



EUROPEAN COMMISSION
DG Competition

***Case M.7919 -
SANOFI /
BOEHRINGER
INGELHEIM
CONSUMER
HEALTHCARE
BUSINESS***

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: 3/5/2017



EUROPEAN COMMISSION

Brussels, 3.5.2017
C(2017) 3102 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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:

Dear Sir/Madam,

Subject: Case M.7919 – Sanofi / Boehringer Ingelheim Consumer Healthcare Business
Approval of Ipsen as purchaser following your letter of 17 February 2017 and the Trustee's opinion of 24 February 2017 and additional information submitted on 12 April 2017

I. FACTS AND PROCEDURE

1. By decision of 4 August 2016 ("the Decision") based on Article 6(1)(b) in connection with Article 6(2) of Council Regulation (EC) No 139/2004¹, the Commission declared the operation by which Sanofi S.A. ("Sanofi", France) acquired sole control over Boehringer Ingelheim Consumer Healthcare business ("BI CHC", Germany) compatible with the internal market subject to conditions and obligations (the "Commitments").
2. Pursuant to the Commitments, Sanofi in particular committed to divest the following products:
 - a. Sanofi's Suppositoria Glycerini business in the Czech Republic;
 - b. Sanofi's Mucothiol business in Greece;

¹ OJ L 24, 29.1.2004, p. 1 (the "Merger Regulation").

- c. Sanofi's Mucodune business in Ireland;
- d. BI CHC's Prontalgine business in France;
- e. BI CHC's Buscopan business in the Czech Republic;
- f. BI CHC's Buscopan business in Estonia;
- g. BI CHC's Buscopan business in Hungary;
- h. BI CHC's Buscopan business in Latvia;
- i. BI CHC's Buscopan business in Poland; and
- j. BI CHC's Buscopan business in Slovakia;

hereafter referred to as the "Divestment Businesses".

- 3. By letter of 17 February 2017, Sanofi proposed Ipsen as purchaser of all the Divestment Businesses (hereinafter referred to as Ipsen or the "Proposed Purchaser") and submitted the Sale and Purchase Agreement and the related agreements (the "Transaction Agreements"). On 24 February 2017 the monitoring trustee Grant Thornton (the "Trustee") submitted an assessment of Ipsen's suitability as the purchaser of Divestment Businesses ("Reasoned Opinion"). On 12 April 2017 the Trustee submitted additional information and the revised Transaction Agreements. In its Reasoned Opinion the Trustee considered that it considers that Ipsen fulfils the purchaser criteria, defined in paragraph 16 of the Commitments and that that the Divestment Business would be sold in a manner consistent with the Commitments.

II. ASSESSMENT OF THE PROPOSAL

(a) Legal Framework

- 4. According to paragraph 16 of the Commitments, in order to be approved by the Commission, the purchaser(s) of the Divestment Businesses must fulfil the following criteria:
 - a. the purchaser(s) shall be independent of and unconnected to Sanofi;
 - b. the purchaser(s) shall have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with Sanofi and other competitors;
 - c. the acquisition of the Divestment Business must not be likely to create, in the light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the purchaser(s) must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business; and
 - d. the purchaser(s) shall have existing market presence in the field of branded over-the-counter ("OTC") pharmaceutical products and have a local footprint including sales and distribution network in each country concerned by the Divestment Business. As regards Mucodyne business

(Ireland), the purchaser shall have existing market presence in the field of pharmaceutical products in Ireland and have a local footprint including sales and distribution network.

(b) Description of the Proposed Purchaser

5. Ipsen is a global pharmaceutical company headquartered in France listed on the Euronext stock exchange. The company was created in 1929 as family-owned business. It offers a wide range of pharmaceutical products in primary care, oncology, endocrinology and neurology. It is present in 115 countries, with approximately 5,000 employees worldwide. Ipsen's global sales in 2016 amounted to EUR1.56 billion.

(c) Independence from the Parties

6. Based on the information available to the Commission, Ipsen has neither cross-shareholdings with Sanofi, nor any shared directors. Furthermore, Sanofi and Ipsen do not participate in any joint ventures together and there have been no mergers or acquisitions in the past three years involving Sanofi on the one hand and Ipsen on the other.
7. Furthermore, there are no significant commercial relationships between Sanofi and Ipsen which could impact its independence. A minor commercial relationship between Sanofi and Ipsen exists but not in Europe and not in the area of OTC products. Sanofi distributes certain specialty care products of Ipsen in [...]. These relationships are at arm's length and relatively insignificant, as they represented approximately EUR [...] of Sanofi's sales in 2016 compared to Sanofi's total revenues of more than EUR [30-40] billion and to Ipsen's annual revenues of EUR 1.56 billion. This relationship cannot be considered to have a material impact on the independence of Ipsen. Ipsen does not have any other relationships with Sanofi, in particular in Europe, or in the field of the OTC products.
8. Post-divestment, Sanofi and Ipsen will enter into a certain number of agreements to ensure the economic continuity of the Divestment Businesses. These agreements will be only transitory, as provided for in the Commitments, and Ipsen already possess the qualified personnel to operate the Divestment Businesses. Therefore, following the transitory period, Ipsen will not be dependent upon Sanofi for the manufacture, distribution and sales of the Divestment Businesses.
9. In view of the above the Commission considers that Ipsen is independent of and unconnected to Sanofi.

(d) Financial resources, proven expertise, and incentive to maintain and develop the Divested Business as a viable and active competitor

Financial resources

10. In 2016, Ipsen achieved a turnover of approximately EUR 1.6 billion, up from EUR 1.44 billion in 2015. Ipsen has a strong balance sheet and intends to finance the acquisition of the Divestment Business with the available cash which largely exceeds the purchase price of EUR 83 million.

Incentives to develop the business

11. Ipsen has a strong presence and long track record in the OTC market, with sales amounting to EUR 374 million in 2015. Ipsen is experienced in promoting branded products to consumer groups, pharmacies and to general practitioners.
12. Ipsen has also experience in acquiring brands through both acquisition and licensing and integrating them into its business model. In particular, the acquisition of the Divestment Business would be the second of its kind in 2017 for Ipsen, after it entered into an agreement for a purchase of an equity stake in Akkadeas Pharma private consumer healthcare business in Italy at the end of January.²
13. Ipsen plans to grow the Divestment Business through a policy of investment in promotional activity. Furthermore, according to its business plan, Ipsen expects that over a ten year period the Divestment Business will generate cash flows in excess of the purchase price and a positive return on investment in excess of Ipsen's cost of capital. The Trustee has reviewed the Ipsen's business plans and projections and considers that they are realistic.
14. The acquisition of the Divestment Business is in line with Ipsen's strategy to grow its OTC business. Ipsen estimates that the revenues generated by the Divestment Businesses will grow in the next five years. Furthermore, Ipsen paid EUR 83 million for the Divestment Business and it expects to see a return on its investment of [5-15]%.
15. Ipsen's strategy across all markets is to increase brand awareness and customer loyalty of the divested products. In addition, Ipsen believes that Suppositoria Glycerini (the Czech Republic) and Buscopan (Estonia, Hungary, Latvia, Poland, Slovakia and the Czech Republic) are complementary to its existing brands in the gastro-intestinal market. Furthermore, it considers that the acquisition of Prontalgine (France) will bring critical mass to Ipsen's OTC portfolio and enable it to enter a new therapeutic area in this country.
16. Whilst it is acknowledged that some of the Divestment Businesses are small in size, the following factors support Ipsen's incentive to develop the businesses. First, Ipsen itself operates on a relatively small scale, which means that all the Divestment Businesses represent a meaningful level of opportunity. Second, Ipsen considers that limited investment and promotion in some of the divestment products by Sanofi and BI create an opportunity for the owner to build the products. Third, Ipsen has set aside EUR [...] integration budget to fully incorporate the business into its existing portfolio.
17. Overall Ipsen believes that it will be able to grow sales over the long term of all the products purchased, [...].

² Ipsen acquired an equity stake in Akkadeas Pharma with an option to take control of the company in the future. Akkadeas Pharma is a privately held consumer health care company in Italy with a diversified portfolio with gastro-intestinal focus. <http://www.ipsen.com/investors/regulated-information/ipsen-acquire-primary-care-platform-italy-akkadeas-pharma/>

Existing market presence in each country concerned by the Divestment Businesses

18. Ipsen's experience and presence in the field of branded OTC products, including a local footprint with sales and distribution networks in each country concerned by the Divestment Business are summarised below.

a. France (Prontalgine)

19. Ipsen has a direct presence in France, where its second largest subsidiary in terms of sales is located. Overall in France Ipsen employs [...] people dedicated to promotion and [...] medical representatives who conduct visits to pharmacies and general practitioners. Ipsen has commercial relationships with the main wholesalers in France covering [...]% of its sales. As regards the remaining [...]% of sales they are organised through direct sales to pharmacies. Ipsen also conducts promotional activities (for example including realising visits to pharmacies, in 2016 there were [...] visits made).

20. In France Ipsen generated overall sales of almost EUR [...], including the sales of OTC products amounting to almost EUR [...]. Its main brands are Smecta, Tanakan, Forlax and Bedelix which are all well-known products.

21. Ipsen considers that the acquisition of Prontalgine should enable Ipsen to increase its footprint in the French OTC market. It will allow Ipsen to enter into a new OTC therapeutic area and improve the profitability of Ipsen's current OTC product portfolio in France by the absorption of fixed costs and the creation of synergies. Ipsen considers Prontalgine to be a pillar product in pain management and thus it will boost its execution strategy as it will enable Ipsen's OTC Business to grow by [...] in France. Ipsen aims to grow Prontalgine sales by [10-20]% between 2017 and 2021.

b. Poland (Buscopan)

22. Ipsen has a direct presence in Poland, with a team of [...] key account managers and [...] in support fully dedicated to marketing activities of Ipsen's OTC business in Poland. Sales are operated through direct relationships with wholesalers, [confidential information regarding some of Ipsen's wholesalers].

23. In 2015 in Poland Ipsen generated total sales of EUR [...], including around EUR [...] in the OTC area. The main OTC brands marketed by Ipsen in Poland include Smecta and Forlax, which, like Buscopan, are products within the gastro-intestinal area. Buscopan will, thus, complement and widen Ipsen's portfolio in this therapeutic area in Poland.

24. According to Ipsen's projections between 2017 and 2021 Buscopan sales in Poland are to increase by [10-20]%.

c. Slovakia (Buscopan)

25. In Slovakia Ipsen has a long-term distribution partnership with [...] for the sale of its current gastro-intestinal product portfolio. [...] has [...] representatives marketing Ipsen's products, who are expected to conduct almost [...] promotional visits to pharmacies in Slovakia in 2017 to promote Ipsen's OTC products.

26. In Slovakia Ipsen generated overall sales of more than EUR [...], including EUR [...] in the OTC area. Its main brands are Smecta and Fortrans within the gastro-intestinal area (as is Buscopan). Ipsen has ambition to grow their OTC presence in Slovakia in the coming years.
27. Buscopan will, thus, complement and widen Ipsen's portfolio in this therapeutic area in Slovakia.
28. According to Ipsen's projections between 2017 and 2021 Buscopan sales in Slovakia are to increase by [20-30]%.

d. Hungary (Buscopan)

29. Ipsen has a direct presence in Hungary, with [...] employees promoting its products. From 2017, the promotion and sales of Ipsen's products [confidential information regarding Ipsen's actual and future organisation of its promotions and sales].
30. In Hungary Ipsen's total sales amounted to EUR [...], including sales of the OTC products worth EUR [...]. The main OTC brand of Ipsen in Hungary is Smecta and it plans to grow their OTC presence in Hungary in the coming years.
31. According to Ipsen's projections between 2017 and 2021 Buscopan sales in Hungary are to increase by [10-20]%.

e. The Czech Republic (Buscopan and Suppositoria Glycerini)

32. Ipsen has a direct presence in the Czech Republic with [...] employees marketing Ipsen products. Sales are operated through wholesalers [confidential information regarding Ipsen's wholesalers].
33. In the Czech Republic Ipsen generated overall sales of EUR [...], including the OTC sales of EUR [...] (2015). Its main OTC brands in the Czech Republic include well-known Smecta and Forlax.
34. According to Ipsen's projections between 2017 and 2021 Buscopan sales in the Czech Republic are to increase by [0-5]%.

f. Estonia and Latvia (Buscopan)

35. Ipsen has a direct presence in Estonia and Latvia (as part of Ipsen's Baltics cluster, including Lithuania), with [...] employees entrusted with the task of promoting and managing the wholesale of Ipsen's products. Sales are generated through a number of wholesalers in both countries, [confidential information regarding Ipsen's wholesalers].
36. In Estonia Ipsen generated total sales of EUR [...], including OTC sales of [...]. In Latvia Ipsen generated total sales of [...], including the OTC sales of EUR [...]. Ipsen's main OTC brands were Smecta and Forlax. As submitted by Ipsen, the acquisition of Buscopan will enlarge its gastro-intestinal product portfolio with a well-known OTC brand. Ipsen has ambition to grow their OTC presence in Estonia and Latvia in the coming years.

g. Greece (Mucothiol)

37. Ipsen has a direct presence in Greece, with [...] employees in charge of marketing. Promotion is handled by [confidential information regarding Ipsen's actual organisation of the promotion of its products], a local specialised OTC company. In Greece Ipsen markets OTC brands such as Smecta and Forlax. In 2015 it has generated overall turnover of EUR [...] including EUR [...] in OTC products.
38. The acquisition of Mucothiol will enable Ipsen to enlarge its product portfolio in Greece with a new brand indicated in the area of cough and cold. It will allow Ipsen to strengthen its execution strategy by bringing a critical mass to its product portfolio and by [one of Ipsen's means to strengthen its execution strategy in Greece] in value in Greece.
39. Ipsen plans to actively promote Mucothiol and contemplates an increase of its sales by [10-20]% between 2017 and 2021.

h. Ireland (Mucodyne)

40. Ipsen has a direct presence in Ireland with [...] sales employees in charge of its portfolio in Ireland. In 2015 it has generated sales of EUR [...] in Ireland, Ipsen has no OTC products in Ireland. [confidential information regarding Ipsen's wholesaler].
41. According to the Commitments, the purchaser is required to have existing market presence in the field of pharmaceutical products in Ireland and have a local footprint including sales and distribution network, but, contrary to the requirements relating to other markets, the purchaser is not required to have the OTC sales in Irelands. The Commission notes that in Ireland Ipsen only markets prescription drugs, thus is has no OTC sales, but it does have presence in the pharmaceutical field, as required under the Commitments, including the relevant expertise and capabilities to maintain the Divestment Business on the market.
42. In view of the above the Commission considers that Ipsen has the market presence and the required local footprint including sales and distribution network in each country concerned by the Divestment Businesses.
43. In view of the above, the Commission considers that Ipsen has the financial capabilities, proven expertise and incentive, from both financial and strategic perspective to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors.

Absence of prima facie competition concerns

44. According to Ipsen the purchase of the Divestment Business will not be reportable to any competition authority, so no regulatory approvals as regards compliance with competition rules will be required.³

³ The acquisition requires approval from the French Ministry of Finance and Economy under foreign investment rules, but such approval, according to the Trustee and Sanofi, is expected to be obtained without undue difficulty.

45. There are no overlaps between the activities of Ipsen and the Divestment Businesses except for Suppositoria Glycerini in the Czech Republic. In this country Ipsen sells Forlax, which is also a product used for constipation. However, this is unlikely to give rise to any *prima facie* competition concerns.
46. This is because, first, Forlax and Suppositoria Glycerini are not closely competing products. As discussed in the Decision, Suppositoria Glycerini is one of the few products with high efficacy, while Forlax is considered to be of medium efficacy. Furthermore they are sold in different galenic forms: Forlax is presented in the form of single-dosed sachets, while Suppositoria Glycerini is a suppository.
47. Second, according to the Decision, on a market comprising all products for constipation in the Czech Republic, Ipsen's current market share amounts to 3%; following the purchase it will reach 18%. As described in more detail in the Decision, on this market a number of players will remain active: Sanofi, the market leader, with a market share of [20-30]%, Stada with the market share of [10-20]%, Mylan with a market share of [5-10]% and a number of other competitors including Biomedica, Ferrer, Krka, Valeant, Teva and Novartis. As also explained in the Decision, the market shares would be very similar should the market comprise OTC products only.
48. The Trustee verified and confirmed that there are no vertical links between the activities of Ipsen and the Divestment Business.
49. To conclude, in light of the information available, the Commission considers that Ipsen is neither likely to create *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed, and is expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.

III. ASSESSMENT OF THE TRANSACTION AGREEMENTS

50. The Master Asset Purchase Agreement between Sanofi and Ipsen was signed on 10 February 2017. Following Commission's and Trustee's comments, the ancillary agreements were signed on 13 April 2017.
51. The Trustee has reviewed and provided an assessment of the updated Transaction Agreements and concluded that they fulfil the requirements of the Commitments and that the Divestment Business is sold in a manner consistent with the Commitments.
52. Based on the above, the Commission concludes, in agreement with the assessment of the Trustee in the Reasoned Opinion that the Divestment Business is sold in a manner that is consistent with the Commitments.

IV. CONCLUSION

53. On the basis of the above assessment, the Commission approves Ipsen as a suitable purchaser for the above-mentioned reasons.
54. On the basis of the Transaction Agreements, the Commission further concludes that the Divestment Business is being sold in a manner consistent with the Commitments.

55. This decision only constitutes approval of the proposed purchaser identified herein and of the Transaction Agreements. This decision does not constitute a confirmation that Sanofi has complied with its Commitments.
56. This decision is based on paragraph 16 of the Commitments attached to the Commission Decision of 4 August 2016.

For the Commission
(signed)
Johannes LAITENBERGER
Director-General