EN

Case No COMP/M.7339 - ABBVIE/ SHIRE

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 16/10/2014

In electronic form on the EUR-Lex website under document number 32014M7339

Office for Publications of the European Union
L-2985 Luxembourg

EUROPEAN COMMISSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

Brussels, 16.10.2014
C(2014) 7681 final

PUBLIC VERSION

MERGER PROCEDURE

To the notifying party:

Dear Sir/Madam,

Subject: **Case M.7339 - ABBVIE/ SHIRE**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1]

(1) On 11 September 2014, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which the undertaking AbbVie Inc**.** ("AbbVie", USA) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of the undertaking Shire Inc. ("Shire", Ireland) by way of purchase of shares.[2] AbbVie is referred to as "Notifying Party" and AbbVie and Shire are collectively referred to as "Parties" to the proposed concentration.

1. THE PARTIES

(2) AbbVie is a US based biopharmaceutical company active globally in the discovery, development, manufacture and sale of proprietary pharmaceutical products. AbbVie's

---

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 Publication in the Official Journal of the European Union No C 325, 19.9.2014 p. 6.

Commission européenne, DG COMP MERGER REGISTRY, 1049 Bruxelles, BELGIQUE
Europese Commissie, DG COMP MERGER REGISTRY, 1049 Brussel, BELGIË

Tel: +32 229-91111. Fax: +32 229-64301. E-mail: COMP-MERGER-REGISTRY@ec.europa.eu.

products are used to treat: chronic autoimmune diseases, including rheumatoid arthritis, psoriasis, ulcerative colitis ("UC"), and Crohn's disease ("CD"); testosterone deficiency; HIV; endometriosis; thyroid disease; Parkinson's disease; complications associated with chronic kidney disease and cystic fibrosis, among other health conditions. AbbVie's key products include Humira, the world's top selling drug in 2013, used for the treatment of arthritis, psoriasis, UC and CD.

(3) Shire is a biopharmaceutical company, headquartered in Ireland and active globally. Shire is mainly active in the manufacturing and sales of pharmaceuticals products used for the treatment of rare diseases, neuroscience, gastrointestinal diseases and internal medicine. Its leading brands and products include Vyvanse, Lialda/Mezavant, Cinryze, Elaprase and Replagal.

2. THE OPERATION

(4) On 18 July 2014, the Parties signed a Cooperation Agreement and announced a recommended bid, pursuant to which AbbVie acquires 100% of the share capital and voting rights of Shire through its wholly owned subsidiaries AbbVie Private Limited and AbbVie Holdings Private Limited[3]. Therefore, the proposed transaction qualifies as a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

3. EU DIMENSION

(5) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[4] (AbbVie: EUR 14 148 million, Shire: EUR 4 047 million). Each of them has an EU-wide turnover in excess of EUR 250 million (AbbVie: EUR […] million, Shire: EUR […] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State. The notified operation therefore has an EU dimension within the meaning of Article 1(2) of the Merger Regulation.

4. COMPETITIVE ASSESSMENT

(6) The Parties' activities overlap in the area of treatment of UC and CD. UC and CD are chronic inflammatory diseases affecting the digestive system. They are the two main forms of inflammatory bowel disease.

(7) The principal difference between UC and CD is the location and the nature of the inflammation. UC causes inflammation and ulceration of the inner superficial lining of the large intestine, whereas CD can affect any part of the gastrointestinal tract from the mouth to the rectum, affecting the full thickness of the intestinal wall.

(8) In both diseases, as a matter of common clinical practice, patients are classified as displaying mild, moderate or severe symptoms, with treatment calibrated according to symptom type.

---

3 As part of the transaction, AbbVie will move its headquarters from the United States to the Island of Jersey.

4 Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p1).

(9) As UC and CD are chronic diseases they are treated medically, in some cases surgically, but are medically not curable. The aims of treatment are to reduce symptoms and maintain or improve quality of life, while minimising drug-related toxicity over both the short- and long-term. Clinical management will depend on many variables, including disease activity, symptom severity, response to previous medications, and the costs and side-effect profiles of available medications.

(10) Accordingly, treatment is generally undertaken on a phased basis, through use of first-, second- and third-line treatments, with drug use calibrated according to patient circumstances, particularly symptoms severity.[5]

4.1. Product Market Definition

(11) AbbVie commercialises Humira (adalimumab), a biologic6 anti-TNF product. In the gastrointestinal area, Humira is primarily used for the treatment of patients suffering from CD, but is also prescribed for the treatment of UC. Shire commercialises Mezavant (mesalamine, in the EEA referred to as mesalazine), essentially used for the treatment of UC; however it is also used off-label for patients suffering from mild to moderate symptoms in CD.

(12) The Commission has previously not analysed the market for the treatment of UC or of CD. As a starting point of its analysis of the relevant product market, the Commission generally refers to the Anatomical Classification of Pharmaceutical Products (ATC) devised for marketing purposes by the European Pharmaceutical Marketing Association (EphMRA)[7] and more specifically to level ATC 3, namely the therapeutic indication and the intended use. However, the Commission may also consider appropriate to conduct the analysis across ATC classes, if specific circumstances indicate that ATC3 is not the most appropriate level. Lastly, the Commission may also take into account additional characteristics, such as the ATC 4 level, the "molecule", the "active ingredient" or the galenic form or the line of treatment.[8]

(13) The Notifying Party submits that Mezavant and Humira are not part of the same product market for several reasons. First, they do not belong to same ATC 3 class: Humira is classified under ATC 3 L4B "anti-TNF immuno-suppressants", whereas Mezavant is classified under ATC 3 A7E "Intestinal anti-inflammatory agents". In addition, Mezavant is approved for the treatment of UC only, although the Notifying Party acknowledges some off-label use in CD.

(14) Second, the Notifying Party submits that clinical guidelines[9] recommend a treatment in three lines for UC and CD, starting in first line with aminosalicylates (which include mesalazine compounds, such as Mezavant) followed in second line by

---

5 The lines of treatment are based on the Guidelines of European Crohn's and Colitis Organisation ("ECCO"), which are widely followed by physicians across the EEA.

6 A biologic is a medicine whose active substance is made by or derived from living organisms (e.g., immunological products and medicines derived from human blood and plasma).

7 See for example Cases M.5865 Teva/Ratiopharm, M.1835 Monsanto / Pharmacia & Upjohn, paragraphs 17-19 and M.1397 Sanofi / Synthélabo, paragraphs 31, 32.

8 See for example Cases M.6969-Valeant Pharmaceuticals International/Bausch & Lomb Holding, M.6705 Procter & Gamble/Teva Pharmaceuticals, M.5778 – Novartis/Alcon, M.5476-Pfizer/Wyeth.

9 Such as the Guidelines by the European Crohn's and Colitis Organisation ("ECCO").

immuno-suppressants (neither of the Parties produces such a drug) and may continue into third line with an anti-TNF product, such as adalimumab (Humira).

(15) Third, the treatment with anti-TNF is via the intravenous or subcutaneous route and is only indicated where there has been no response to conventional therapies. This treatment may have severe side effects. In addition, the mechanism of action of Mezavant is believed to be predominantly topical, at the side of the inflammation and particularly in the colon. In contrast Humira is systemic product, acting on the bloodstream to supress the action of the naturally occurring protein, TNF, which plays a role in the body's immune system.

(16) Fourth, Mezavant and Humira use different active ingredients, respectively a small molecule chemical drug (mesalazine) and a biological product (adalimumab).

(17) Fifth, the products are distributed through different distribution channels; while Mezavant is available under prescription in pharmacies, Humira is purchased by Hospital pharmacies and distributed to patients in a hospital setting. An annual cost per patient treated differs significantly.

(18) Accordingly, the Notifying Party considers that Mezavant and Humira are not substitutable; neither from demand side, nor from supply-side, and should not be regarded as part of the same product market.

(19) Respondents to the market investigation indicated that pharmaceuticals which belong to ATC 3 L4B and ATC 3 A7E are not substitutable either from the supply or from the demand side perspective.

(20) As to the demand side, competitors as well as key opinion leaders active as physicians and researchers in the field of UC and CD indicated that the two diseases are increasingly treated in a similar way, while in the past there were differences regarding the treatment of UC and CD. However, mesalazine is less commonly used to treat CD.

(21) Also, responses received during the market investigation indicated that Mezavant and Humira do not belong to the same line of treatment. Physicians prescribe mesalazine (Mezavant) in first line of treatment. Mesalazine is most commonly used to maintain remission in UC, even though the product is also prescribed for the treatment of CD. Anti-TNF products such as adalimumab are used in the third line treatment for patients with severe symptoms.

(22) Respondents to the market investigation also indicated that,the purchasing mechanism of mesalazine and Anti-TNFs is different. In particular, Humira is sold to hospital pharmacies which distribute the product to the patients in a hospital setting and the initial purchase is made by health insurers, whereas Mezavant can be purchased by the patients themselves as they purchase Mezavant in pharmacies outside hospitals.

(23) Respondents to the market investigation also indicated that Humira and Mezavant have different modes of administration: Humira is administrated trough an injection, while Mezavant is taken orally as a systemic product or administrated locally as a topical product. Further, the market investigation revealed a substantial price difference between the treatment with Humira and Mezavant. The cost of the treatment with Humira is estimated at more than 10 times higher than the cost of the treatment with Mezavant.

(24) From the supply side, mesalazine and Anti-TNF products such as adalimumab are produced following different production processes and with different types of ingredients.

(25) Further, respondents indicated during the market investigation that the Parties are not competitors and their products are rather complementary for the treatment of UC and CD. In particular, respondents suggested that AbbVie competes with Janssen Biologics and Merck which market a product similar to Humira, namely Remicade (infliximab), an anti-TNF agent. The market investigation also suggested that Shire competes with other companies marketing mezalasine or similar products namely Ferring (Pentesa), Actavis (Asacol), Falk Pharma (Salofalk) and USB Pharma (Olsalazine).

(26) Companies generally produce one or the other product and they are active in the market for one or the other product respectively.

(27) On the basis of the result of the market investigation, the Commission concludes that Mezavant (mesalazine) and Humira (adalimumab) are part of separate product markets, since they have different mechanism of action and are intended for use in different lines of treatment and for the treatment of different symptoms.

4.2. Geographic market definition

(28) In the area of finished pharmaceutical products, the Commission has considered that the markets for pharmaceutical products are national in scope. This conclusion has generally been reached because of (i) varying national regulatory controls for pharmaceutical products; (ii) perceived differences in price setting and purchasing patterns/reimbursement by Member States; (iii) differences in brand, pack size and distribution systems.[10]

(29) For the case at hand, the Notifying party submits that the market should be national.

(30) Based on the results of the market investigation,[11] the Commission notes that suppliers usually deliver and customers usually purchase mesalazine and anti-TNFs at national level. Accordingly, the Commission considers the relevant geographic market(s) for the case at hand would be national in scope.

4.3. Competitive Assessment

(31) The proposed concentration does not give rise either to horizontal or vertical concerns since the substitutability between mesalazine and the anti-TNFs belong to different product markets, and none of the Parties is active in any upstream or downstream related areas. In addition, the Parties do not have overlapping pipelines products.

(32) Further, based on the evidence gathered in the market investigation, the Commission considers that the Parties will likely continue to face competitive constraints in their respective markets from generic companies. Generic mesalazine is

---

10 See, for example, Case M.6705 - Procter & Gamble /Teva Pharmaceuticals OTC II, paragraph 11.

11 See replies to questions 15, 16, 17 of questionnaire M.7339 – Q1- Questionnaire to Competitors and replies to questions 19, 20, 21 of questionnaire M.7339 – Q2 – Questionnaire to Customers

already marketed in the EEA. As to adalimumab (Humira), several companies have phase III pipeline products for bio-similar anti-TNFs, among which are Pfizer and Sandoz. Celltrion Healthcare has obtained a regulatory approval for marketing a biosimilar anti-TNF (Infliximab) in the European Union.

(33) Potential conglomerate effects appear unlikely in particular because Mezavant and Humira are dedicated to different groups of patients and the purchasing mechanisms are different for both products.

(34) Further, neither customers nor competitors perceive Shire to be a particularly innovative competitor in the market for mesalazine based products. The Parties also submit that their respective pipelines are complementary, both at Phase III and Phase II level, so that there would be neither an overlap between marketed and pipeline products nor between pipeline and pipeline products.

(35) Finally, no market participant expressed any concerns with regard to the combination of the existing products of the Parties. In this light, the Commission does not have serious doubts as to the compatibility of the proposed concentration with the internal market.

5. 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.

For the Commission

(signed)
Joaquín ALMUNIA
Vice-President

Commission européenne, DG COMP MERGER REGISTRY, 1049 Bruxelles, BELGIQUE
Europese Commissie, DG COMP MERGER REGISTRY, 1049 Brussel, BELGIË

Tel: +32 229-91111. Fax: +32 229-64301. E-mail: COMP-MERGER-REGISTRY@ec.europa.eu.