EUROPEAN COMMISSION

DG Competition

Case M.7746 - TEVA / ALLERGAN GENERICS

Only the English text is available and authentic.

REGULATION (EC) No 139/2004

MERGER PROCEDURE

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

Date: 20.12.2017

EUROPEAN COMMISSION

Brussels, 20.12.2017
C(2017) 9074 final

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

To the notifying party:

Subject: Case M.7746 – TEVA/ALLERGAN GENERICS
Approval of Intas as purchaser of the Other EEA Divestment Business following your letter of 18 December and the Trustee's opinion of 18.12.2017

Dear Sir/Madam,

I. FACTS AND PROCEDURE

1. By decision of 10 March 2016 ("the Decision") based on Article 6(1)(b) in connection with Article 6(2) of Council Regulation (EC) No 139/2004 (the "Merger Regulation"), the European Commission (the "Commission") declared the operation by which Teva Pharmaceuticals Industries Limited ("Teva") acquired control over the global generic pharmaceuticals business of Allergan plc ("Allergan Generics") compatible with the internal market following modifications by Teva, subject to conditions and obligations (the "Commitments").

2. In particular, the Commitments provide that Teva commits to divest either Teva or Allergan Generics' generic products listed in Schedule A, together with, for each of those products, the assets listed in Schedule G-I ("*On-Market Overlaps Divestment Businesses*").[1] The Other Countries On-Market Overlaps Divestment Businesses also include any pipeline products that the Divesting Party may have for the relevant molecule in the relevant country together with, for each of those pipeline products, the assets listed in Schedule G-II(1). [2]

3. Teva also committed to divest for all products listed in Schedule B-I either (i) the on-market product of one of either Allergan Generics or Teva, together with the assets listed in Schedule

1 Paragraph 8 of the Commitments.

2 Paragraph 9 of the Commitments.

G-I or (ii) the pipeline product of the other Allergan Generics or Teva in the relevant country together with the assets listed in Schedule G-II(1) (collectively the "*On-market-to-Pipeline Divestment Businesses*").[3]

4. The Commitments additionally provide that for all the molecules listed in Schedule B-III, Teva commits to divest either Teva's or Allergan's Generics Business' pipeline product in the EEA, together with the assets listed in Schedule G-II(2) (collectively the "*EEA Pipeline-to-Pipeline Divestment Businesses*").[4]

5. Finally, Teva committed to divest Allergan Generics Business' pipeline for Rasagiline for the following countries: Austria, Denmark, Estonia, Finland, Greece, Hungary, Latvia, Lithuania, Malta, Norway, Poland, Romania, Slovakia and Sweden, together with the assets listed in Schedule G-II(1) (collectively the "*Azilect Divestment Businesses*").[5] For the avoidance of doubt, with respect specifically to Rasagiline, the assets do not comprise any licence on the IP rights owned by Teva.

6. During the sale process, Teva defined six baskets of divested products to be sold to one or several purchasers, based mainly on geographic criteria. The Other EEA Divestment Business covers the acquisition of Basket 5 (Risedronic Acid, EEA Regional Pipeline and Rasagiline). This basket contains both the Risedronic Acid products and the regional EEA pipeline products that Teva has committed to divest. The table below presents the products included in the Other EEA Divestment Business.

Country	Molecule	Schedule/paragraph(s) of the Commitments
Belgium	Risedronic Acid	Schedule A
Croatia	Risedronic Acid	Schedule A
Estonia	Risedronic Acid	Schedule A
Finland	Risedronic Acid	Schedule A
France	Risedronic Acid	Schedule A
Germany	Risedronic Acid	Schedule A
Italy	Risedronic Acid	Schedule A
Netherlands	Risedronic Acid	Schedule A
Portugal	Risedronic Acid	Schedule A
Spain	Risedronic Acid	Schedule A
Sweden	Risedronic Acid	Schedule A
[…]	[…]	Schedule B-I
	[…]	Schedule B-III
	[…]	Schedule B-III
	[…]	Schedule B-III
	[…]	Schedule B-III
	[…]	Schedule B-III
	[…]	Schedule B-III

3 Paragraph 10 of the Commitments.

4 Paragraph 12 of the Commitments.

5 Paragraph 13 of the Commitments.

Country	Molecule	Schedule/paragraph(s) of the Commitments
[…]	[…]	Schedule B-III
	[…]	Schedule B-III
	[…]	Schedule B-III
	[…]	Schedule B-III
	[…]	Schedule B-III
	[…]	Schedule B-III
	[…]	Schedule B-III
[…]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…][6]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…]	Rasagiline	Paragraph 13
[…][7]	Rasagiline	Paragraph 13

7. These molecules, together with the divested assets, are referred to in this Decision as the "Other EEA Divestment Business".

8. On January 9 2017, Teva signed an Asset and Purchase Agreement ("APA") and related agreements (the "***Proposed Agreements***") regarding the acquisition of the Other EEA Divestment Business by Intas Pharmaceutical Ltd. ("***Intas***" or the "***Purchaser***").

9. By letter of 18 December 2017, Teva proposed Intas for approval by the Commission as purchaser of the Other EEA Divestment Businesses and submitted the APA as well as the other proposed agreements.

10. On 18 December 2017, the monitoring trustee (Duff & Phelps, hereinafter referred to as the "the Trustee") submitted a reasoned opinion regarding Intas' suitability as a purchaser.

6 For Rasagiline, no volumes are included for […] given that Teva never intended to launch Rasagiline in that country but intended instead to launch the product in […]. Consequently, Intas added volumes for this product for […].

7 See the previous footnote.

II. ASSESSMENT OF THE PROPOSAL

11. As set out in Section E of the Commitments, the Purchaser must fulfil the following criteria:

    a. The Purchaser shall be independent of and unconnected to the Notifying Party and its Affiliated Undertakings,

    b. The Purchaser shall have the financial resources, proven expertise, ability and incentive to maintain and develop the Other EEA Divestment Business as a viable and active competitive force in competition with Teva and other competitors,

    c. The Purchaser shall be an established pharmaceutical company having the incentive and ability to become independent of the Notifying Party with respect to the manufacturing of the Divested Products.

    d. The Purchaser shall be a generic company already active in the EEA, and shall have the incentive and the ability to maintain and develop each of the Divested Products.

    e. The acquisition of the Other EEA Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, prima facie competitive concerns nor give rise to a risk that the implementation of the Commitments will be delayed,

12. This section provides a short description of the Purchaser, as well as an assessment of its suitability in view of these criteria.

Description of the Purchaser

13. Intas, founded in 1976 and headquartered in Ahmedabad, India, is engaged in the manufacturing, marketing, distribution, and sale of finished pharmaceutical formulations, active pharmaceutical ingredients ("APIs"), medical appliances, and medical devices worldwide. The company markets its products through wholesalers, mail order pharmacies, and retail pharmaceutical chains. Intas has a presence in more than 70 countries and has 13 manufacturing sites worldwide.

14. On 23 December 2016, the Commission approved Intas as a purchaser of a substantial part of Allergan Generics' business in the United Kingdom and Ireland which was also being divested as part of the Commitments ("IE-UK Divestment Business").[8]

Assessment of the purchaser criteria

(a) Independence from Teva

15. Teva does not have any ownership stake or equity connections in Intas and *vice versa*. Teva has no joint venture or alliances with Intas. There are no cross-memberships in the management boards of the two companies. Teva and Intas have not acted as counterparties in any transaction between March 2014 to March 2017, except for the acquisition of the IE-UK Divestment Business.

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8 Case M.7746 – Teva/Allergan Generics, Approval of Intas as purchaser of IE-UK Divestment Business, 23 December 2016.

16. With respect to commercial operations, Teva purchases […] from Intas […] for a total amount of EUR […]. In addition, Intas purchases […] from Teva for approximately EUR […] based on the year ending March 31, 2017 (i.e. FY 2017). The latter revenues come from […]. These agreements amount to only [0-5]% of Intas' global revenues.

17. Also, as a result of its acquisition of the IE-UK Divestment Business, Intas concluded several agreements with Teva. However, these agreements are transitional and together accounted for less than [0-5]% ([0-5]%) of Intas' global revenues.

18. In view of the above, the Commission considers that there are no structural links or material commercial links that could cast doubts on Intas' independence from Teva. Therefore, based on the information provided and the reasoned opinion of the Trustee, the Commission considers Intas to be independent of and unconnected to Teva.

(b) Financial resources

19. Intas generated revenues of more than EUR […] for FY 2017. This represents a substantial annual increase compared to FY 2014. Its revenues have been growing throughout this period. In terms of profitability, the EBITDA margin has substantially increased between FY 2014 and FY 2017.

20. In addition, Intas' total assets have grown substantially every year between FY 2014 and FY 2016**.** This growth is primarily financed […].

21. The consideration for the acquisition of the Other EEA Divestment Business of EUR […] thus comprises only a small part of (i) Intas' EBIT for FY 2017 and (ii) Intas' total book value of assets.

22. In view of the above, the Commission, based on the information provided and the reasoned opinion of the Trustee, considers that Intas has the financial resources to maintain and develop the Other EEA Divestment Business.

(c) Proven expertise

23. Intas is engaged in the manufacturing, marketing, distribution and sale of finished pharmaceutical formulations, APIs, medical appliances, and medical devices on a worldwide basis. Over 2,500 Stock Keeping Units (SKUs) are currently on-market in Europe and a […] launches are planned in the next […] years. Intas generated important revenues in the EMENA region[9] in 2016.

24. Intas' operations are fully vertically integrated. More in particular, its operations comprise in-house API production, research and development ("R&D"), regulatory, manufacturing, quality, supply chain, marketing and sales and pharmacovigilance functions.

25. Intas has long-lasting experience in global manufacturing and supplying into European markets. The company's entire network comprises 13 sites, 7 with European good manufacturing practice ("GMP") approvals, and several new sites scheduled for development and upgrade. Overall, Intas has several thousand manufacturing employees and produces several billion tabs on an annual basis.

9 Europe, Middle East and North Africa.

26. As for Intas' EEA sites, until recently, Intas operated one primary and secondary packing site in Haverhill, United Kingdom, and a European test and release laboratory in London, United Kingdom. Intas has recently invested to reinstate a facility in Newcastle, United Kingdom and has acquired a plant in Barnstaple, as part of its acquisition of the IE-UK Divestment Business on January 9, 2017.

27. Intas expects [Confidential information on personnel].

28. Following the acquisition of the Other EEA Divestment Business, Intas will perform […] technology transfers, given that out of the 14 divested products, […] products are also included in the IE-UK Divestment Business and […] product is already manufactured by Intas. According to the Trustee, Intas has extensive expertise in technology transfer as it has performed numerous technology transfers of products to new production facilities. In particular, Intas has extensive experience regarding technology transfers from external organizations into Intas-owned facilities.

29. Concerning its sales and marketing capabilities, Intas has a solid presence in the EEA countries where the Other EEA Divestment Business generates revenues as it currently employs commercial employees in 18 EEA countries.

30. The Trustee noted that Intas' distributor agreements include all the relevant products and […]. The Trustee deemed the distributors suitable both in terms of distribution and in terms of marketing capabilities as well as financially able and incentivised to execute the distributor agreements. The distributors are furthermore sufficiently independent from Teva.

31. The Commission shares the assessment above and considers that Intas has the proven expertise to maintain and develop each of the Divestment Products as all as the Other EEA Divestment Business as a viable and active competitive force in competition with Teva and other competitors. Intas is additionally an established pharmaceutical company having the incentive and the ability to become independent from Teva with respect to the manufacturing of the products included in the Other EEA Divestment Business.

(d) Incentive to maintain and develop the Divested Business as a viable and active competitor

32. The acquisition of the Other EEA Divestment Business fits into [Confidential information on Intas' development strategy].

33. [Confidential information on Intas' development strategy].

34. In general, the Trustee deems Intas' business plan for the Other EEA Divestment Business to be reasonable. In particular, the Trustee considers that Intas will be able to grow the market shares of the divested products given its proven expertise in launching new products and ramping up their net sales.

35. The Commission shares the assessment above and considers that Intas has strong incentive both from a strategic and a financial point of view to maintain and develop the Other EEA Divestment Business and all the accompanying divested products post-closing.

(e) Absence of prima facie competition problems

36. The transfer of the Other EEA Divestment Business is not subject to any regulatory authorization, except from the buyer approval by the Commission.

37. The transfer of the Other EEA Divestment Business is not subject to any regulatory authorization, except from the buyer approval by the Commission.

38. In its reasoned proposal, Teva presented an analysis of the overlaps between Intas and the Other EEA Divestment Business, including on-market to pipeline overlaps, pipeline to pipeline overlaps and on-market to on-market overlaps.

39. For the vast majority of overlaps, in view in particular of the limited market shares of Intas and/or the Divested Product, and the number of remaining competitors, the Commission concludes that these overlaps do not raise any prima facie competition concerns.

40. The remaining overlaps, where Intas has a stronger market position in two countries, concern […]. The Other EEA Divestment Business includes the EEA-wide pipeline project of […] (from Allergan Generics), while Intas has an on-market […] product in Poland and in Norway, with high market shares in 2016.

41. In both countries, however, Intas is facing recent entrants as well as likely further market entries in the near future. Indeed, in Poland, there are a large number of competitors who have marketing authorisations. In particular, two competitors are already present on the market ([…], and […]) following the acquisition of a marketing authorisations in the last two years. Furthermore, five additional competitors ([…]) hold a recently obtained marketing authorisation. Out of these five players, […] has recently won a tender while […] is expected to launch its product very shortly. The three other players have dormant marketing authorisations.

42. Given the high level of recent entry and the increasing competitive pressure that Intas is facing in Poland, the overlap between its marketed […] product and the EEA-wide pipeline for the same molecule it will acquire as part of the Other EEA Divestment Business does not raise prima facie competitive concerns.

43. In Norway, Intas, whose market position has weakened in recent months, would face significant competition from […] and […]. In particular, strong competition can be expected from […], who entered the market in January 2017 and is rapidly growing. In addition, there are four other competitors who already have marketing authorisations and are thus able to impose a competitive constraint on Intas post-acquisition, namely […]. Out of these four dormant marketing authorisation holders, […] acquired them in the last two years, suggesting that a launch of these products in the near term is likely. Furthermore, Teva is planning to launch its […] product in Norway in early 2019.

44. Given the high level of recent entry and the increasing competitive pressure that Intas is facing in Norway, the overlap between its marketed […] product and the EEA-wide pipeline for the same molecule it will acquire as part of the Other EEA Divestment Business does not raise prima facie competitive concerns.

45. Therefore, based on the information provided and the reasoned opinion of the Trustee, the Commission considers that the approval of Intas as the purchaser of the Other EEA Divestment Business does not create prima facie competition concerns.

46. This prima facie assessment is based on the information available for the purpose of this buyer approval and does not prejudge the competition assessment of the acquisition of the Other EEA Divestment Business by Intas by a competent competition authority under applicable merger control rules.

Conclusion on the purchaser criteria

47. In light of the above considerations, taking into account the reasoned opinion submitted by the Trustee, and in light of the information available to it, the Commission concludes that Intas meets the purchaser criteria set out in Section E of the Commitments.

III. ASSESSMENT OF THE PROPOSED AGREEMENTS

48. As to the compliance of the Proposed Agreements with the Commitments, the Trustee reviewed the trackers provided by Teva on (i) how the Commitments are reflected in the Proposed Agreements and (ii) how the guidance sought from the Commission during the sale process has been implemented in the Proposed Agreements.

49. The Trustee made a number of observations concerning the compliance of the Proposed Agreements with the Commitments, which led to several amendments by the Parties. Following these amendments, the Trustee concluded that the Other EEA Divestment Business is sold in a manner consistent with the Commitments.

50. In light of the above considerations, taking into account the reasoned opinion submitted by the Trustee, and in light of the information available to it, the Commission concludes that the Other EEA Divestment Business is being sold in a manner consistent with the Commitments.

IV. CONCLUSION

51. On the basis of the above assessment, the Commission approves Intas as a suitable purchaser for the above-mentioned reasons.

52. On the basis of the Proposed Agreements, the Commission further concludes that the Other EEA Divestment Business is being sold in a manner consistent with the Commitments.

53. This decision only constitutes approval of the proposed purchaser identified herein and of the Proposed Agreements. This decision does not constitute a confirmation that Teva has complied with its Commitments.

For the Commission

(Signed)
Johannes LAITENBERGER
Director-General