

***Case No COMP/M.5479 -
LONZA / TEVA / JV***

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004
MERGER PROCEDURE**

Article 6(1)(b) NON-OPPOSITION
Date: 14/05/2009

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EUROPEAN COMMISSION

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PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying parties:

Dear Sir/Madam,

**Subject: Case No COMP/M.5479 - LONZA/ TEVA/ JV
Notification of 3 April 2009 pursuant to Article 4 of Council Regulation
No 139/2004¹**

1. On 03/04/2009, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 (the "EC Merger Regulation") by which Lonza Group Ltd ("Lonza", Switzerland) and Teva Pharmaceuticals industries Ltd ("Teva", Israel) acquire, within the meaning of Article 3(1)(b) of the EC Merger Regulation, joint control of the newly created undertaking ("JV") by way of purchase of shares.

I. THE PARTIES

2. **Lonza** is a pharmaceutical company having its headquarters in Switzerland. It is active in the supply of various services from research to final product manufacture in the pharmaceutical, health care and life science industries.
3. **Teva** is a global pharmaceutical company with its corporate headquarters in Israel. It specializes in the development, production and marketing of generic and propriety branded pharmaceuticals as well as APIs (active pharmaceutical ingredients).
4. The JV will be active in the development, production and commercialization of biosimilar products worldwide.

¹ OJ L 24, 29.1.2004 p. 1.

II. THE OPERATION

5. The parties intend to establish a 50-50% JV within the meaning of Article 3(4) of the EC Merger Regulation. The JV will be active in the development, manufacturing and marketing of biosimilar pharmaceuticals².
6. As set out in the Joint Venture Agreement between Lonza and Teva, the JV will be set up to operate on a lasting basis for an initial duration of [...] years [...]. The JV will focus on the development of a number of biosimilar products ("Portfolio Products"), with the first expected to be in the market in [...]. Teva will transfer to the JV the research already started for [...] products, and in connection thereof the parties will grant the JV [...] to all necessary intellectual property rights. The parents will provide the JV upfront with USD [...] million, sufficient financial resources to cover its initial activities to commercialisation of its products and will have its own management structure. The JV is responsible and has control over all aspects of the development of the products, will own all the resulting IPRs and is free to decide on the development of future products. Ultimately the JV will commercialise its products in the marketplace.
7. However, during the initial research and development start-up phase to [...], before the first product will be put on the market, the JV will have a light structure essentially relying on outsourcing contracts with the parent companies (at arms' length) and with third parties. The characteristics of the biosimilar industry, with long lead times (it may take six to eight years from development to marketing), high upfront investments (significantly more than those required for the development of generic pharmaceuticals) and the high risk of failure of R&D and commercialisation, mean that in any event, outsourcing in this industry is commonplace at all phases of the development of a project, up to and including bringing biosimilars to market. The parties submitted a number of examples of such practices in this industry. Teva itself, for [...], has outsourced to a third party the services of [...], and this contract will also be transferred to the JV. After this initial start-up phase, the JV will be free to pursue its own recruitment policy as well as to develop and acquire its own facilities, and/or to decide to continue to outsource some of its functions to the parents and third parties, whichever it deems more beneficial.
8. Based on the above, it can be concluded that the transaction leads to the acquisition of joint control and that the JV constitutes a full-function joint venture and hence that the notified operation constitutes a concentration within the meaning of Article 3(1)(b) of the EC Merger Regulation.

III. COMMUNITY DIMENSION

9. The transaction has a Community dimension pursuant to Article 1(2) of the EC Merger Regulation. The undertakings concerned have a combined aggregate worldwide turnover in excess of EUR 5 billion³ (Lonza EUR 1,900 million; Teva

² Biopharmaceuticals are pharmaceuticals that have been produced using biological processes, whilst biosimilars are drugs that aim to mimic the original patented biopharmaceutical molecule with identical therapeutic mechanism and clinical attributes. Biosimilars are therefore, in effect, the biopharmaceutical equivalent of a generic drug.

³ Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover, OJ C 66, 2.3.1998, p. 25.

EUR 8,660 million) and a Community-wide turnover in excess of EUR 250 million (Lonza EUR [...] million; Teva EUR [...] million). Neither of the parties realises more than two-thirds of its Community-wide turnover in one and the same Member State.

10. The notified operation therefore has a Community dimension within the meaning of Article 1(2) of the EC Merger Regulation.

IV. RELEVANT MARKETS

Finished Dose Pharmaceuticals

11. In previous recent cases⁴, the Commission has taken as a starting point for market definition purposes the Anatomical Therapeutic Chemical ("ATC") division of medicines by therapeutic use and indications as devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and the Intercontinental Medical Statistics ("IMS") The EphMRA classification consists of four levels and is regularly updated. The ATC is hierarchical and has 16 categories (A, B, C, D etc.) each with different levels⁵. The third level, referred to as ATC3, allows medicines to be grouped in most cases according to their therapeutic indications i.e. their intended use.
12. As referred to above, the JV will initially focus on the development of [...]biosimilar products ("Portfolio Products") with uses in [...]. Similarly to generic drugs, biosimilar drugs are the new versions of originator biopharmaceutical drugs that are brought to the market following the latter's patent expiry. However, as opposed to generics, biosimilars are not exact copies of the originator drugs and, as mentioned above, are subject to significantly more complex, rigorous and costly R&D and regulatory approval processes (although these procedures are still not as onerous as in the case of originator biopharmaceuticals). This is explained by the high molecular complexity of biopharmaceutical drugs as compared to drugs produced by traditional chemical synthesis. Because of this complexity, biopharmaceuticals are quite sensitive to manufacturing process changes.
13. There are different types of biopharmaceutical products. Biopharmaceuticals are based on either mammalian or microbial cell cultures. The first biosimilars (growth hormones) were launched on the market in Europe in 2006 following the adoption of a

⁴ See for instance cases COMP/M.5253 *Sanofi-Aventis/Zentiva* Commission Decision of 4 February 2008, COMP/M.5295 *Teva-Barr*, Commission Decision of 19 December 2008, COMP/M.4049 *Novartis/Chiron* Commission Decision of 6 February 2006, COMP/M.3751 *Novartis/Hexal* Commission Decision of 27 May 2005.

⁵ The first level/category of the ATC indicates the anatomical main group. The second level indicates the main therapeutic group. The third level indicates the therapeutic/pharmacological subgroup while the fourth level indicates the chemical/therapeutic/pharmacological subgroup. The first level (ATC1) categories are subdivided into ATC2 categories, which are in turn sub-divided into ATC3 categories. Some ATC3 categories are sub-divided into ATC4 categories, whereas some others are not.

special approval process for biosimilar products at the EU level. The JV will focus on
6[...] for which patents will expire as of[...].

14. More specifically, the JV intends to bring biosimilar versions of the following [...] biopharmaceuticals to the market:[...].[...]is grouped under the ATC3 group [...]. [...]

[...]

15. [...] are substances used to [...] and are mainly used at the [...] but also for a number of other indications such as [...].
16. The Commission previously considered [...] to be included in the ATC3 classification [...] under the EphMRA ATC3 category [...] ⁷. [...] ⁸
17. Parties submit however, that based on an alternative [...].⁹ [...] In these decisions the Commission considered products used for the treatment of [...]. According to the parties, [...] are not currently used for the treatment of [...] as that is not included in their labelled approved indications. Accordingly, there would be an overlap between Teva's and the JV's activities only within the group of [...] products with indications [...].
18. According to the parties, Teva sells a limited number of products that fall under the [...] classes.
19. [...] is indicated for the treatment of [...] and [...]. In the Commission Decision [...], was considered to fall under the [...] class. According to the Parties, [...] ¹⁰
20. Teva also sells [...] other [...], falling under the [...] class [...]. These products are primarily used for [...].¹¹ As the JV's products are not used for [...], there would be no horizontal overlap between these products and the JV's products within the possible sub-group of [...]. In addition, for regulatory purposes these products are considered as chemical products and not as biosimilars. They were approved under the standard

⁶ [...] are used for the treatment of [...], and [...]

⁷ [...]

⁸ The ATC1 category [...] contains [...] ATC2 sub-categories. The first of these ATC2 categories, [...], contains [...] products. The ATC2 category, [...], is sub-divided into [...] ATC3 categories [...]. The ATC3 category[...] is not further sub-divided into any narrower ATC4 categories.

⁹ [...]

¹⁰ The parties further assert that [...] has a different mechanism of action and a different dosage form (oral vs. injected) than the [...] JV products [...].

¹¹ Although such products are also sometimes used to treat [...], the parties note that their use is limited for this treatment, given the potentially serious side effects.

procedure that applies to generic products and are therefore not comparable to the complex biopharmaceuticals included in the Portfolio Products¹².

21. In the present case, however, the exact product market definitions may be left open as the proposed transaction is unlikely to lead to serious doubts on any of the alternative market definitions considered, where Teva's activities would overlap with the JV's activities. These are i) the ATC3 [...] ii) a possible narrower market of products within the [...] market used for indications [...] and iii) a possible narrower market within the [...]market for products used to treat [...].
22. As regards the geographic scope, the Commission has consistently considered that the markets for finished dose pharmaceutical products were national and there is no reason to depart from this conclusion in the present case.

[...]

23. The ATC3 group [...] includes [...].[...].

The JV's [...] Portfolio Products, [...] fall under the ATC4¹³ [...].

24. According to the parties, TEVA currently sells [...] generic drugs that belong to the [...] class. However, these drugs are of [...] and none of them, as opposed to the JV products, are [...].
25. The Commission has previously considered [...] ¹⁴ [...]
26. In the present case, however, the exact product market definitions can be left open, as the proposed transaction is not likely to lead to serious doubts within the [...] ATC3 category and there is no horizontal overlap on the possible narrower ATC4 sub-categories of [...] or on the molecule level.
27. As regards the geographic scope, the Commission has consistently considered that the markets for finished dose pharmaceutical products were national.

Contract Manufacturing Services

Relevant Product Markets

28. The Commission did not analyse contract manufacturing services for the production of biosimilar products in its previous decisions. In Sanofi Aventis/Zentiva¹⁵ the Commission analysed contract manufacturing services in the pharmaceutical sector in general. In that case a distinction was considered between certain core technologies in

¹² According to the Parties, whilst some of Teva's products have a biological origin, as they are produced using micro-organisms, they are not complex molecules (as is the case for biosimilars) and for regulatory purposes are considered as chemical products and not as biosimilars – they were approved under the standard procedure that applies to generic products.

¹³ [...]

¹⁴ [...]

¹⁵ *op cit* Sanofi Aventis/Zentiva.

contract manufacturing which are widely available and correspond to the most common pharmaceutical forms and certain other technologies which are more specialized. From both the demand and supply side, these technologies are not substitutable. In that case it was found that most of the core technologies were offered by most of the undertakings active in the contract manufacturing business either as their core business or as an adjunct to their captive production activities.

29. Lonza offers both types of contract manufacturing services using both traditional chemical synthesis and biopharmaceuticals manufacturing. The JV will only be engaged in biopharmaceutical production. The manufacturing of biopharmaceuticals requires dedicated facilities, equipment and know-how, which means only a manufacturer having specialised capabilities would be able to offer contract manufacturing services for biopharmaceuticals.
30. The Parties also submit that the market upstream of contract manufacturing services ("CMO") (where Lonza is present) would be limited to biopharmaceuticals. In their view, it should comprise all biopharmaceutical CMO services. Parties submit that from a manufacturing perspective there is no relevant difference between contract manufacturing for innovator biopharmaceuticals and for biosimilars. The market investigation largely confirmed this.
31. The parties concede, however, that relevant product markets could potentially be divided more narrowly.
32. One such potential division could be on the basis of the host system used for the manufacturing process of the Bulk Drug Substance¹⁶, i.e., either (a) mammalian cell culture or (b) microbial fermentation process. The parties have submitted, and the market investigation has confirmed, that there is limited scope for supply-side substitution between the two processes. Manufacturing facilities are distinct given the need to minimise risk of mutual contamination and, the significant number of specific requirements needed for each process means that switching from one process to the other is not possible in the short term. As the initial Portfolio Products in which the JV will focus in the coming years are all of mammalian origin, the analysis will focus exclusively on this type of CMO services.
33. Within the mammalian segment there is, according to the Parties, virtually full substitutability within the research, development and manufacturing of different biosimilar drugs of mammalian origin regarding production equipment, facilities, processes and know-how. Lonza offered examples of its own facilities, used to produce different types of biopharmaceutical products of mammalian origin. Another possible distinction may be made between the early stages of the manufacturing process (which the parties refer to as "process development") and large scale commercial manufacturing. According to the Parties virtually all CMOs provide process development services, even if some companies specialize in only this type of service, whilst a smaller number of CMOs provide commercial scale production, which requires significantly larger capacity. The market investigation provided similar indications.

¹⁶ The biopharmaceutical equivalent of an Active Pharmaceutical Ingredient

34. The market investigation confirmed that CMOs offering contract manufacturing are capable of offering process development while this may not be the case vice versa. The market investigation has indicated that companies with capacities below 10,000 L may be less likely to have the commercial mammalian capabilities. The market investigation further indicated that it is possible to switch capacity between the different manufacturing stages (i.e. between commercial manufacturing and process development).
35. The market investigation indicated some differences in the production of different types of biopharmaceutical products of mammalian origin, e.g., recombinant proteins and monoclonal antibodies. However, it was also indicated that the market players able to offer large-scale commercial manufacturing would in general be able to offer services for the manufacturing of these different types of products. Manufacturing of the different types of mammalian products may require some changes to production equipment and processes and a corresponding lead time. However, the need for commercial manufacturing for the JV's products is not imminent. As mentioned above, even the JV's products are still in development.
36. In the present case, the exact product market definitions for contract manufacturing services can be left open, as the proposed transaction is not likely to lead to serious doubts regarding its compatibility with the common market in the market for mammalian commercial manufacturing. Pursuant to paragraphs 34 and 35, the transaction is unlikely to raise competition concerns under narrower market definitions (i.e. based on type of product or process).

Relevant Geographic Markets

37. It appears that currently biopharmaceutical production is largely concentrated in Europe and the US. However, according to the PharmSource study, mammalian biopharmaceutical production capacity in Asia will expand significantly in the coming years.
38. Parties submit that the geographic scope of contract manufacturing is global. To justify this position, the parties argue that the purified BDS¹⁷ produced by the CMO exhibit a very high value to weight ratio, with the finished dose product selling for thousands of Euro per gram, so that even considering airfreight and chilled handling, shipping costs between continents represent less than 1% of the selling price.
39. Additionally, CMO facilities typically comply with the regulatory and certification requirements of all major jurisdictions, including inspections by regulatory authorities. To back these arguments, the parties provide examples of Lonza's [...] customers using Lonza's CMO facilities in [...], as well as a few more examples of the same occurring with some of Lonza's commercial scale competitors. Furthermore, third party market data is according to the notifying parties collected and provided on a global basis¹⁸, and Lonza itself states that it does not track market data on an EEA basis nor prepare such estimates in its ordinary course of business.

¹⁷ Bulk Drug Substance - the biopharmaceutical equivalent of an API (active pharmaceutical ingredients).

¹⁸ E.g., the PharmSource special market report "Cell culture manufacturing capacity: trends and Outlook through 2013".

40. In the only case where contract manufacturing services in the pharmaceutical sector were analysed¹⁹, albeit in a context of finished dose pharmaceuticals, the Commission considered there to be a strong degree of consensus in the market investigation that these were worldwide markets, even if it considered that it could leave the market open as to whether it was EEA-wide or wider, indicating that this "is clearly at least EEA-wide".
41. The market investigation in the present case provided strong indications that the market for contract manufacturing services for biopharmaceuticals was worldwide, although geographic proximity may in some cases be the preferred option, according to one respondent.
42. In the present case the exact geographic market definitions for contract manufacturing services can be left open, as the proposed transaction is not likely to lead to serious doubts as to its compatibility with the common market, regardless of the exact market definition considered.

V. COMPETITIVE ASSESSMENT

43. The JV does not commercialise any products for the moment but is set up to bring products to market, with the first of the Portfolio Products[...] to reach the market in[...]. Consequently, there is presently no horizontal overlap between the JV's activities and Teva's activities downstream in the markets for finished dose pharmaceuticals. However, Teva is currently active with chemical pharmaceutical products²⁰, in some of the possible relevant markets where the JV will be active. Teva will transfer to the JV all of its biosimilar development programmes related to the JV's pipeline products.
44. Lonza is not present in any finished dose pharmaceutical markets and is active only in the upstream market of contract manufacturing for biopharmaceuticals. Moreover, Lonza does not currently manufacture any biosimilar drugs, nor does it supply any CMO services for the production of any of the initial set of Portfolio Products downstream, that is to say either to innovator companies or to biosimilar companies.

Horizontal effects

45. [...]As referred to above, the JV will produce [...]products, [...], that may be classified under [...]. Whilst Teva is active in [...] these [...], its current market share does not exceed 15% in any of the EEA Member States. The Parties also confirm this to be the case even when considering a fraction of [...] markets comprised of [...]used for indications [...]and for the even narrower possible segment of [...]used specifically for [...].
46. Furthermore, the parties have listed a number of innovative products (i.e., originators) that are expected to be introduced and compete with these Portfolio Products. These are forecast to be introduced in the marketplace approximately around the time when

¹⁹ In the decision issued in the COMP M. 5253 *Sanofi-Aventis/ Zentiva*, para 191 and 192.

²⁰ *C.f.* footnote 12.

the JV will also bring to market its products. This does not exclude the entry of other biosimilars, as the original patents expire in [...] ²¹.

[...]

47. As referred to above, the JV will produce [...] that may be classified under the ATC3 category of [...] in the ATC4 sub-category of [...]. TEVA's and the JV's activities would only overlap at the ATC3 level and not at the ATC4 or molecule level. At the ATC3 class level, Teva currently holds less than 15% in all EEA member states. Furthermore, Teva's products are chemical generics, whereas the JV's products are biosimilars.
48. According to the parties, the Portfolio Products are easily substitutable by a number of other treatments and products that are currently already on the market, as well as those that have just recently been launched, or are at a final phase prior to commercialisation. Furthermore, the notification has identified a number of other innovative products that are expected to be introduced and compete with the Portfolio Products in the future.

Potential competition

49. Teva will retain some biosimilar programmes alongside the JV. However, the parties confirmed that [...]. [...] there is no overlap in pipeline products, so that the merger does not result in any removal of pipeline products.

Conclusion

50. In the light of these considerations, the Commission has concluded that the concentration does not raise serious doubts as to its compatibility with the common market in respect of any of the possible market definitions on account of horizontal effects.

Vertical effects

51. Lonza provides upstream contract manufacturing services for the biopharmaceutical industry ²²²³. Even though the first of the JV's products will only come to market in [...], it may be concluded that effective competition in the relevant product markets will not be significantly impeded due to vertical effects resulting from the creation of the JV. Given that the initial products of the JV will be exclusively mammalian, the analysis below will focus on this segment.

²¹ More specifically, [...]

²² Whilst it is present in the provision of biopharmaceutical contract manufacturing services it does not presently manufacture any biosimilar drugs.

²³ Teva has a very limited offering of contract manufacturing services (representing less than 1% of the total estimated world biopharmaceutical CMO capacity), and in particular has a very small scale operation of mammalian capacity (less than [...]).

Market structure

52. Based on the information provided by the Parties, the highest worldwide market share of Lonza would be in the segment for commercial mammalian manufacturing, where Lonza would have [30-40%] based on 2008 sales figures. As EEA figures are not available for the overall market size for 2008, Lonza was unable to provide market shares on an EEA basis. Lonza's breakdown of their sales reveals, however, that less than [30-40%] of their sales are in the EEA (EUR [...] million against EUR [...] million worldwide sales).²⁴
53. Given that any potential concern regarding vertical effects would relate to the future foreclosure of downstream competitors of the JV, a more relevant measure of market power and the power to foreclose would be Lonza's share of capacity. Indeed, shares of current revenues are based on contracts already awarded in the past and do not therefore reflect Lonza's market power going forward.
54. The assessment below uses as a basis a market report prepared by PharmSource²⁵. Based on the data provided in the PharmSource report²⁶, the share of Lonza of **total mammalian capacity** (including captive) would be [5-10]%. There are eight vertically integrated competitors with comparable capacity to Lonza.
55. Looking at the overall capacity, the share of Lonza of the **total mammalian CMO** capacity (excluding captive capacity and including both clinical and commercial capacities) would be [20-30]%. The EEA-based Boehringer would have [30-40]% and Korea-based Celltrion [10-20]%.
56. The PharmSource report lists 49 companies currently active as CMOs offering clinical, or process development, production. Many of these companies do not offer commercial production. Lonza's market share would be [30-40]% if the overall capacities of only companies with commercial capabilities were to be included. This is only slightly higher than its market share of total mammalian capacity. Boehringer-Ingelheim, Celltrion and Dyosinth (a US-based subsidiary of Schering-Plough) would have shares of [30-40]%, [10-20] % and [5-10] % respectively and there would be some other competitors with smaller capacities. The table below includes only those companies that are considered by PharmSource to be primarily CMOs, it does not include therefore pharmaceutical companies with primarily captive production which also offer CMO services²⁷.

²⁴ The parties set out that there is no publicly available data that would allow an estimate of market size by volume, but given that the products are not homogenous, volume would not be a meaningful measure of industry capacity as both yields and dosages vary significantly from drug to drug.

²⁵ PharmSource special market report "Cell culture manufacturing capacity: trends and Outlook through 2013".

²⁶ It should be noted that the capacity figure provided for Lonza in the PharmSource report is slightly overestimated. According to the Parties their overall capacity is [...]L. However, for the sake of consistency, the study's figures will be used.

²⁷ In this respect the notifying parties have stated that Human Genome Sciences and Abbott Laboratories should be considered as relevant competitors of Lonza in the provision of mammalian biopharmaceutical CMO services as these "actively market" their excess mammalian capacity. For the purposes of the

Table 1: Capacity of companies indicated as primarily CMO with commercial capacity in litres (Source: Pharmsource report)

Company	Plant Locations	2007	2007%
Lonza	UK/ES/US/Singapore		[30-40]%
Baxter	US/CH		[0-5]%
Biovitrum	SE		[0-5]%
Boehringer	DE		[30-40]%
Celltrion	Korea		[10-20]%
CMC	US/DK		[0-5]%
Diosynth	US/NL		[5-10]%
DSM	NL		[0-5]%
GSK	US/UK		[0-5]%
Rentschler	DE		[0-5]%
Sandoz	AT		[0-5]%
Total			

57. As the market investigation indicated that a relevant threshold for sufficient capacity for large scale commercial CMO services might be 10,000L, the Commission also looked at the capacities of CMOs with capacities above 10,000 L. This does not change the above figures significantly. Neither would the share of Lonza be materially different if the present overall capacities of only the CMOs indicated as credible alternatives in the market investigation were to be taken into account.
58. The PharmSource report also foresees a significant expansion of capacity by some players, including Lonza, by 2013. Lonza confirmed to the Commission a capacity increase of [...] L in a new facility in Singapore, with Lonza not increasing its proportional share of capacity by a significant extent. It should be noted that according to the report, significant capacity will come on stream in Asia as well by 2013 (Celltrion which is forecast by the report to reach a capacity of [...]L, an increase of nearly [...] L). Furthermore, the PharmSource report foresees some transferring of excess capacity from the captive to the merchant market (either in form of facility sales or CMO offerings from vertically integrated companies), which in their view would counteract any possible "tightening" of capacity in merchant markets.

current analysis these two companies are excluded as, although it might overstate the market power of Lonza, it already provides the worse case scenario.

59. Finally, as only [...] L of Lonza's [...] L capacity is located in the EEA, the transaction does not appear to lead to high market shares within the EEA either. The PharmSource report estimates European capacity to be around 300,000 litres, Lonza's capacity representing therefore approximately [10-20]%. The total capacity of those competitors listed in the PharmSource report with production plants only within the EEA (and excluding those with production plants both within and outside the EEA) would be 255,445 L. Lonza's share of EEA capacity would therefore not be higher than [10-20]%. The main competitor, Boehringer Ingelheim would have [70-80]% as all of their plants are located in the EEA according to the study.
60. Lastly, even though some respondents in the market investigation indicated that certain production differences may exist between the different types of biosimilar mammalian products (see recital 35), the market investigation also showed that the main players referred in recital 55 and 56, would be able to offer these manufacturing services, and in any event, should they need to adapt their equipment to do so, they could do so within the timeframe of the JV entering its commercial manufacturing. As the competitive assessment would therefore not be different in this case for this possible segmentation, it will not be analysed further.

Competitive impact - Input foreclosure?

61. In order for input foreclosure to occur Lonza would have to have the ability and the incentive to foreclose and this would have to lead to harm in the downstream markets where the JV will be active.
62. Firstly, and as to Lonza's ability to foreclose access to its contract manufacturing services, and according to the estimates provided by Lonza in [...] when it is expected the JV will peak its capacity usage it will represent [...]% of Lonza's commercial capacity. In [...] it expects the JV to be using only [...]% of Lonza's capacity, so that in all events it will have always at least [...]% of its capacity available for the merchant market.
63. Further, the market investigation did not reveal a significant degree of market power of Lonza in the different possible market definitions upstream. For mammalian process development CMO services, a significant number of alternative suppliers to Lonza were indicated by respondents. In the provision of mammalian commercial CMO services there are less suppliers as only a relatively small number of companies have sufficient capacity to offer commercial contract manufacturing services. However, the market investigation confirmed that Boehringer Ingelheim and Celltrion, but also others such as Sandoz, Diosynth and Baxter are credible alternatives to Lonza. Further, the respondents did not refer to any essential inputs held by Lonza over its rival CMOs for the provision of any CMO services, including the commercial manufacturing segment.
64. As mentioned above, Lonza does not currently manufacture any biosimilar drugs, nor does it supply any CMO services for the production of any of the initial set of Portfolio Products downstream, that is to say either to innovator companies or to biosimilar companies. There will therefore be no impact on existing customers that are active in the relevant downstream markets.
65. Secondly, it would also be unlikely that Lonza would have the incentive to foreclose access to its capacity. First, the revenues obtained in the downstream markets via the JV would have to be shared [...] with Teva, and, as seen above, the JV will be subject

to a number of effective competitive constraints downstream from innovative products, chemical and biopharmaceutical, as well as generics. Second, according to the Parties any lost revenues from ceasing to supply upstream CMO services would be fully borne by Lonza. As mentioned above, even at the expected capacity peak requirement in [...], the JV is not expected to use more than [...] % of Lonza's installed capacity. Finally, the lost revenues may be further magnified as any such foreclosure behaviour might have important reputational effects that could affect the remaining (core) of its business²⁸.

66. Lastly, the creation of the JV is unlikely to cause detrimental effect to downstream competition in essence given the number of competitors that could provide credible alternatives of supplying CMO services (see above), but also given the significant number of vertically integrated firms, which would therefore not be affected by any foreclosing strategies for contract manufacturing services. The existence of a number of large vertically integrated players with captive or in-house capacity – and these account for three times the capacity held by all the CMOs considered together, might also be considered as possible competitive constraints on Lonza, as some respondents referred during the market investigation, as they might make their capacity available to third parties on the merchant CMO market. These vertically integrated players may therefore provide further credible capacity alternatives, and it should be noted that some of these are currently Lonza's main customers²⁹, that may therefore decide to take their production in-house in reaction to any possible foreclosing strategies. Finally, as referred to above, and confirmed by the market investigation, significant additional capacity is expected to come on-stream in the next few years, with Lonza not increasing its proportional share of capacity by a significant extent³⁰.

Conclusion –no input foreclosure

67. In the light of these considerations, the Commission has concluded that the concentration does not raise serious doubts as to its compatibility with the common market in respect of any vertical effects.

²⁸ It should be noted that in the Contract Manufacturing services sector biosimilars are likely to account, according to the notifying parties, for a relatively small share of the total biopharmaceutical production for the foreseeable future.

²⁹ This relates only to pharma products other than biosimilars, as Lonza has no biosimilar production.

³⁰ According to PharmSource, at p. 94, it is expected that total capacity will nearly double to 2013 from 2.3 million litres in 2007 to 4 million litres.

VI. CONCLUSION

68. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of Council Regulation (EC) No 139/2004.

For the Commission
(signed)
Neelie KROES
Member of the Commission