EUROPEAN COMMISSION
DG Competition

Case M.8083 - MERCK / 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: 15/11/2016

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EUROPEAN COMMISSION

Brussels, 15.11.2016
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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 Where possible the information omitted has been replaced by ranges of figures or a general description.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:

Subject: **Case M.8083 – Merck/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]

Dear Sir or Madam,

(1) On 7 October 2016, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which Merck & Co., Inc. ("Merck", USA), hereinafter "the Notifying Party", acquires within the meaning of Article 3(1)(b) of the Merger Regulation sole control of Sanofi Pasteur MSD SNC ("SPMSD", France), currently jointly controlled by Merck and Sanofi Pasteur S.A., by way of purchase of shares, hereinafter "the Transaction". Merck and SPMSD are jointly referred to as "the Parties".[3]

1. THE PARTIES

(2) Merck is a healthcare company, headquartered in Kenilworth, New Jersey, United States. Merck's operations are comprised of four operating segments: pharmaceutical, animal health, alliances, and healthcare services. Its core product

1 OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.

2 OJ L 1, 3.1.1994, p. 3 (the 'EEA Agreement').

3 Publication in the Official Journal of the European Union No C 382, 15.10.2016, p. 17.

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categories in the pharmaceutical segment include diabetes, cancer, vaccines, and hospital acute care.

(3) SPMSD is headquartered in Lyon, France and is active in the development and commercialisation of human vaccines in 18 EEA countries and in Switzerland ("the JV territory"), directly or through affiliates or branches. SPMSD was created in 1994 as a joint venture ("JV") between Sanofi Pasteur and Merck. Each of the parent companies contributed vaccines to SPMSD for their development and commercialization.

(4) The JV 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) None of the parent companies is active in the commercialisation of the contributed vaccines in these 18 EEA States.

2. THE OPERATION AND THE CONCENTRATION

(6) 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"). Pursuant to the MTA, Sanofi Pasteur will acquire a range of assets including 36 vaccines and three pipelines products currently owned by SPMSD.[6] Simultaneously, MSD will control the SPMSD entity as well as other 10 vaccines and the tangible and intangible assets related to the distribution of those vaccines.

(7) While some of the acquired vaccines had been contributed to SPMSD by Merck at the time of the creation of the former (HIB, Hepatitis B and pneumococcus), a number of other vaccines were contributed by Merck between 1994 and 2015 (Rotateq, Gardasil, Zostavax, Vaqta, Varivax, and ProQuad). Merck will obtain direct and full control of all IP rights developed by SPMSD with respect to all those vaccines in the course of the Phase III and Phase IV research & development work performed by SPMSD (as well as clinical samples).

(8) As a result of the Transaction, Merck will take over the distribution business in the SPMSD Territory of these vaccines.

(9) Merck will obtain (through SPMSD) all the legal entities created by SPMSD since its establishment in 1994 (with the exception of Sanofi Pasteur Europe, a special purpose new entity established for the aggregation of the assets to be reacquired by Sanofi Pasteur) and a number of employees. It will also obtain the

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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 The acquisition of these assets was examined by the Commission in a parallel transaction: Case M.8016 – SANOFI PASTEUR / VACCINES OF SANOFI PASTEUR MSD, of 28/10/2016

lease for the 6,000 sq.m. headquarter of SPMSD in France and leases in several other Member States.

(10) In 2015, SPMSD generated total sales of EUR […], of which approximately EUR […] is attributable to the products to be acquired by Merck.

(11) Based on the above the Transaction results in a change of control of an undertaking or a part of an undertaking from joint to sole and therefore constitutes a concentration within the meaning of Article 3 (1) (b) of the Merger Regulation.

3. EU DIMENSION

(12) The undertakings concerned have a combined aggregate worldwide turnover of more than EUR 5 000 million[7] (Merck: EUR 35 368 million[…], SPMSD: EUR […]). Each of them has an EU-wide turnover in excess of EUR 250 million (Merck: EUR […], SPMSD: EUR […]), 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 CO and could qualify for simplified treatment pursuant to points 5(b) and 5(d) of the Commission Notice on a simplified procedure for treatment of certain concentrations.[8] However, on 19 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

5. THIRD-PARTY OBSERVATIONS

(15) Prior to the transaction, SPMSD had the ownership over two vaccines, namely Vaxelis and Hexyon, protecting 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.

(16) A market participant submitting observations considers that if 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.

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

8 Official Journal C 366, 14.12.2013, p. 5

(17) It has also been brought to the Commission's attention that Sanofi Pasteur supplies antigens to the owner of Vaxelis, which would give Sanofi Pasteur direct control over Vaxelis' capacity and may therefore influence the ability of Vaxelis' owner to effectively compete on the hexavalent DTPa market segment.

6. COMMISSION ASSESSMENT

(18) The transaction does not give rise to any horizontal overlaps. Merck is not active in the manufacturing, supply or distribution and marketing of any competing vaccine in any of the countries in SPMSD's territory. Further, Merck submits that it does not have any pipeline products that can compete with any vaccine currently commercialised by SPMSD.

6.1. MARKET DEFINITION

6.1.1. PRODUCT MARKET DEFINITION

(19) 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.[9] 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. Finally, the Commission has previously taken the view that conjugated and polysaccharide vaccines protecting against the same serotypes are part of the same product market.[10]

6.1.2. GEOGRAPHIC MARKET DEFINITION

(20) The Commission has previously analysed the markets for the manufacture and supply of human vaccines as national in scope. 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. [11]

6.2. COMPETITIVE ASSESSMENT

6.2.1. HORIZONTAL OVERLAPS

i. Pneumococcal vaccines

(21) SPMSD commercializes two pneumococcal polysaccharide vaccine in the SPMSD Territory under the brand names Pneumovax23 and Pneumo23. Following the transaction, Merck will acquire Pneumovax 23 and Sanofi Pasteur Pneumo23.

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9 Case COMP / M.7276 - GSK / Novartis vaccines business (excl. influenza) / Novartis Consumer Health business, Case M. 7583 - CSL/Novartis Influenza Vaccines Business, para 13-37.

10 Case COMP / M.7276, GSK / Novartis vaccines business (excl. influenza) / Novartis Consumer Health business, paras 39-40. Case M. 7583 - CSL/Novartis Influenza Vaccines Business, para 38-40.

11 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.

(22) Merck currently develops 15-valent pneumococcal vaccine V114, a pneumococcal conjugate vaccine ("PCV"), which is in a clinical trials process (phase II) […]. This pipeline vaccine will protect against 15 serotypes of Streptococcus pneumonia.

(23) The Notifying party submits that the Transaction does not lead to an overlap between marketed and pipeline product regarding vaccines protecting against Streptococcus pneumonia.

(24) First, Pneumovax23 and the pipeline vaccine does not protect against the same serogroups and therefore the two vaccines are rather complementary than competing products.

(25) Second, the two vaccines […]. In paediatric use for instance, Pneumovax23 is suitable for immunisation of children above the age of 2 years, in whom there is an increased risk of morbidity from pneumococcal disease. The pipeline V114 targets […].

(26) Should the vaccines be considered as overlapping, SPMSD current market share on a market for pneumococcal vaccines remains well below [10-20]% in any of the countries in which it is active. The market leader appears to be Pfizer with a market share exceeding [60-70]% in […] of the 18 countries of the SPMSD territory, followed by GSK. Accordingly, the Transaction does not lead to the creation or the strengthening of a dominant position.

(27) In addition, according to the Notifying Party, there are seven pipelines of vaccines competing with V114 in different phase of development; only two of them are in phase II clinical trials as V114. One of the products is being developed by a company having strong position on the market for pneumococcal vaccines. This indicates that V114 and the marketed products are rather complementary.

(28) In view of the above, and in particular the complementarity between the two vaccines, Merck is likely to have an incentive to continue the clinical trials post – transaction and subject to the outcome to commercialise the two vaccines in parallel.

ii. *Hexavalent DTPa vaccines*

(29) As concerns the observations of the third party, the Commission understands that Vaxelis will be transferred to a new joint venture, set up by Merck and Sanofi Pasteur after the termination of SPMSD. The Commission analysed the acquisition of Hexyon by Sanofi Pasteur in a parallel transaction.[12] The Commission therefore considers that the observations brought to its intention are outside of the scope of the proposed transaction.

6.2.2. NON-HORIZONTAL RELATIONSHIPS

i. VERTICAL RELATIONSHIPS

(30) Merck and Sanofi Pasteur supply their respective finished products to SPMSD for sale in the EEA countries in which SPMSD is active. SPMSD sources these

[12] Case M.8016 – SANOFI PASTEUR / VACCINES OF SANOFI PASTEUR MSD, of 28/10/2016.

products solely from Merck and Sanofi Pasteur, and Merck and Sanofi Pasteur supply these finished products solely to SPMSD. Thus, SPMSD has no third-party supply relationships, and Merck and Sanofi Pasteur do not manufacture these products for sale in the EEA countries in which SPMSD is active for any party other than SPMSD.

(31) Accordingly, the Transaction leads to only pre-existing vertical links for the manufacture of vaccines where Merck is active and the distribution of vaccines in the territory SPMSD that are not merger specific.

ii. Conglomerate relationships

(32) The Transaction will merely enable Merck to sell the same vaccines throughout the EEA (rather than having SPMSD sell Merck's vaccines in the SPMSD Territory) and will not expand Merck's vaccine product range. Merck does not currently sell any vaccines in the SPMSD Territory.

(33) In EEA countries outside the SPMSD Territory, Merck currently sells only the same vaccines as those it will reacquire in the Transaction for the SPMSD Territory. Thus, Merck will not have a broader vaccine portfolio in any EEA country because of the Transaction.

(34) Based on the above it follows that Merck would have no ability to foreclose rivals to the detriment of consumers as a result of the Transaction. Accordingly, the Commission considers that the Transaction does not lead to conglomerate effects.

6.2.3. CONCLUSIONS REGARDING THE COMPETITIVE ASSESSMENT

(35) Based on the above it follows that the Transaction does not raise serious doubts as to its compatibility with the internal market.

7. CONCLUSION

(36) 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.

(signed)
For the Commission
Margrethe VESTAGER
Member of the Commission