EUROPEAN COMMISSION

DG Competition

Case M.9517 – MYLAN / UPJOHN

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Decision on the implementation of the commitments - Purchaser approval
Date: 14/09/2020

EUROPEAN COMMISSION

Brussels, 14.9.2020
C(2020) 6369 final

PUBLIC VERSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

Mylan NV
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Trident Place, Mosquito Way,
AL 10 9UL – Hatfield, Hertfordshire
United Kingdom

Pfizer Inc.
235 East 42nd Street
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United States of America

Dear Sir/Madam,

Subject: **Case M.9517 – Mylan/Upjohn**
Approval of GL Pharma as purchaser of the Third Divestment Business following your letter of 03.07.2020 and the Trustee's opinion of 21.08.2020

1. FACTS AND PROCEDURE

(1) By decision of 22 April 2020 (the "Decision") based on Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation (EC) No 139/2004[1] and Article 57 of the EEA Agreement, the Commission declared the operation by which Mylan N.V. ("Mylan", the Netherlands) and Upjohn, a business division of Pfizer Inc. ("Pfizer", the United States of America) intend to merge (the "Transaction"),

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

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compatible with the internal market and the EEA Agreement. Mylan and Upjohn are designated hereinafter as the "Parties" to the Transaction. The Decision is subject to the conditions and obligations laid down in the commitments annexed to the Decision ("the Commitments").

(2) In particular, under the Commitments, Mylan undertook to divest to suitable buyers Mylan's rights, titles and interests together with all associated assets, necessary for the purchaser(s) to be able to operate a viable and competitive business of the following country/molecule combinations in the EEA[2] (the "Mylan Divestment Business"):

(i) Mylan's atorvastatin in Norway;
(ii) Mylan's doxazosin in Czechia;
(iii) Mylan's doxazosin in France;
(iv) Mylan's eplerenone in Belgium;
(v) Mylan's eplerenone in Hungary;
(vi) Mylan's sildenafil (PAH) in Estonia;
(vii) Mylan's sildenafil (PAH) in France;
(viii) Mylan's tadalafil in France;
(ix) Mylan's sildenafil (PAH) in Latvia;
(x) Mylan's sildenafil (PAH) in Lithuania;
(xi) Mylan's sildenafil (PAH) in Romania;
(xii) Mylan's sildenafil (PAH) in the United Kingdom;
(xiii) Mylan's eletriptan in Denmark;
(xiv) Mylan's eletriptan in Finland;
(xv) Mylan's eletriptan in France;
(xvi) Mylan's eletriptan in Norway;
(xvii) Mylan's eletriptan in Sweden;
(xviii) Mylan's pregabalin in Belgium;
(xix) Mylan's pregabalin in Czechia;
(xx) Mylan's pregabalin in Luxembourg;
(xxi) Mylan's pregabalin in Norway;
(xxii) Mylan's gabapentin in Ireland;
(xxiii) Mylan's ziprasidone in Czechia;
(xxiv) Mylan's alprazolam in Greece;
(xxv) Mylan's alprazolam in Iceland;
(xxvi) Mylan's alprazolam in Ireland;
(xxvii) Mylan's alprazolam in Italy;
(xxviii) Mylan's alprazolam in Portugal;
(xxix) Mylan's venlafaxine in Belgium;
(xxx) Mylan's latanoprost in Belgium;
(xxxi) Mylan's latanoprost in Luxembourg;
(xxxii) Mylan's latanoprost/timolol in Belgium;
(xxxiii) Mylan's latanoprost/timolol in France;
(xxxiv) Mylan's latanoprost/timolol in Italy;

[2] For the purpose of this Decision, although the United Kingdom withdrew from the European Union as of 1 February 2020, according to the Withdrawal Agreement, Union law continues to apply to the United Kingdom during the transition period. Accordingly, any references made to the EEA in this Decision are meant to also include the United Kingdom

(xxxv) Mylan's latanoprost/timolol in Luxembourg;
(xxxvi) Mylan's latanoprost/timolol in the Netherlands; and
(xxxvii) Mylan's latanoprost/timolol in Portugal.

(3) By letters of 3 July of 2020, Mylan proposed to divest the Mylan Divestment Business to four purchasers.

(4) Mylan intends to sell the following country/molecule combinations to) G.L. Pharma GmbH ("GL Pharma", Austria), a subsidiary of the Bartenstein Holding GmbH (the "Bartenstein Group", Austria):

Country	Molecule
Czechia	Doxazosin
Estonia, Latvia, Lithuania	Sildenafil (PAH)
Hungary	Eplerenone

(5) These country/molecule combinations are together referred to as the "Third Divestment Business", which is a sub-set of the Mylan Divestment Business.

(6) This decision only concerns the approval of the proposed purchaser of the Third Divestment Business.

(7) By one of the reasoned submissions dated 3 July 2020, Mylan proposed GL Pharma for approval by the Commission as purchaser of the Third Divestment Business. GL Pharma specializes in commercializing of generics and originator products on a worldwide scale, with a focus on Central and Eastern Europe. GL Pharma is part of the Bartenstein Group. In the financial year 2019, GL Pharma's revenues amounted to EUR 174 million, while in the financial year 2018, the Bartenstein Group generated a turnover of EUR 1,702 million.

(8) GL Pharma has two production sites located in Austria. The firsthe site manufactures solid forms pharmaceuticals (i.e. the same form as all of the products comprising the Third Divestment Business). The second site manufactures liquid forms and semi-solid forms pharmaceuticals. In 2019, GL Pharma produced over 4.2 billion single doses of medicines in the EEA, including 270 million doses, which were sold in the countries covered by the Third Divestment Business. GL Pharma sells a large number of molecules in 50 countries, including 18 countries in the EEA and has its own marketing infrastructure in 12 EEA countries, including all the countries covered by the Third Divestment Business. GL Pharma markets all of the Third Divestment Business products already in other markets in the EEA. The portfolio of GL Pharma markets covers a broad range of therapeutic areas.

(9) Additionally, the Bartenstein Group holds the following shareholdings in the pharmaceutical sector in addition to GL Pharma:

(a) Genericon Pharma GmbH, Austria: the Bartenstein Group through BAHOPHARM GmbH ("Bahopharm") has a share of 50% in this company which is active in the marketing of pharmaceuticals;

(b) Apeiron Biologics AG, Austria: the Bartenstein Group has a share of approximately 6% in this company which is active in the development and research for pharmaceuticals;

(c) AEP GmbH, Germany: the Bartenstein Group has a share of cumulated 29.15% (through Adelheid GmbH and through ABAHO GmbH) in this company, which is a pharmaceutical wholesaler in Germany;

(d) Lannacher Heilmittel GmbH, Austria: the Bartenstein Group has a share of cumulated 100% (50% direct and 50% through ABAHO GmbH) in this company, which only holds marketing authorisations in some countries for GL Pharma (otherwise there are no further activities); and

(e) Gerot Pharmazeutika GmbH, Austria: the Bartenstein Group has a share of cumulated 100% (50% direct and 50% through ABAHO GmbH) in this company, which only holds a marketing authorisation in one country for GL Pharma (otherwise there are no further activities).

(10) Mylan submitted to the Commission the agreements to be entered into between Mylan and GL Pharma, consisting of the asset sale agreement (the "Asset Sale Agreement") together with the schedules and exhibits (all together the "GL Pharma Transaction Agreements") on 19 August 2020.

(11) In its opinion of 21 August 2020 (the "Reasoned Opinion") pursuant to paragraph 29 of the Commitments, Monitoring Trustee Partners, acting as monitoring trustee ("the Trustee"), concludes that:

a. GL Pharma fulfils the Purchaser Criteria[3] as set out in paragraph 18 of the Commitments and there are no indications that the Third Divestment Business would not be viable after the sale; and

b. the Third Divestment Business would be sold in a manner consistent with the Commitments under the GL Pharma Transaction Agreements.

2. ASSESSMENT OF THE PROPOSAL

(12) According to paragraphs 18 and 19 of the Commitments, in order for the Commission to approve the purchaser, the purchaser(s) must fulfil(s) the Purchaser Criteria and the divestment businesses should be sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market.

2.1. Assessment of the Purchaser Criteria

(13) As set out in paragraph 18 of the Commitments, the purchaser(s) of the divestment businesses must fulfil the following criteria:

(a) The Purchaser shall be independent of and unconnected to the Parties and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture);

[3] Capitalised terms in this decision will have the meaning as set out in the Commitments, unless indicated otherwise.

(b) The Purchaser shall have the financial resources, proven expertise and incentive to maintain and develop the relevant Divestment Business (or Divestment Businesses) as a viable and active competitive force in competition with the Parties and other competitors;

(c) The Purchaser shall be an established generic supplier with presence in the EEA that can market the relevant Divestment Business (or Divestment Businesses) through its own commercial infrastructure or through distributors in the relevant countries where each relevant Divestment Business is currently active; and

(d) The acquisition of the relevant Divestment Business (or Divestment Businesses) by the Purchaser must neither be likely to create, in 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 must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business(es).

2.1.1. Independence from Mylan and Upjohn

(14) Mylan is publicly traded. Mylan is listed on the Nasdaq Stock Market. Upjohn is currently a wholly owned subsidiary by Pfizer Inc. ("Pfizer"). Pfizer is publicly traded. GL Pharma is part of the Bartenstein Group which is a private company. Neither Mylan nor Pfizer holds directly any shareholding in the Bartenstein Group. Therefore, GL Pharma is neither owned nor controlled by Mylan, Pfizer or any of their affiliates.[4] Moreover, there are no investors that hold any shareholdings in both GL Pharma and/or the Bartenstein Group on the one hand and the Parties on the other.

(15) The controlling shareholder of GL Pharma, namely Martin Bartenstein, has no material shareholding in Mylan or Upjohn.

(16) No director of Mylan or Upjohn serves on the board of GL Pharma and/or the Bartenstein Group or any of its affiliates and *vice versa*.[5]

(17) The Trustee also reviewed the existing business relations and contractual relations between GL Pharma and/or the Bartenstein Group and the Parties and concludedthat no material agreements exist between the Parties and their Affiliated Undertakings on the one side and GL Pharma on the other side.[6] Commercial relationships are limited and represent less than [0-5]% of the Bartenstein Group annual revenues in 2019.[7]

4 Monitoring Trustee Reasoned Opinion on the acquisition of the Third Divestment Business by GL Pharma of 21 August 2020 ("Reasoned Opinion"), Section 4.

5 Reasoned Opinion, Section 4.

6 Reasoned Opinion, Section 4.

7 Reasoned Opinion, Section 4.

(18) In light of the above and the Trustee's Reasoned Opinion, the Commission concludes that GL Pharma fulfils the purchaser criterion of being independent of and unconnected to Mylan and Upjohn and their Affiliated Undertakings[8].

2.1.2. Financial resources, proven expertise and incentive to maintain and develop the Fist Divestment Business as a viable and active competitor

2.1.2.1. Financial resources

(19) GL Pharma's turnover in the last financial year amounted to EUR 174 million, representing an increase of 9% on the previous year. The Bartenstein Group generated a turnover of EUR 1,702 million in the financial year 2018.

(20) The Trustee reviewed the financial results of GL Pharma and concluded that GL Pharma is a healthy and profitable business that has achieved steady growth while maintaining a sound solvency position. The balance sheet of the company does not include any interest-bearing debt and, hence, GL Pharma has a strong potential to attract further debt financing if and when needed.[9]

(21) GL Pharma agrees to pay EUR […] for the Third Divestment Business. GL Pharma will fund the acquisition price of the Third Divestment Business through its existing cash resources, and, therefore, the company does not need to obtain any additional external financing. The Trustee considers that GL Pharma has ample resources to fund the acquisition and subsequent developments of the Third Divestment Business considering the company's capability to generate significant positive operating cash flows as evidenced by its EBITDA performance, its current cash position and its additional loan capacity as evidenced by its strong balance sheet that does not include any interest-bearing debt.[10]

(22) Based on the information above and the Trustee's Reasoned Opinion on the financial situation of GL Pharma, the Commission concludes that GL Pharma fulfils the criterion of having the financial resources to maintain and develop the Third Divestment Business as a viable and active competitive force in competition with the Parties and other competitors.

2.1.2.2. Proven experience

(23) According to paragraph 18 of the Commitments, the proposed purchaser(s) must have the proven expertise to maintain and develop the divestment business as a viable and active competitive force in competition with the Parties and other competitors. Moreover, the purchaser(s) shall be an established generic supplier with presence in the EEA that can market the relevant molecule/country combinations through its own commercial infrastructure or through distributors in the relevant countries where each relevant molecule/country combinations is sold.

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8 According to the Commitments, Affiliated Undertakings are undertakings controlled by the Parties and/or by the ultimate parents of the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "Consolidated Jurisdictional Notice").

9 Reasoned Opinion, Section 5.

10 Reasoned Opinion, Section 5.

(a) *Marketing, Promotion and Distribution of Generic Products in the Relevant Countries*

(24) GL Pharma commercializes generics and originator products on a worldwide scale, with a focus on Central and Eastern Europe. In 2019, GL Pharma produced over 4.2 billion single doses of medicines in the EEA, including 270 million doses, which were sold in the countries covered by the Third Divestment Business. GL Pharma sells a large number of molecules in 50 countries, including 18 in the EEA and has its own marketing infrastructure in 12 EEA countries, including all the countries covered by the Third Divestment Business. GL Pharma markets all of the Third Divestment Business products already in other markets in the EEA. The portfolio of GL Pharma markets covers a broad range of therapeutic areas.

(25) The Third Divestment Business includes molecules in Czechia, Estonia, Latvia, Lithuania and Hungary (all together, the "Relevant Countries").

(26) GL Pharma has already a significant presence in all Relevant Countries. The Third Divestment Business revenues amount, in all Relevant Countries, to a fraction of GL Pharma's existing revenues in each of the Relevant Countries. Considering this, the Trustee concludes that the integration from a commercial point is deemed to be straightforward.[11]

(27) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that GL Pharma is an established generic supplier with presence in the EEA and in particular in all Relevant Countries, that can market all the molecule/country combinations included in the Third Divestment Business.

(b) *Manufacturing, Transfer and Regulatory Capabilities*

(28) GL Pharma has two production sites located in Austria. the first site, manufactures solid forms (i.e. the same form as all of the products comprising the Third Divestment Business). The second site, manufactures liquid forms and semi-solid forms. In 2019, GL Pharma produced over 4.2 billion single doses of medicines in the EEA, including 270 million doses, which were sold in the countries covered by the Third Divestment Business.

(29) GL Pharma is planning to transfer the manufacturing of Sildenafil (PAH) in-house. GL Pharma has sufficient spare capacity to integrate the production of Sildenafil it its Austrian facility. Moreover, this plant already manufactures oral solid forms (the same from as Sildenafil) and the technology required for the manufacturing of Sildenafil tablets is already present in the plant. The Sildenafil product can therefore easily be integrated into GL Pharma's current manufacturing set-up. Moreover, GL Pharma performs technology transfers regularly.[12]

(30) With regards to the production of Doxazosin and Eplerenone, it will be performed going forward by the current CMOs, and therefore there will be no change with regards to the current situation in terms of production.[13]

(31) Moreover, GL Pharma has significant experience when dealing with regulatory authorities. It has a large regulatory team and performed a large number of marketing

11 Reasoned Opinion, Sections 5 and 7.

12 Reasoned Opinion, Sections 5 and 7.

13 Reasoned Opinion, Sections 5 and 7

authorization transfers in 2018 and 2019. Based on its experience, it expects the transfer to take approximately one to four months.[14]

(32) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that GL Pharma has proven expertise to maintain and develop the Third Divestment Business as a viable and active competitive force.

2.1.2.3. Incentives to maintain and develop the Divestment Business

(33) The Trustee's Reasoned Opinion concludes that the purchase of the Third Divestment Business represents for GL Pharma an opportunity to broadening its portfolio offering in the Relevant Countries, as well as further optimizing its current manufacturing capacity by increasing the production in its Austrian facility. Therefore, through the acquisition of the Third Divestment Business, GL Pharma will strengthen its presence in the Relevant Countries, at the same time that it generates synergies with respect to manufacturing. Furthermore, GL Pharma indicated that through the acquisition of the Third Divestment Business, it will broaden its Central and Eastern European product portfolio. More in particular, the company explained that Doxazosin in Czechia is a good addition to its urology portfolio in which it already commercialises five substances. Sildenafil will be added to its cardiology portfolios in both the Baltics (three molecules). It already is part of its portfolio in Austria (35 molecules). [15]

(34) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that GL Pharma has the incentives to maintain and develop the Third Divestment Business.[16]

2.1.3. Absence of prima facie competition concerns

(35) The acquisition of the Third Divestment Business by GL Pharma is *prima facie* not likely to give rise to competition concerns.

(36) The acquisition of the Third Divestment Business by GL Pharma does not give rise to any horizontal or vertical overlaps between the Third Divestment Business and the molecules/country combinations currently commercialized by any companies of the Bartenstein Group, including GL Pharma, in the Relevant Countries.

(37) Moreover, the proposed GL Pharma Transaction does not require any merger control filings.

(38) Lastly, the controlling shareholders of GL Pharma, namely Martin Bartenstein, has no controlling interest in other companies active in the relevant markets, that is molecule/country pairs covered by the Third Divestment Business.

(39) In light of the above and the Trustee's Reasoned Opinion, the Commission considers that the acquisition of the Third Divestment Business by GL Pharma is neither likely to create *prima facie* competition concerns, nor to give rise to a risk that the implementation of the Commitments will be delayed.

14 Reasoned Opinion, Sections 5 and 7.

15 Reasoned Opinion, Section 5.

16 Reasoned Opinion, Section 5.

2.1.4. Conclusion

(40) In view of the above, the Commission considers that GL Pharma meets the Purchaser Criteria.

2.2. The Divestment business is being sold in a manner consistent with the Commitments

(41) The Commission has reviewed the GL Pharma Transaction Agreements and considers that the GL Pharma Transaction Agreements reflect the Parties' obligations set out in the Commitments. The Trustee observed no deviations between the Commitments and the GL Pharma Transaction Agreements with the exception described below. Moreover, GL Pharma confirmed that it is satisfied with the manner the Commitments are reflected in the GL Pharma Transaction Agreements.[17]

(42) As per the Commitments, the purchaser also acquires the full rights to develop the molecule outside of the territory for which it acquired the marketing authorization and for which competition concerns were identified. As per the License Agreement, schedule 3, however, the Trustee observed that this right is limited, such that the purchaser can only develop the molecule in territories for which there were no further marketing authorizations included in the Mylan Divestment Business. Although this inclusion in the License Agreement may be regarded as a limitation with regards to the rights to develop the molecule in other territories as envisaged in the Commitments, the Trustee considers that this limitation is helpful to protect the future viability of the other purchasers of parts of the Mylan Divestment Business. The Commission shares the views of the Trustee, as this limitation is justified to preserve the viability and value of the other molecule/country combinations included in the Mylan Divestment Business. Moreover, this limitation will not negatively affect the viability of the Third Divestment Business.[18]

(43) Therefore, based on the information above and the Trustee's Reasoned Opinion the Commission concludes that the Third Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market.

3. CONCLUSION

(44) Based on the above assessment, the Commission approves GL Pharma as a suitable purchaser of the Third Divestment Business.

(45) Based on the GL Pharma Transaction Agreements, the Commission further concludes that the Third Divestment Business is being sold in a manner consistent with the Commitments.

(46) This Decision only constitutes approval of the Proposed Purchaser identified herein and of the GL Pharma Transaction Agreements. This decision does not constitute a confirmation that the Parties have complied with the Commitments.

17 Reasoned Opinion, Section 6.

18 Reasoned Opinion, Section 6.

(47) This Decision is based on paragraphs 18 and 19 of the Commitments attached to the Decision.

For the Commission

(Signed)
Olivier GUERSENT
Director-General