EUROPEAN COMMISSION
DG Competition

Case M.8016 - SANOFI PASTEUR / VACCINES OF SANOFI PASTEUR MSD

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 28/10/2016

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EUROPEAN COMMISSION

Brussels, 28.10.2016
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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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 notyfing party:

Dear Sir/Madam,

Subject: **Case M.8016 - SANOFI PASTEUR / VACCINES OF SANOFI PASTEUR MSD**
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]

1. On 23 September 2016 the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which Sanofi Pasteur S.A. ("Sanofi Pasteur", France), hereinafter "the Notifying Party", acquires within the meaning of Article 3(1)(b) of the Merger Regulation sole control of parts of Sanofi Pasteur MSD S.N.C. ("SPMSD", France), by way of purchase of assets, hereinafter "the Transaction".[3] Sanofi Pasteur and the acquired assets of SPMSD are referred to as "the Parties".

1. THE PARTIES

2. Sanofi Pasteur is headquartered in Lyon, France and is a wholly owned subsidiary of Sanofi S.A., a publically listed company on Euronext and the New York Stock Exchange.

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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 OJ C 359, 30.09.2016, p.11.

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3. Sanofi Pasteur is active in the research, development, manufacturing and sales of vaccines in the US, Asia, Latin America, Africa, Middle East and Eastern Europe. It offers broad range of vaccines focusing on five areas: paediatric, influenza, adult and adolescent booster, meningitis, and travel and endemic vaccines.

4. SPMSD is headquartered in Lyon and active in the development and commercialisation of human vaccines in 18 EEA countries and in Switzerland, directly or through affiliates or branches. SPMSD was created in 1994 as a joint venture ("JV") between Sanofi Pasteur and Merck and was assessed by the Commission as a non-full function joint venture and notified to the Commission under Article 101 of the Treaty on the Functioning of the European Union as a cooperation agreement.[4] The scope of the JV's activities was *"to facilitate the research of, oversee the development of, register, arrange for the manufacture of, distribute, market and sell vaccines, immunoglobulines, diagnostics and sera and such additional products as the partners may from time to time determine".*[5]

5. Both Merck & Co., Inc. ("Merck") and Sanofi transferred the distribution of human vaccines located in the JV's territory consisting in 18 EEA countries and Switzerland.[6] They maintained their respective vaccines related R&D activities, since they were organised on a worldwide basis while the JV's scope was limited to its territory. However, the JV has had access to Merck and Sanofi R&D through a Development Committee created within the JV entitled to select, fund and direct products in development stage (post phase II stage). The JV was permitted to obtain the related patents, manufacturing know-how and registration rights or licenses for these products in its territory, subject to a same retention clause by the originating company (Merck or Sanofi) in order to be able "*to manufacture any such pipeline product solely for sale for use outside the Territory or for sale to the Joint Venture for use within the Territory".*[7]

6. Merck and Sanofi did not contribute any production facilities to the JV; the vaccines distributed by the JV have been produced by the parent companies on the basis of Toll Manufacturing and Supply Agreements.

2. THE OPERATION

7. On 29 February 2016, Merck and Sanofi Pasteur entered into a process agreement aiming at preparing the termination of the SPMSD joint venture and signing a Master Termination Agreement ("MTA").

8. Pursuant to the MTA, Sanofi Pasteur will re-acquire its assets that were contributed to the JV. The acquired assets consist in 36 marketed vaccines, three pipelines products, tangible assets (furniture, IT equipment, real estate rights, product inventory) and intangible assets (internet sites relating to vaccination, vaccine e-commerce sites,

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4 Then Article 85 EC Treaty; Commission decision M.285 Pasteur Mérieux/Merck, 5.07.1993, para 30, Commission decision IV/34.776, Pasteur Mérieux/Merck, 6 October 1994.

5 Commission decision M.285 Pasteur Mérieux/Merck, 5.07.1993, para 4, Commission decision IV/34.776, Pasteur Mérieux/Merck, 6 October 1994.

6 Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, the United Kingdom.

7 Commission decision M.285 Pasteur Mérieux/Merck, 5.07.1993, para 16.

trademarks and some intellectually property on phase III and IV for products developed by SPMSD).

9. After the Transaction, Sanofi Pasteur will own all relevant assets related to the commercialisation of 36 vaccines and 3 vaccines in development and will run the corresponding business, representing a total turnover of EUR […] million in the EEA in 2015 (excluding vaccines in development). Accordingly, the acquired assets constitute a business with market presence to which a market turnover can be clearly attributed. The Transaction therefore consists in the acquisition of control of parts of an undertaking and thus amounts to a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

10. Simultaneously, Merck will acquire sole control over SPMSD which will contain exclusively its own contributed vaccines and assets.[8]

11. Further, Merck and Sanofi Pasteur will continue to jointly control the development and commercialisation of the vaccine PR5I (Vaxelis).[9]

3. EU DIMENSION

12. The undertakings concerned have a combined aggregate worldwide turnover of more than EUR 5 000 million[10] (Sanofi Pasteur: […] million, SPMSD's assets: EUR […]million). Each of them has an EU-wide turnover in excess of EUR 250 million (Sanofi Pasteur: EUR […] million, SPMSD' assets: EUR […] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within the same Member State.

13. The notified operation therefore has an EU dimension within the meaning of Article 1(2) of the Merger Regulation.

4. PROCEDURE

14. The case was notified on a Short Form COand could qualify for a simplified treatment pursuant point 5 (d) of the Commission Notice on a simplified procedure for treatment of certain concentrations.[11] However, on 10 October 2016, the Commission received observations in which a third party expressed substantiated concerns about the Transaction. The case was therefore reviewed under the normal procedure, in accordance with point 19 of the Commission Notice on a simplified procedure for treatment of certain concentrations.

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8 Case M.8083 – Merck / Sanofi Pasteur MSD.

9 Vaxelis is currently controlled by SPMSD and will be transferred to a company MCM Vaccine Co. which will hold the marketing authorisation (through MCM Vaccine BV) for Vaxelis; it will remain indirectly owned jointly by Sanofi Pasteur and Merck.

10 Turnover calculated in accordance with Article 5 of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.4.2008, p. 1).

11 Official Journal C 366, 14.12.2013, p. 5.

5. COMMISSION ASSESSMENT

5.1. Product market definition

15. The Commission has previously considered that the product market for human vaccines can be defined based on two main criteria, namely the disease and the serogroups against which each vaccine intends to protect, and the targeted population i.e. the patient group which can or should receive the vaccine. The Commission has also considered that generally monovalent and multivalent vaccines are likely part of separate markets, but ultimately left the precise market definition open[12]. In the present case, the Notifying Party agrees with the product market definition previously considered by the Commission.

16. SPMSD currently has two (competing) vaccines protecting against six diseases: diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases (such as pneumonia and meningitis) caused by H. influenza type-b bacteria (Hib). The first is Hexyon, launched in 2013 in Belgium, Denmark, France, Germany, Greece, Italy and Spain and distributed by Sanofi under the brand name of Hexacima in other EEA countries outside of SPMSD's territory. The second is Vaxelis, for which SPMSD obtained marketing authorisation in 2016 and has not yet been launched in the EEA […].

17. Both products are indicated for primary and booster vaccination in infants and toddlers from six weeks of age. However, among the six antigens which are part of the hexavalent vaccine, Vaxelis and Hexyon have only one in common: only the antigen against Polio is the same. Hexyon does and Vaxelis will compete against Infanrix, another hexavalent vaccine having the same indications currently commercialised by GlaxoSmithKline.

18. For the purpose of the present decision, the Commission therefore considers that there is a relevant product market comprising Hexyon, Infanrix and Vaxelis.

5.2. Geographic market definition

19. The Commission has previously analysed the markets for (i) manufacture and supply and (ii) distribution of human vaccines as national in scope.[13] This is mainly due to national regulatory frameworks, national vaccination schedules, prices and reimbursement established at national level. The Parties agree with the proposed geographic market definition.

5.3. Competitive assessment

5.3.1. Third-party observations

20. The observations brought to the Commission attention concern the acquisition of Hexyon by Sanofi Pasteur. The company submitting the observation considers that if

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12 Case COMP / M.7276, GSK / Novartis vaccines business (excl. influenza) / Novartis Consumer Health business.

13 Case COMP / M.7583, CSL / Novartis Influenza Vaccines business, para 73, COMP/ M.4049, Novartis/Chiron para 32; Case COMP/IV/34.776, Pasteur Mérieux-Merck (1994), para 55.

Vaxelis is to remain under common ownership of Sanofi Pasteur and Merck, the post-transaction market structure and dynamics will be adversely impacted and may give rise to anti-competitive effects and non-independent behaviour among Vaxelis and Hexyon suppliers. In particular, Sanofi Pasteur would have the abilities and the incentives to coordinate the products' positioning and pricing of Hexyon and Vaxelis.

21. It is also submitted that Sanofi Pasteur is the owner of antigens necessary for the production of Vaxelis, thus, Sanofi Pasteur may have ability to indirectly limit the production and marketing of Vaxelis competing with Hexyon. Given that Sanofi Pasteur will be the sole owner of competing Hexyon, it may have an incentive to promote this vaccine rather than the one under the joint ownership, regardless of any customer preference as between the two.

5.3.2. Horizontal overlaps

22. Apart from its interest in SPMSD, Sanofi Pasteur is not active in the manufacture, supply or the distribution and marketing of any other competing vaccine in any of the countries in SPMSD's territory. Accordingly, the Transaction does not lead to horizontal overlaps.

23. The Commission considers that, given that the Transaction consists in a de-merger, it will increase the number of market players supplying vaccines against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases (such as pneumonia and meningitis) caused by H. influenzae type-b bacteria (Hib) for paediatric use from two to three competitors. Any concern regarding possible coordinated behaviour with respect to the market positioning and pricing of Hexyon and Vaxelis linked to the fact that Vaxelis will continue to be jointly controlled by Sanofi Pasteur and Merck would not result from the Transaction, since Vaxelis will remain under the joint control of the same parent companies.

5.3.3. Vertical links

24. Sanofi does not supply any antigens or carrier proteins as an input to vaccines to any third party that could be used in competing other vaccines than those supplied by SPMSD in the EEA. Sanofi does not distribute any third party vaccines.

25. Sanofi Pasteur manufactures SPMSD's vaccines forming part of this Transaction that are distributed by SPMSD. Accordingly, the vertical links are not merger specific since they are pre-existing.

26. In particular, Sanofi Pasteur and MCM Vaccine Co (a joint venture between Sanofi Pasteur and Merck) signed […] a supply agreement for the antigens to be used in the production of Vaxelis. According to this supply agreement, MCM will be supplied with antigens on the basis of […]. The supply agreement between Sanofi Pasteur and MCM Vaccine Co is pre-existing and the Transaction will have no impact in this respect.

27. Post-transaction, Sanofi Pasteur will continue to supply antigens for the production of Vaxelis and will use its own antigens for the production of Hexyon. Since the antigens supplied for Vaxelis are specifically developed for this vaccine, […] Sanofi will have no incentives to discontinue the manufacturing because it will lose business.

28. Even if Sanofi Pasteur had an incentive after the Transaction to limit supply of antigens to the jointly owned product Vaxelis in order to favour its solely owned product Hexyon, Merck, having joint control over MCM Vaccine Co, will be able to ensure that Sanofi Pasteur, as a partner, will always supply the antigens to MCM Vaccine Co.

29. Based on the above, it follows that the Transaction does not lead to any vertical links, and the supply arrangements described above lead to links, which would not be merger specific.

6. CONCLUSION

30. 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)
Phil HOGAN
Member of the Commission