl. in Others)	(incl. in Others)
SuHeung	[0-5]%	[0-5]%	(incl. in Others)	(incl. in Others)
Roxlor	(incl. in Others)	(incl. in Others)	[5-10]%	[5-10]%
Others	[30-40]%	[20-30]%	[5-10]%	[5-10]%
Total	**100%**	**100%**	**100%**	**100%**
Total market size	**475 billion units**	**EUR 986 million**	**62 billion units**	**EUR 197 million**

Source: Parties' estimates

(53) In the hypothetical global market for hard gelatine capsules, Lonza held 2018 market shares of up to [40-50]% (based on value), followed by ACG [10-20]% and Qualicaps [10-20]%. Under the alternative of an EEA-wide geographic market definition, Lonza's share was at [50-60]% (based on value) and [50-60]% (based on volume), followed by ACG ([10-20]%) and Qualicaps ([10-20]%). However, irrespective of Lonza's strong market position in the hypothetical segment for hard gelatine capsules at either global or EEA level, no foreclosure risks appear likely to arise post-Transaction.

(54) On the downstream market for the supply of CDMO services at FDP level, the JV is expected to hold a very limited market presence (well below [0-5]%both at EEA-wide and global level) over the […] year period following the start of its activities. Customer foreclosure is unlikely to occur, as the Notifying Parties represented that the JV will account for less than [0-5]% of the total demand for hard gelatine capsules. Suppliers of this type of capsules will therefore retain a large array of customers to whom to sell their products.

(55) Similarly, input foreclosure regarding access to Lonza's hard gelatine capsules is unlikely to materialise.

(56) First, there is no technical bundling possible between Lonza's hard gelatine capsules (including its enteric capsules) and the FDP manufactured by the JV because, as explicitly and repeatedly confirmed by the Notifying Parties, the JV's customers will remain free to purchase capsules from any alternative supplier such as AGC, Qualicaps or Roxlor.[46]

(57) Second, a sufficient number of alternative players will remain active in the supply of hard gelatine capsules, including AGC, Qualicaps, and Roxlor both at EEA and worldwide level. Should Lonza engage into an input foreclosure strategy towards competing CDMO service providers at the FDP level, these downstream competitors would still be able to source the necessary capsules on the market. As regards enteric delivery capsules more specifically, all potential customers who replied to the market investigation indicated that there are alternatives to enteric capsules for the manufacture of LBP-based FDPs, so that these specific capsules do not constitute a critical input.[47]

(58) Third, given the limited size of the JV's future purchases of hard gelatine capsules (less than [0-5]%) compared to Lonza's total current sales of hard gelatine capsules, it is unlikely that Lonza would have any economic incentive of discontinuing supplies to its other downstream customers, which are not necessarily CDMO players (e.g., pharmaceutical companies with in-house capabilities at the FDP level) or active in the development and manufacture of LBP-based drugs at the FDP level.

(59) In view of the above and all the information obtained over the course of the market investigation, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the vertical link between Lonza's upstream activities in the supply of hard gelatine capsules, on the one hand, and the JV's future downstream activities in the supply of CDMO services at the FDP level, on the other hand.

5.2.2. *Vertical relation between the Chr. Hansen's supply of bacterial strains (upstream) and Lonza and the JV's supply of biopharmaceutical CDMO services at the API level*

(60) The Transaction gives rise to a vertically affected link between the downstream market for biopharmaceutical CDMO services, where both Lonza and the JV will be active, and the upstream market for bacterial strains, where only Chr. Hansen is active.

(61) The vertical relationship between Chr. Hansen's upstream activities in relation to bacterial strains and the JV's future downstream activities in the supply of

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46 For instance: "*Ultimately* […], *the choice of SODDM provider, will remain with the customers of the Joint Venture*" (Form CO, paragraph 71); "*The choice of a specific delivery mechanism (and its supplier) will ultimately be decided by the customer of the Joint Venture in each case*" (Form CO, paragraph 113); "*Lonza will not have an exclusive SODDM supply agreement with the Joint Venture, and the delivery mechanism and choice of supplier will ultimately be decided by the Joint Venture's customers*" (Form CO, footnote 27); "*The Joint Venture will purchase SODDM either from Lonza* […], *or from an alternative supplier as instructed by its customers*" (Form CO, paragraph 287).

47 Responses to questionnaire Q3 to potential customers of the JV, question 25 and 25.1.

biopharmaceutical CDMO services is indirect since the JV's customers (and not the JV itself) will be involved in the drug discovery process and the selection of bacterial strains. Irrespective of this, even if the JV were to license bacterial strains directly from Chr. Hansen and rely on them to develop and manufacture LBP-based API, no risk of foreclosure is likely to materialise in the context of the present case.

(62) In fact, Chr. Hansen only holds a limited position on the upstream market for the supply of bacterial strains and any of its possible segments ([0-5]% both at EEA-wide and global level), in particular in relation to bacterial strains suitable for LBPs. Respondents to the Commission's market investigation confirmed that there is a large number of suppliers that could provide bacterial strains for the development of LBP-based API.[48] Given Chr. Hansen's limited presence in the upstream market, the Parties would lack the ability to successfully engage into any input foreclosure strategy.

(63) Likewise, customer foreclosure regarding access to bacterial strains is unlikely to materialise post-Transaction given the marginal position that the JV is expected to hold at the downstream level (up to [0-5]% both at EEA-wide and global level) over the […] year period following the start of its activities.

(64) In view of the above and all the information obtained over the course of the market investigation, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the vertical link between Chr. Hansen's activities in the upstream supply of bacterial strains and any of its potential segments, on the one hand, and the activities of Lonza and the JV in the downstream supply of biopharmaceutical CDMO services at the API level, on the other hand.

6. CONCLUSION

(65) 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
Member of the Commission

48 Responses to questionnaire Q1 to CDMO competitors, question 24.