

Complaint

IN THE MATTER OF

**PFIZER INC.,
UPJOHN INC.,
VIATRIS INC.,
MYLAN N.V.,
AND
UTAH ACQUISITION SUB INC.**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

Docket No. C-4727; File No. 191 0182

Complaint, October 30, 2020 – Decision, January 25, 2021

This consent order addresses the combination of certain assets of Pfizer Inc. and Mylan N.V. to form Viatriis Inc. The complaint alleges that the Combination, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening current competition in the markets for: (1) amlodipine besylate/atorvastatin calcium tablets, (2) eplerenone tablets, (3) gatifloxacin ophthalmic solution, (4) medroxyprogesterone acetate injectable solution, (5) phenytoin chewable tablets, (6) prazosin hydrochloride (“HCl”) capsules, and (7) spironolactone hydrochlorothiazide (“HCTZ”) tablets in the United States. The complaint also alleges that the Combination would violate the aforementioned statutes by lessening future competition in the markets for: (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets. The consent order requires the parties to divest Upjohn’s generic drug rights and assets related to six products and Mylan’s rights and assets related to eplerenone tablets to Prasco, LLC. The consent order also requires prior Commission approval before Upjohn, Mylan, or Viatriis may gain an interest in or exercise control over any third party’s rights to (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets.

Participants

For the *Commission*: *Jasmine Y. Rosner, Danielle Sims and David von Nirschl.*

For the *Respondents*: *Harry T. Robins and Scott Stempel, Morgan, Lewis & Bockius LLP; Maggie D’Amico, Yonatan Even, and Christine Varney, Cravath, Swain & Moore LLP; Logan Breed, Chuck Loughlin, and Edith Ramirez, Hogan Lovells U.S. LLP.*

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Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Pfizer Inc. proposes to combine certain of its assets and liabilities, including Respondent Upjohn Inc. and Respondent Utah Acquisition Sub Inc., with Respondent Mylan N.V. to form Respondent Viatriis Inc., all Respondents being corporations subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such combination, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it

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appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Pfizer Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017.

2. Respondent Upjohn Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017. Upjohn houses Pfizer's authorized generic distributor, Greenstone LLC. After the proposed transaction, Upjohn Inc. is to be renamed Viatris Inc.

3. Respondent Viatris Inc. is or will be a successor corporation of Upjohn Inc. Viatris is or will be a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

4. Respondent Mylan N.V. is a public limited liability company organized, existing, and doing business under and by virtue of the laws of the Kingdom of the Netherlands with its executive offices and principal place of business located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. Mylan N.V. includes Mylan I B.V. and Mylan II B.V. (collectively, "Respondent Mylan"). Mylan N.V.'s United States address for service of process is Mylan Inc., 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

5. Respondent Utah Acquisition Sub Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017.

6. Each Respondent is, and at all times relevant herein has been or will be, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and engages in business that is in or affects commerce, as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED COMBINATION

7. Pursuant to a Separation and Distribution Agreement by and between Pfizer Inc. and Upjohn Inc., dated July 29, 2019, and the Business Combination Agreement by and among Pfizer Inc., Upjohn Inc., Utah Acquisition Sub Inc., Mylan N.V., Mylan I B.V., and Mylan II B.V., dated July 29, 2019 (collectively, the "Agreements"), Respondent Pfizer will combine certain of its assets and liabilities with Respondent Mylan to form Respondent Viatris (the "Combination"). Respondent Pfizer will receive \$12 billion in cash from Viatris as partial consideration in connection with the Combination, and Respondent Pfizer's shareholders will

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gain an interest in Respondent Viatrix. The Combination is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

8. The relevant lines of commerce in which to analyze the effects of the Combination are the development, license, manufacture, marketing, distribution, and sale of the following generic pharmaceutical products:

- a. Amlodipine besylate/atorvastatin calcium tablets;
- b. Eplerenone tablets;
- c. Gatifloxacin ophthalmic solution;
- d. Levothyroxine sodium tablets;
- e. Medroxyprogesterone acetate injectable solution;
- f. Phenytoin chewable tablets;
- g. Prazosin hydrochloride capsules;
- h. Spironolactone hydrochlorothiazide tablets;
- i. Sucralfate tablets; and
- j. Varenicline tartrate tablets.

9. The United States is the relevant geographic area in which to assess the competitive effects of the Combination in the relevant lines of commerce.

IV. THE STRUCTURE OF THE MARKETS

10. Amlodipine besylate/atorvastatin calcium tablets combine a calcium channel blocker to treat hypertension with a lipid-lowering agent to treat high cholesterol. Only four companies sell generic amlodipine besylate/atorvastatin calcium tablets: Greenstone, Mylan, Dr. Reddy's Laboratories Ltd., and Apotex Inc. The Combination will reduce the number of current suppliers from four to three. In all eleven strengths of amlodipine besylate/atorvastatin calcium tablets, Greenstone and Mylan account for greater than 30 percent of the market combined.

11. Eplerenone is a diuretic that is prescribed as an adjunctive therapy when treating hypertension or congestive heart failure after a heart attack. Significant sellers of eplerenone include Greenstone, Mylan, Breckenridge Pharmaceutical, Inc., and Accord Healthcare Inc. In both the 25mg and 50mg strengths, the Combination would reduce the number of significant suppliers and result in the combined entity accounting for approximately 50 percent of eplerenone tablets sold.

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12. Gatifloxacin ophthalmic solution is an eye drop that treats bacterial conjunctivitis caused by susceptible strains of certain bacteria. The market for gatifloxacin has faced historical supply disruptions. Five companies supply this product today: Greenstone, Mylan, Sandoz International GmbH, Akorn, Inc., and Lupin Ltd. Together, Greenstone and Mylan account for more than 60 percent of gatifloxacin sales.

13. Levothyroxine sodium tablets are offered in a host of strengths and are prescribed to treat hypothyroidism or as an adjunct therapy for patients undergoing treatment for thyroid cancer. Suppliers for levothyroxine sodium tablets vary by strength. Should Upjohn or Greenstone launch an authorized generic of Pfizer's levothyroxine sodium branded product (Levoxyl®), the Combination would likely allow the combined entity to reduce the number of independent suppliers of some strengths of generic levothyroxine sodium tablets from three to two.

14. Medroxyprogesterone acetate is an injectable solution used to treat certain types of dysfunctional uterine bleeding. Injectable products, such as medroxyprogesterone acetate, often experience shortages and supply disruptions. Greenstone, Mylan, Amphastar Pharmaceuticals, Inc., Teva Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Ltd. currently supply medroxyprogesterone acetate. Combined, Greenstone and Mylan account for more than 50 percent of the market.

15. Phenytoin chewable tablets are an anti-epileptic drug that slows down impulses in the brain that cause seizures. Only three suppliers provide phenytoin chewable tablets today: Greenstone, Mylan, and Taro Pharmaceutical Industries Ltd. The Combination would reduce the number of available suppliers and result in Greenstone and Mylan accounting for more than 40 percent of phenytoin chewable tablets sold.

16. Prazosin hydrochloride (HCl) capsules are an alpha-adrenergic blocker that treats hypertension by relaxing the veins and arteries so that blood can more easily pass. The market for prazosin HCl capsules is supplied by four companies: Greenstone, Mylan, Teva, and Novitium Pharma LLC. Across the three strengths of prazosin HCl available today, the Combination would reduce the number of available suppliers and result in the combined entity accounting for approximately half of prazosin HCl capsules sold.

17. Spironolactone hydrochlorothiazide (HCTZ) tablets are a diuretic used to treat hypertension. Only three suppliers provide spironolactone HCTZ tablets: Greenstone, Mylan, and Sun. The Combination would reduce the number of suppliers from three to two and result in Greenstone and Mylan accounting for more than 30 percent of the market.

18. Sucralfate tablets are used to treat and prevent ulcers in the small intestines. Prior to the proposed Combination, only three companies sold sucralfate tablets historically: Greenstone, Mylan, and Teva. While Mylan has stopped selling sucralfate recently, the proposed Combination likely alters Mylan's incentives to relaunch sucralfate tablets and would reduce the number of firms capable of selling sucralfate tablets from three to two.

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19. Varenicline tartrate tablets are a smoking cessation aid offered under Pfizer's brand Chantix®. Currently, only branded Chantix® is available in the market. Mylan is one of a limited number of companies likely to share the Hatch-Waxman 180-day exclusivity period when the generic market forms. Should Upjohn or Greenstone launch an authorized generic of Pfizer's Chantix®, the Combination would likely allow the combined entity to reduce the small number of independent suppliers that would have sold generic varenicline tartrate tablets during the Hatch-Waxman exclusivity period absent the Combination.

V. ENTRY CONDITIONS

20. Entry into the relevant markets described in Paragraphs 10-19 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Combination. *De novo* entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Combination.

VI. EFFECTS OF THE COMBINATION

21. The effects of the Combination, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Upjohn and Greenstone and Mylan and reducing the number of independent significant competitors in the markets for: (1) generic amlodipine besylate/atorvastatin calcium tablets; (2) generic eplerenone tablets; (3) generic gatifloxacin ophthalmic solution; (4) generic medroxyprogesterone acetate injectable solution; (5) generic phenytoin chewable tablets; (6) generic prazosin HCl capsules; and (7) generic spironolactone HCTZ tablets, thereby increasing the likelihood that: (a) Viatris would be able to unilaterally exercise market power in these markets; (b) the remaining competitors would engage in coordinated interaction between or among each other; and (c) customers would be forced to pay higher prices; and
- b. by eliminating future competition between (1) Upjohn and Greenstone and (2) Mylan in the market for generic levothyroxine sodium tablets, generic sucralfate tablets, and generic varenicline tartrate tablets, thereby (a) increasing the likelihood that the combined entity would forego or delay relaunching this product, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of this product.

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VII. VIOLATIONS CHARGED

22. The Combination described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

23. The Combination described in Paragraph 7, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of October, 2020 issues its Complaint against said Respondents.

By the Commission, Commissioners Chopra and Slaughter dissenting.

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The Federal Trade Commission initiated an investigation of Respondent Pfizer Inc.'s ("Pfizer") proposal to spin off its Upjohn division and combine it with the assets of Respondent Mylan N.V. Upon consummation, the combination is expected to be renamed Viatris Inc. and will be comprised of certain legacy Pfizer assets held by Upjohn Inc. and its subsidiaries, Respondent Pfizer's Greenstone LLC business, and all of the assets of Respondent Mylan N.V. The Commission's Bureau of Competition prepared and furnished to each Respondent the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an Agreement Containing Consent Orders ("Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint; (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true; (3) waivers and other provisions as required by the Commission's Rules; and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and determined to accept the executed Consent Agreement to place it on the public record for a period of 30 days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

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1. Respondent Pfizer Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017.
2. Respondent Upjohn Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017. Upon completion of the combination, Upjohn Inc. is expected to be renamed Viatrix Inc. and will become Respondent Viatrix Inc. with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.
3. Respondent Mylan N.V. is a public limited liability company organized, existing, and doing business under and by virtue of the laws of the Kingdom of the Netherlands with its executive offices and principal place of business located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. Mylan N.V.'s United States address for service of process in this matter is as follows: 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.
4. Respondent Utah Acquisition Sub Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017. Upon completion of the combination, Utah Acquisition Sub Inc. will become a subsidiary of Respondent Viatrix Inc. with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.
5. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER**I. Definitions**

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and all other definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), shall apply:

A. "Decision and Order" means:

1. The proposed Decision and Order contained in the Consent Agreement in this matter, until the issuance of a final Decision and Order by the Commission; and

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2. The final Decision and Order, once it is issued by the Commission in this matter.

B. “Orders” means the Decision and Order and Order to Maintain Assets.

II. Divestitures

IT IS FURTHER ORDERED that:

- A. Prior to the Divestiture Date, Respondents shall provide the Acquirer with the opportunity to review Product Contracts related to each of the Divestiture Products so that the Acquirer can determine whether to assume each Product Contract;

provided, however, that in cases in which any Product Contract also relates to a Retained Product the Respondent shall, at the option of that Acquirer, assign or otherwise make available to that Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product.

- B. Prior to the Divestiture Date, Respondents shall secure all approvals, consents, ratifications, waivers, or other authorizations from all non-governmental third parties that are necessary to permit Respondents to divest the Divestiture Assets and to grant or assign rights to the Divestiture Products to the Acquirer, and to permit that Acquirer to continue in the related Divestiture Product Business in the United States without interruption or impairment.

- C. As related to the Product Manufacturing Technology and any ingredient, material, or component used in the manufacture of the Divestiture Product, Respondents shall not enforce any agreement against a third party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the third party a license or other right to the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product. Such agreements include agreements that might limit the ability of a third party to disclose Confidential Business Information related to such Product Manufacturing Technology to the Acquirer. No later than 10 days after the Divestiture Date, Respondents shall grant a release to each third party that is subject to any agreement that allows the third party to provide the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product to the Acquirer. Within 5 days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer;

provided, however, Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant third parties.

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- D. Respondents shall transfer the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer, with the consent of the Acquirer, or at the Acquirer's option, to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Respondent Pfizer shall be responsible for validating and qualifying the manufacture of these Products at either a facility that is retained by Respondent Pfizer after the Acquisition Date or at a facility owned or controlled by the Manufacturing Designee in order to obtain FDA Approvals to manufacture these Products from such facilities and Respondents shall bear all costs related to these transfers.
- E. If, at any time during the term of the Authorized Generic Product License, the Acquirer notifies the Respondents that the Acquirer wants to move manufacturing of an Authorized Generic Product out of a facility owned or controlled by a Respondent, then such Respondent shall transfer the Product Manufacturing Technology to that Acquirer, or to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Such Respondent shall be responsible for ensuring the validation and qualification of the manufacture of these Products at the facility chosen by that Acquirer in order to obtain FDA Approvals to manufacture these Products from that facility. Such Respondent shall bear all costs related to this transfer.
- F. No later than 10 days after the Divestiture Date, Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale of each of the Divestiture Products to assist the Acquirer of each of the Divestiture Products to transfer and integrate the related Divestiture Product Business.
- G. No later than 10 days after the Divestiture Date, Respondents shall provide the following to the relevant Acquirer of each of the Divestiture Products:
1. A list of any finished batch or lot of the relevant Divestiture Product that any Respondent, any manufacturer for a Respondent, or regulatory Agency determined to be out-of-specification at any time during the three-year period immediately preceding the Divestiture Date, and, for each such batch or lot: (i) a detailed description of the known deficiencies or defects (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure); (ii) the corrective actions taken to remediate any cGMP deficiencies in that Divestiture Product; and (iii) to the extent known by any Respondent, the employees (whether current or former) responsible for taking such corrective actions;
 2. A list by stock-keeping unit by Customer that contains the current net price per unit as packaged for sale (*i.e.*, the price net of all customer-level discounts, rebates, or promotions) for the relevant Divestiture Product for

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each order sold to that Customer during the two-year period prior to the Divestiture Date;

3. A list of the inventory levels (weeks of supply) of the relevant Divestiture Product in the possession of each Customer to the extent known or available to any Respondent, as of the date prior to and closest to the Divestiture Date as is available;
 4. A list of any pending reorder dates for the relevant Divestiture Product by Customer as of the Divestiture Date to the extent known by any Respondent;
 5. A list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by law, to control, prohibit, or otherwise limit the use, including the use in Customer cross-referencing, of such NDC numbers by the Respondents, *unless* that Divestiture Product has not been marketed or sold in the United States prior to the Divestiture Date; and
 6. The quantity and delivery terms in all unfilled Customer purchase orders for the relevant Divestiture Product as of the Divestiture Date.
- H. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Product Releasees under any Patent that was pending or issued on or before the Acquisition Date if such suit would limit or impair the Acquirer's freedom to research and Develop, or manufacture anywhere in the world the Divestiture Product(s), or to distribute, market, sell, or offer for sale within the United States any such Divestiture Product.
- I. Upon reasonable written request from the Acquirer to a Respondent, that Respondent shall provide, in a timely manner, assistance of knowledgeable employees of that Respondent (*i.e.*, employees of that Respondent that were involved in the Development of the Divestiture Products) to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a third party related to the Product Intellectual Property for the Divestiture Products acquired by that Acquirer from a Respondent. A Respondent shall make its employees available to that Acquirer for the fee provided in the relevant Divestiture Agreement, or if no fee is provided, at no greater than Direct Cost.
- J. For any patent infringement suit that is filed or to be filed within the United States that is (i) filed by, or brought against, a Respondent prior to the Divestiture Date related to any Divestiture Product or (ii) any potential patent infringement suit that a Respondent has prepared, or is preparing, to bring or defend against as of the Divestiture Date that is related to any Divestiture Product, that Respondent shall:

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1. Cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of such patent infringement suit;
2. Waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the Acquirer in any such patent infringement suit; and
3. Permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to such patent infringement suit.

III. Transition Services and Manufacturing by Respondents**IT IS FURTHER ORDERED** that:

- A. At the request of the Acquirer, in a timely manner, at no greater than Direct Cost or at such cost as provided in a Divestiture Agreement, Respondents shall provide transition services sufficient to enable the Acquirer of each of the Divestiture Products to operate the related Divestiture Product Business in substantially the same manner that Respondents have operated that Business prior to the Acquisition Date.
- B. Upon reasonable written notice and request from the Acquirer of the rights to the Authorized Generic Products, Respondents shall manufacture, deliver and supply, or cause to be manufactured, delivered, and supplied, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, that Acquirer's requested supply of each of the Authorized Generic Products and any of the active pharmaceutical ingredients used in the Authorized Generic Products that are made by a Respondent, as applicable, hereinafter "Supplied Products." For the initial 10-year term of the Authorized Generic Agreement, the requested supply of Supplied Products shall be provided at no greater than Supply Cost or at such cost as provided in a Divestiture Agreement.
- C. The Respondents shall make representations and warranties to the Acquirer that the Supplied Products meet the relevant Agency-approved specifications.
- D. The Respondents shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Supplied Products to meet cGMP, but the Respondents may make this obligation contingent upon the Acquirer giving the Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the Respondents may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such

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settlement is consistent with the Respondents' responsibilities to supply the Supplied Products in the manner required by the Decision and Order;

provided further, however, that this obligation shall not require the Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the Respondents to the Acquirer in a Divestiture Agreement.

- E. The Respondents shall agree to hold harmless and indemnify the Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of the Respondents to deliver the Supplied Products to the Acquirer in a timely manner *unless* (i) Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents, and (ii) Respondents are able to cure the supply failure no later than 30 days after the receipt of notice from that Acquirer of a supply failure.
- F. The Respondents shall give priority to supplying the Acquirer over the supplying of Products for any Respondent's own use or sale.
- G. During the term of any agreement for a Respondent to supply the Supplied Products, upon written request of the Acquirer or a Monitor, the Respondent shall make available to the supplied Acquirer and a Monitor all records generated or created after the Divestiture Date that relate directly to the manufacture of the applicable Supplied Products.
- H. The Respondents shall provide the Acquirer with the actual costs incurred or the price paid for active ingredients, components, and excipients the Respondents use to manufacture the applicable Supplied Products.
- I. During the term of any agreement for a Respondent to supply the Supplied Products, Respondents shall take all actions as are reasonably necessary to ensure an uninterrupted supply of each of the Supplied Products.
- J. Respondents shall not be entitled to terminate any agreement to supply the Supplied Products due to (i) a breach by the Acquirer of a Divestiture Agreement, or (ii) that Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;

provided, however, that this Paragraph shall not prohibit a Respondent from seeking compensatory damages from the Acquirer for that Acquirer's breach of its payment obligations to the Respondent under the agreement.

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- K. The Respondents shall permit the Acquirer to terminate the agreement for the supply of the Supplied Products on a product-by-product basis, at any time, upon commercially reasonable notice, and without cost or penalty (other than costs or penalties due by the Respondent to third parties pursuant to the termination of such agreement, which may be the responsibility of that Acquirer).
- L. In the event that that a Respondent becomes (i) unable to supply or produce a Supplied Product from the facility that has been supplying the Acquirer, and (ii) any Respondent has a different facility that is listed on the FDA Authorization for that Supplied Product and is still suitable for use to manufacture the Supplied Product, or any Respondent has a facility that manufactures the Therapeutic Equivalent of such Supplied Product, then such Respondent shall, at the option of the supplied Acquirer, provide a supply of either the Therapeutic Equivalent or the Supplied Product from the other facility under the same terms and conditions as contained in the Divestiture Agreement to supply.
- M. During the term of any agreement for a Respondent to supply the Supplied Products, the Respondents shall provide consultation with knowledgeable employees of Respondents and training, at the written request of the supplied Acquirer and at a facility chosen by the supplied Acquirer, for the purposes of enabling that Acquirer (or its Manufacturing Designee) to obtain all Product Approvals to manufacture the applicable Supplied Products in final form in the same quality achieved by, or on behalf of, Respondents and in commercial quantities, in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of that Acquirer that its personnel (or its Manufacturing Designee's personnel) are adequately trained in the manufacture of the applicable Supplied Products.
- N. For any Supplied Product that, after the Acquisition Date, is made in a facility owned by Respondent Upjohn or Respondent Viatris, Respondents shall transfer such manufacturing to a facility owned, controlled, or operated by Respondent Pfizer or, at the option of the Acquirer, to its Manufacturing Designee. Respondents shall bear all costs for this transfer including the cost to validate the Supplied Products at the changed facility and the costs for any changes in the specifications for any Supplied Product required by the FDA prior to the FDA's granting approval to market such Product from the changed site of manufacture.
- O. For any Authorized Generic Product that, after the Acquisition Date, has as its source of the active pharmaceutical ingredient either Respondent Upjohn or Respondent Viatris: (i) Respondents shall give priority to supplying the active pharmaceutical ingredients for use in such Authorized Generic Product over supplying the active pharmaceutical ingredients for any Product for any Respondent's own use or sale, and (ii) at the Acquirer's option, Respondents shall bear the costs to qualify and obtain FDA regulatory approval to change the source of the active pharmaceutical ingredient(s).

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IV. Asset Maintenance

IT IS FURTHER ORDERED that, until the Respondents have physically transferred the Eplerenone Divestiture Assets, granted the Authorized Generic Product License and assigned the rights to the Gatifloxacin Products to the Acquirer pursuant to Paragraph II of the Decision and Order, Respondents shall operate and maintain each of the respective Divestiture Assets and each of the respective Divestiture Product Businesses in the ordinary course of business consistent with past practices. Included in these obligations, Respondents shall:

- A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses, to minimize the risk of loss of competitive potential of such Divestiture Product Businesses, to operate such Divestiture Product Businesses in a manner consistent with applicable laws and regulations, and to prevent the destruction, removal, wasting, or deterioration of any of the Divestiture Assets, except for ordinary wear and tear.
- B. Not sell, transfer, encumber, or otherwise impair such Divestiture Assets, or terminate any of the operations of such Divestiture Product Businesses, other than in the ordinary course of business consistent with past practice or as prescribed in the Orders.
- C. Make all payments required to be paid under any contract or lease when due, and pay all liabilities and satisfy all obligations associated with such Divestiture Product Businesses.
- D. Provide such Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls, to perform routine or necessary maintenance, to repair or replace facilities and equipment, and to carry on, at least at their scheduled pace, all capital projects, business plans, promotional plans, capital expenditure plans, research and development plans, and commercial activities for such Divestiture Product Businesses.
- E. Use best efforts to preserve the existing relationships and goodwill with suppliers, customers, employees, vendors, distributors, landlords, licensors, licensees, government entities, brokers, contractors, and others having business relations with such Divestiture Product Businesses.
- F. Maintain the working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with such Divestiture Product Businesses, including by:
 - 1. Filling vacancies that occur in the regular and ordinary course of business consistent with past practice; and
 - 2. Not transferring any employees from such Divestiture Product Businesses to another of Respondents' businesses.

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- G. Maintain and preserve the Business Information of such Divestiture Product Businesses.
- H. Provide the resources necessary for such Divestiture Product Businesses to respond to competition, prevent diminution in sales, and maintain its competitive strength.
- I. Continue providing customary levels of support services to such Divestiture Product Businesses.
- J. Maintain all licenses, permits, approvals, authorizations, or certifications used in the operation of such Divestiture Product Businesses, and operate such Divestiture Product Businesses in accordance and compliance with all regulatory obligations and requirements.
- K. Maintain the levels of production, quality, pricing, service, or customer support typically associated with such Divestiture Product Businesses.

Provided, however, Respondents may take actions that the Acquirer has requested or agreed to in writing and that has been approved in advance by a Monitor (in consultation with Commission staff), in all cases to facilitate that Acquirer's acquisition of the Divestiture Assets and rights in the Divestiture Products and consistent with the purposes of the Orders.

V. Employees**IT IS FURTHER ORDERED** that:

- A. Until 2 years after the Divestiture Date, Respondents shall cooperate with and assist the Acquirer to evaluate independently and offer employment to the Relevant Employees for the Divestiture Products acquired by that Acquirer.
- B. Respondents shall:
 - 1. No later than 10 days after a request from the Acquirer, provide to that Acquirer a list of all Relevant Employees and provide Employee Information for each Relevant Employee;
 - 2. No later than 10 days after a request from the Acquirer, provide that Acquirer or its Manufacturing Designee an opportunity to meet individually and outside the presence or hearing of any employee or agent of Respondents with any of the Relevant Employees, and to make offers of employment to any of the Relevant Employees;
 - 3. Remove any impediments within the control of Respondents that may deter Relevant Employees from accepting employment with the Acquirer

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or its Manufacturing Designee, including, but not limited to, removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee, and shall not make any counteroffer to a Relevant Employee who receives an offer of employment from that Acquirer or its Manufacturing Designee; *provided, however*, that nothing in the Orders shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee; and

4. Not interfere, directly or indirectly, with the hiring or employing by that Acquirer or its Manufacturing Designee of any Relevant Employees, not offer any incentive to such employees to decline employment with that Acquirer or its Manufacturing Designee, and not otherwise interfere with the recruitment of any Relevant Employees by that Acquirer.
- C. Respondents shall continue to provide Relevant Employees compensation and benefits, including regularly scheduled raises and bonuses, until the Divestiture Date or as may be necessary to comply with the provisions of the Orders to provide manufacturing and supply of Divestiture Products or transition services to the Acquirer.
 - D. Respondents shall provide reasonable financial incentives for Relevant Employees to continue in their positions, and as may be necessary, to facilitate the employment of such Relevant Employees by the Acquirer.
 - E. If, at any point within 6 months of the Divestiture Date, the Commission, in consultation with the Acquirer and a Monitor, determines in its sole discretion that the Acquirer or its Manufacturing Designee should have the ability to interview, make offers of employment to, or hire any of Respondents' employees who were not included as Relevant Employees, but who either (i) were involved with any of the Divestiture Products, or (ii) provided manufacturing and supply of Divestiture Products or transition services to the Acquirer, then the Commission may notify Respondents that such employees are to be designated as Relevant Employees, and Paragraph IV of the Decision and Order shall apply to such employees as of that notification date.
 - F. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any of the Relevant Employees who have accepted offers of employment with the Acquirer or its Manufacturing Designee to terminate his or her employment with the Acquirer or its Manufacturing Designee; *provided, however*, Respondents may:
 1. Hire an employee whose employment has been terminated by the Acquirer;

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2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more of Relevant Employees; and
3. Hire an employee who has applied for employment with Respondents, as long as such application was not solicited or induced in violation of this Paragraph.

VI. Business Information**IT IS FURTHER ORDERED** that:

- A. Respondents shall transfer and deliver all Business Information related to a Divestiture Product Business to the Acquirer pursuant to the following:
 1. Respondents shall deliver the Business Information to that Acquirer, at Respondents' expense, in good faith, in a timely manner (*i.e.* as soon as practicable, avoiding any delays in transmission), and in a manner that ensures the completeness and accuracy of all information and ensures its usefulness;
 2. Pending complete delivery of all Confidential Business Information, Respondents shall provide that Acquirer with access to all Business Information and to employees who possess or are able to locate this information for the purposes of identifying the Business Information that contains Confidential Business Information and facilitating the delivery in a manner consistent with the Orders;
 3. Not use, directly or indirectly, any such Confidential Business Information other than as necessary to comply with the following:
 - a. The requirements of the Orders;
 - b. Respondents' obligations to that Acquirer under the terms of the related Divestiture Agreements; or
 - c. Applicable law;
 4. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person *except* (i) that Acquirer, (ii) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (*e.g.*, employees of a Respondent providing transition services, manufacturing Divestiture Products, or who are engaged in the transfer and delivery of the Product Manufacturing

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Technology), (iii) the Commission, or (iv) a Monitor, and *except* to the extent necessary to comply with applicable law;

5. Not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information to the employees associated with the business that is being retained, owned, or controlled by a Respondent, other than those employees specifically authorized as described above;
 6. Institute procedures and requirements to ensure that those employees of a Respondent that are authorized by that Acquirer to have access to such Confidential Business information:
 - a. Do not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information in contravention of the Orders; and
 - b. Do not solicit, access, or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose; and
 7. Take all actions necessary and appropriate to prevent access to, and the disclosure or use of, such Confidential Business Information by or to any Person(s) not authorized to access, receive, or use such information pursuant to the terms of the Orders or the Divestiture Agreements, including:
 - a. Establishing and maintaining appropriate firewalls, confidentiality protections, internal practices, training, communications, protocols, and system or network controls and restrictions;
 - b. To the extent practicable, maintaining such Confidential Business Information separate from other data or information of any Respondent; and
 - c. Ensuring by other reasonable and appropriate means that such Confidential Business Information is not shared with a Respondent's personnel engaged in any Business related to the same or substantially the same type of Business as the Divestiture Products, including a Respondent's personnel engaged in the marketing and sale within the United States of Products Developed or in Development for the same or similar indications as the Divestiture Products or that use the same active pharmaceutical ingredients as the Divestiture Products.
- B. As a condition of continued employment after the Divestiture Date, Respondents shall require each employee that has had responsibilities related to the marketing

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or sales of the Divestiture Products within the one-year period prior to the Divestiture Date, and each employee that has responsibilities related to the Development, marketing, or sales of those Retained Products that are Developed or in Development for the same or similar indications as the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all such Confidential Business Information as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of any Respondent (other than as necessary to comply with the requirements of the Orders).

- C. No later than 30 days after the Divestiture Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the above-described Confidential Business Information by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for 2 years after the Divestiture Date. Respondents shall provide a copy of their notifications to the Acquirer. Respondents shall maintain complete records of all such notifications at the respective Respondent's principal executive offices within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide that Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.
- D. Each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to the Acquirer or access original documents provided to that Acquirer, except under circumstances in which copies of documents are insufficient or otherwise unavailable, and for the following purposes:
 - 1. To assure such Respondent's compliance with any Divestiture Agreement, the Orders, any law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable government entity, or any taxation requirements; or
 - 2. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of an Divestiture Product, the Divestiture Assets, or the Divestiture Product Business;

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provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided further, however, that pursuant to this Paragraph, a Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VII. Additional Obligations

IT IS FURTHER ORDERED that, during the term of the license of any Authorized Generic Product to the Acquirer pursuant to Paragraph II of the Decision and Order, Respondent Pfizer shall retain and maintain each FDA Authorization that is the FDA Authorization for an Authorized Generic Product unless:

- A. Respondent Pfizer transfers such FDA Authorization to the Acquirer;
- B. The FDA requires the withdrawal of the FDA Authorization for safety or efficacy reasons;
- C. Respondent Pfizer demonstrates, in consultation with that Acquirer and a Monitor, that a withdrawal of the FDA Authorization is necessary due to safety issues based on adverse events, serious adverse events, unexpected adverse events, or other pharmacovigilance reported to the FDA since the Divestiture Date; or
- D. The Acquirer consents to the Respondent Pfizer's withdrawal of the FDA Authorization.

VIII. Monitor

IT IS FURTHER ORDERED that:

- A. The Commission appoints F. William Rahe and William Hitchings of Quantic Regulatory Services Inc. as Monitors to observe and report on Respondents' compliance with the terms of the Orders. The Monitors shall serve pursuant to the agreement contained in the Monitor Agreement Appendix to the Orders, provided, however, such agreement shall not limit, or be construed to limit, the terms of the Monitor Paragraphs of the Orders.
- B. No later than one day after the Commission issues this Order to Maintain Assets, Respondents shall:

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1. Confer on the Monitors all rights, power, and authorities necessary to permit the Monitors to monitor Respondents' compliance with the terms of the Orders as set forth in the Monitor Paragraphs of the Orders; and
2. Consent to the terms and conditions regarding such rights, powers, and authorities of the Monitors set forth in the Monitor Paragraphs of the Orders.

C. The Monitors:

1. Shall have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;
2. Shall act in consultation with the Commission or its staff;
3. Shall serve as an independent third party and not as an employee, or agent of the Respondents or of the Commission;
4. Shall serve the expense of Respondents, without bond or other security;
5. May employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out that Monitor's duties and responsibilities;
6. Shall enter into a confidentiality agreement related to Commission materials and information received in connection with the performance of that Monitor's duties and each of that Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into such a confidentiality agreement;
7. Shall notify Respondents and staff of the Commission, in writing, of any potential financial, professional, personal, or other conflicts of interest within 5 days should they arise;
8. Within 30 days after this Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission, shall report in writing to the Commission regarding Respondents' compliance with their obligations under the Orders; and
9. Shall serve until that Monitor, in conjunction with Commission staff, determines that all obligations for the Respondents to provide manufacturing and supply of Divestiture Products have expired or been terminated and a final report is filed within 30-days after that date or until such other time as may be determined by the Commission or its staff.

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- D. Respondents shall (i) provide the Monitors full and complete access to all information and facilities, and, as necessary, make such arrangements with third parties, to allow the Monitors to monitor Respondents' compliance with its obligations under the Orders; and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitors to perform their duties pursuant to the Orders.
- E. Respondents shall indemnify and hold the Monitors harmless against losses, claims, damages, liabilities, or expenses (including attorney's fees and out of pocket costs) that arise out of, or in connection with, any claim concerning the Monitors' performance of the Monitors' duties under the Orders, whether or not such claim results in liability, except, to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitors' gross negligence or willful misconduct. For purposes of this Paragraph, the term "Monitor" shall include all persons retained by the Monitors in the performance of their duties under the Orders.
- F. Respondents may require the Monitors and each of the Monitors' consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement; provided, however, that such agreement does not restrict the Monitors from providing any information to the Commission.
- G. Respondents shall not require nor compel the Monitors to disclose to Respondents the substance of communications with the Commission, including the Monitors' written reports submitted to the Commission, or any other Person with whom the Monitors communicate in the performance of their duties.
- H. If the Commission determines that the Monitors have ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor and such substitute Monitor shall be afforded all rights, powers, and authorities and subject to all obligations of a Monitor under the Monitor Paragraphs of the Orders:
 - 1. The Commission shall select the substitute Monitor, subject to the consent of Respondents which consent shall not be unreasonably withheld. Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor if, upon notice by staff of the Commission of the identity of the substitute Monitor to Respondents, Respondents have not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within 10 days after such notice; and
 - 2. Not later than 5 days after the Commission appoints a substitute Monitor, Respondents shall enter into an agreement with the substitute Monitor that (i) contains substantially the same terms as the agreement attached as Monitor Agreement Appendix to the Orders or (ii) is approved by the Commission and confers on the substitute Monitor the rights, powers, and authority of a Monitor under the Monitor Paragraphs of the Orders.

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- I. The Commission may on its own initiative or at the request of a Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

IX. Divestiture Trustee**IT IS FURTHER ORDERED** that:

- A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Assets or the rights to the Divestiture Products as required by the Decision and Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of the Decision and Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by a Respondent to comply with the Orders.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. No later than 10 days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by the Decision and Order. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of the Orders.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee’s powers, duties, authority, and responsibilities:

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1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by the Decision and Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
2. The Divestiture Trustee shall have one year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one- year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission;

provided, however, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by the Decision and Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by a Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to the Acquirer that receives the prior approval of the Commission as required by the Decision and Order;

provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission;

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provided further, however, that Respondents shall select such Person within 5 days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by the Decision and Order.
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by the Decision and Order.
8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 30 days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement;

provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

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- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by the Decision and Order.

X. Prior Approvals

IT IS FURTHER ORDERED that:

- A. Each Respondent (other than Respondent Pfizer) shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any rights or interests in the Levothyroxine Products, the Sucralfate Products or the Varenicline Products, or the Therapeutic Equivalent of any of these Products without the prior approval of the Commission.
- B. Respondent Pfizer shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any voting or non-voting stock, equity, notes convertible into any voting or non-voting stock rights or interests, or debt in Respondent Viatris, Respondent Upjohn, or Respondent Mylan without the prior approval of the Commission.

XI. Compliance Reports

IT IS FURTHER ORDERED that:

- A. Respondents shall:
 - 1. Notify Commission staff via email at bccompliance@ftc.gov of the Acquisition Date and the Divestiture Dates no later than 5 days after the occurrence of each; and
 - 2. Submit the complete copies of each of the Divestiture Agreements to the Commission at ElectronicFilings@ftc.gov and bccompliance@ftc.gov no later than 30 days after the Divestiture Date.

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- B. Respondents shall file verified written reports (“Compliance Reports”) in accordance with the following:
1. Respondents shall submit interim Compliance Reports within 30 days after this Order to Maintain Assets is issued, and every 90 days thereafter until Respondents have completed all of the following: (i) the transfer and delivery of the Divestiture Assets and the rights to the Divestiture Products to the Acquirer, (ii) the transfer and delivery of all of the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer or to Pfizer’s designated third-party contract manufacturer, (iii) the transfer and delivery of all Business Information to the Acquirer, and (iv) Respondent Pfizer or a third-party contract manufacturer (non-Respondent) designated by Pfizer is FDA approved to manufacture each of the Authorized Generic Products at a facility that is owned or controlled by Pfizer after the Acquisition Date or by Pfizer’s designated third-party contract manufacturer; and Respondents shall submit annual Compliance Reports one year after the Order Date, and annually for the following 9 years on the anniversary of the Order Date; and additional Compliance Reports as the Commission or its staff may request;
 2. Respondent Pfizer shall continue to submit interim Compliance Reports every 6 months regarding Respondent Pfizer’s provision of manufacturing and supply of the Authorized Generic Products to the Acquirer, including a detailed explanation of any manufacturing disruptions or any failures to supply the quantity of ordered Product to that Acquirer, and any other related requirements of the Orders;
 3. Each Respondent’s Compliance Report shall contain sufficient information and documentation to enable the Commission to determine independently whether the Respondent is in compliance with the Orders. Conclusory statements that the Respondent has complied with its obligations under the Orders are insufficient. Respondents shall include in their Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance:
 - a. A detailed description of all substantive contacts, negotiations, or recommendations related to the transfer and delivery to the Acquirer of (i) the Divestiture Assets and the rights to the Divestiture Products, (ii) the Business Information related to each of the Divestiture Product Businesses, and (iii) the provision of manufacturing and supply of Authorized Generic Products to that Acquirer;
 - b. A detailed description of the transfer of the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin

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Products, and the Phenytoin Products to Respondent Pfizer or to Pfizer's designated third-party contract manufacturer and progress toward the manufacturing of these products at a facility retained by Pfizer or Pfizer's designated third-party contract manufacturer; and

- c. A detailed description of the timing for the completion of such obligations.
- 4. Each annual Compliance Report shall include the previous year's market information for each market alleged in the Complaint including the aggregate size of the market in units and in dollars; the monthly sales in units and in dollars for each market participant; the market share for each market participant calculated based on units and on dollars; and, to the extent known, an explanation of any significant changes in the total size of the market and any significant adverse impacts to the manufacture or supply of competing products to the market;
- 5. Respondents shall retain all material written communications with each party identified in the Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondents' obligations under the Orders and provide copies of these documents to Commission staff upon request.
- C. Respondents shall verify each Compliance Report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or other officer or employee specifically authorized to perform this function. Respondents shall submit an original and 2 copies of each Compliance Report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov. In addition, Respondents shall provide a copy of each Compliance Report to each Monitor.

XII. Change in Respondents

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least 30 days prior to:

- A. The dissolution of: Pfizer Inc., Upjohn Inc., Viatris Inc., and Mylan N.V.;
- B. Any proposed acquisition, merger, or consolidation of Pfizer Inc., Upjohn Inc., Viatris Inc., and Mylan N.V.; or
- C. Any other change in Respondents including, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

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XIII. Access

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with the Orders, subject to any legally recognized privilege, upon written request, and upon 5 days' notice to a Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with the Orders, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and
- B. To interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

XIV. Purpose

IT IS FURTHER ORDERED that the purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability, and competitiveness of each of the Divestiture Product Businesses through its full transfer and delivery to the Acquirer; to minimize any risk of loss of competitive potential for each of the Divestiture Product Businesses; and to prevent the destruction, removal, wasting, deterioration, or impairment of the Eplerenone Divestiture Assets.

XV. Term

IT IS FURTHER ORDERED that, unless the Commission directs otherwise, this Order to Maintain Assets shall terminate on the earlier of:

- A. 3 days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The day after all of the Eplerenone Divestiture Assets have been transferred to and are in the physical possession of the Acquirer, the rights to the Authorized Generic Products have been granted to the Acquirer, and the Gatifloxacin Products have been assigned to the Acquirer as required by and described in the Decision and Order.

By the Commission, Commissioners Chopra and Slaughter dissenting.

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NON-PUBLIC APPENDIX

MONITOR COMPENSATION

[cover page]

Order to Maintain Assets

PUBLIC APPENDIX**MONITOR AGREEMENT**

This Monitor Agreement ("Monitor Agreement") entered into among Quantic Regulatory Services, LLC ("Quantic"), and Mylan N.V. ("Mylan") and Pfizer Inc. ("Pfizer") (together with Mylan, the "Merging Parties"), provides as follows:

WHEREAS, the United States Federal Trade Commission (the "Commission"), in *In the Matter of Mylan N.V.*, has accepted or will shortly accept for Public Comment an *Agreement Containing Consent Orders* (the "Consent Agreement"), incorporating a Decision and Order ("Decision and Order") and an Order to Maintain Assets, with the Merging Parties (collectively, the "Orders"), which, among other things, require the Merging Parties to divest or transfer certain defined assets and maintain those assets pending such divestiture or transfer, and provide for the appointment of one or more Monitors to ensure that the Merging Parties comply with their obligations under the Orders;

WHEREAS, the Commission may appoint Quantic, and in particular William Hitchings and William Rahe, as such monitor (the "Monitor") pursuant to the Orders to monitor the Merging Parties' compliance with the terms of the Consent Agreement and Orders and with the Remedial (Divestiture) Agreement referenced in the Orders, and to monitor the efforts of the Commission-approved Acquirers (as defined in the Orders) to obtain all necessary FDA approvals, as applicable, and Quantic has consented to such appointment;

WHEREAS, the Orders further provide or will provide that the Merging Parties shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Monitor to carry out such duties and responsibilities pursuant to the Orders;

WHEREAS, this Monitor Agreement, although executed by the Monitor and the Merging Parties, is not effective for any purpose, including but not limited to imposing rights and responsibilities on the Merging Parties or the Monitor under the Orders, until it has been approved by the Commission; and

WHEREAS, the parties to this Monitor Agreement intend to be

legally bound; NOW, THEREFORE, the parties agree as follows:

1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Orders. The term "Divestiture Products" means, individually and collectively, amlodipine besylate/atorvastatin calcium tablets, eplerenone tablets, gatifloxacin ophthalmic solution, medroxyprogesterone acetate injectable suspension, phenytoin chewable tablets, prazosin hydrochloride capsules, spironolactone/hydrochlorothiazide tablets, and mesalamine delayed release capsules, and any other Divestiture Product as required in the Orders.

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2. The Monitor shall have all of the powers and responsibilities conferred upon the Monitor by the Orders, including but not limited to:
 - a. supervising the transfer of the Divestiture Products, including tangible assets, contracts, Product Intellectual Property and Confidential Business Information to Commission-approved Acquirers;
 - b. supervising any redaction of Confidential Business Information retained by the Merging Parties as required by the Orders; and
 - c. supervising the performance of any transition services, including Contract Manufacture, required by the Orders.
3. The Merging Parties hereby agrees that it will fully and promptly comply with all terms of the Orders requiring it to confer all rights, powers, authority and privileges upon the Monitor, or to impose upon itself any duties or obligations with respect to the Monitor, to enable the Monitor to perform the duties and responsibilities of the Monitor thereunder.
4. The Merging Parties further agrees that:
 - a. it will use its best efforts to ensure that Prasco LLC ("Prasco") or any other Commission-approved Acquirer enters into an agreement with the Monitor at or about the Closing Date governing the facilitation of the Monitor's duties under the Orders and the exchange of information between Prasco or any other Commission-approved Acquirer and the Monitor;
 - b. no later than ten (10) business days after the Commission approves this Monitor Agreement, it will provide the Monitor with the following, as applicable:
 - (1) a complete inventory and description of the Divestiture Products, identifying, in particular, those Divestiture Products which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;
 - (2) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Divestiture Products identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;
 - (3) a complete inventory of all activities or operations worldwide that relate to the manufacture of the Products relating to the Divestiture Products, and which relate to the Merging Parties' compliance with the Orders, including processes and process

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- validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture;
- (4) full and complete details of all dealings with any future Commission-approved Acquirer of the Divestiture Products (other than Prasco or any other entity accepted by the Commission), including copies of all correspondence and written reports of all contacts and discussions with any such future Commission-approved Acquirer and any draft and/or executed complete agreements, including any attached exhibits, schedules and appendices;
 - (5) a complete inventory of all Patents included in the Divestiture Products related to the manufacture or sale of the Divestiture Products in the United States, identifying actions needed to maintain such Patents and the person(s) responsible for such actions; and
 - (6) such other information as reasonably requested by the Monitor in order to carry out its duties and responsibilities under the Orders and Consent Agreement.
- c. it will designate a senior individual as a primary contact for the Monitor and provide a written list of the principal individuals to be involved in the transitioning of the Divestiture Products to Prasco, together with their locations, telephone numbers, electronic mail addresses (if available), and responsibilities, and will provide the Monitor with written notice of any changes in such personnel occurring thereafter;
 - d. it will provide the Monitor with prompt notification of significant meetings, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the development, manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Divestiture Products, and such meetings may be attended by the Monitor or its representative, at the Monitor's option or at the request of the Commission or staff of the Commission;
 - e. it will provide the Monitor with the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Merging Parties;
 - f. it will provide the Monitor with all correspondence, meeting minutes, telephone summaries, and reports, sent to or received from

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the FDA relating to the Divestiture Products;

- g. it will provide the Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Consent Agreement and the Orders, simultaneous with the submission of such reports to the Commission;
- h. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Orders, it will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as reasonably requested by the Monitor, electronic or hard copy reports to the Monitor reasonably describing the Merging Parties' activities and obligations under the Orders concerning the Divestiture Products including, without limitation to the extent applicable:
 - (1) all significant activities concerned with the manufacture, supply and technology transfer of the relevant Products that are identified in the Divestiture Products, including, without limitation, negotiation and operation of supply agreements, actual supply and inventory;
 - (2) all minutes and records of significant meetings, action plans, and follow-ups to action plans and meetings with Prasco related to the manufacture, supply, and technology transfer of the Divestiture Products;
 - (3) all significant activities concerning the assistance, advice and consultation provided to Prasco generally as provided in the Decision and Order; and
 - (4) on request, the Merging Parties will provide the Monitor with any and all records that relate to the manufacture of the Products identified in the Divestiture Products with the right to use them to achieve the purposes of the Orders;

provided, however, that, at the time the Decision and Order becomes final, the reports described in this paragraph shall be due to the Monitor either as requested by the Monitor or within five (5) business days of the date that the Merging Parties files the Merging Parties' reports with the Commission as required pursuant to the Decision and Order;

- i. it will comply with the Monitor's reasonable requests for onsite visits and audits of the Merging Parties' facilities (or any Respondent's or contract manufacturer's facility, to the extent within the Merging Parties' control) used to manufacture the Products identified in the

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Divestiture Products;

- j. it will comply with the Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to this Monitor Agreement, including, as applicable, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale and/or divestiture of any Divestiture Product(s) and, further including, actions necessary to maintain all necessary FDA approvals to manufacture and sell any of the Divestiture Products, to maintain the viability and marketability of the Divestiture Products, as well as the tangible assets of the facilities used to manufacture and sell all of the Divestiture Products (to the extent within the Merging Parties' control), and to prevent the destruction, removal, wasting, deterioration or impairment of the Divestiture Products, and will provide the Monitor with access to and hard copies of all other data, records or other information that the Monitor reasonably believes are necessary to the proper discharge of its responsibilities under the Orders; and
 - k. it will provide prompt notice of any meetings or events affecting or likely to affect the maintenance of the Divestiture Products, including, but not limited to, any and all meetings or communications with the FDA.
- 5. The Merging Parties shall promptly notify the Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and the Merging Parties related to the Orders or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be requested by the Monitor, of such communications.
 - 6. The Merging Parties agrees that to the extent authorized by the Orders, the Monitor shall have the authority to employ, at the expense of the Merging Parties, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information.
 - 7. The Merging Parties and the Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Orders, that the Monitor investigate and/or audit the Merging Parties' compliance with the Merging Parties' obligations to maintain assets pursuant to the Orders, and submit such additional written or oral reports, under applicable confidentiality restrictions, to the Commission as the Commission or its staff may at any time request concerning the Merging Parties' compliance with the Merging Parties' obligations to maintain assets pursuant

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to the Orders.

8. The Monitor shall maintain the confidentiality of all information provided to the Monitor by the Merging Parties. Such information shall be used by the Monitor only in connection with the performance of the Monitor's duties pursuant to this Monitor Agreement and the Orders. Such information shall not be disclosed by the Monitor to any third party other than:
 - a. persons employed by, or working with, the Monitor under this Monitor Agreement; or
 - b. persons employed at the Commission and working on this matter.
9. Upon written request, the Monitor will inform the Commission and the Merging Parties of all persons employed by, or working with, the Monitor under this Monitor Agreement (other than, for the avoidance of doubt, representatives of the Commission, the Merging Parties or Prasco) to whom confidential information related to this Monitor Agreement has been disclosed.
10. Upon (i) termination of the Monitor's duties under this Monitor Agreement and the Orders, and (ii) written request by the Merging Parties, the Monitor shall promptly return to the Merging Parties all material provided to the Monitor by the Merging Parties that is confidential to the Merging Parties and that it is entitled to have returned to it under the Orders, and shall destroy any written material prepared by the Monitor that contains or reflects any confidential information of the Merging Parties, provided, that, notwithstanding the foregoing, the Monitor shall be entitled to keep one copy of such information in its confidential files and all electronic records thereof. Nothing herein shall abrogate the Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of ten (10) years after the termination of this Monitor Agreement;
11. To the extent that the Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Monitor in accordance with the Orders, the Monitor shall ensure that, prior to being retained, such persons agree to confidentiality restrictions consistent with those set forth herein.

For the purposes of this Section and Sections 8, 9 and 10, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known to the recipient at the time of receipt or becomes known to the recipient from a source other than the Merging Parties,

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or any director, officer, employee, agent, consultant or affiliate of the Merging Parties, when such source is entitled to make such disclosure to such recipient or such information was independently developed by the Monitor as evidenced by written records.

12. Nothing in this Monitor Agreement shall require the Merging Parties to disclose any material or information that is subject to a legally recognized privilege or that the Merging Parties is prohibited from disclosing by reason of law.
13. The Monitor shall be responsible for monitoring Respondents' compliance with their obligations as set forth in the Orders and the Divestiture Agreements (Remedial Agreements). In doing so, the Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or the Commission. The Monitor shall have all rights, duties, powers and authorities as required by the Orders, and nothing in the Monitor Agreement shall change, amend, modify, or otherwise limits those rights, duties, powers, and authorities. .
14. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Orders as it relates to the Merging Parties.
15. Mylan will pay the Monitor within thirty (30) days of receipt of an invoice in accordance with the fee schedule attached hereto as Confidential Exhibit A for all time spent in the performance of the Monitor's duties including all monitoring activities related to the efforts of Prasco with respect to the Divestiture Products (including any and all such activities performed prior to the date of this Monitor Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time. Every six months such hourly rates should be reviewed and may be adjusted by agreement with the Merging Parties.
 - a. In addition, Mylan will pay within thirty days of receipt of an invoice (i) all reasonable and customary out-of-pocket expenses incurred by the Monitor in the performance of the Monitor's duties, including any auto, train or air travel in the performance of the Monitor's duties, and international telephone calls, and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties.
 - b. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense reimbursement purposes at the exchange rate used for said credit card transaction and

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any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.

- c. The Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.
- d. To the extent that the Monitor is requested to travel in the performance of the Monitor's duties, the Monitor shall use such travel time, to the extent practicable, to work on the FTC monitor process.

16. Mylan hereby confirms its obligation to indemnify the Monitor and hold the Monitor harmless in accordance with and to the extent required by the Orders (and, upon direction by the Commission to the Monitor to divest any Divestiture Products).

Without in any way limiting the generality of the foregoing, Mylan shall indemnify the Monitor and any subcontractor and their respective consultants, agents, partners, principals, directors, officers, members, managers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses arising out of or in connection with, the performance of the Monitor's duties and obligations including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses are determined by final arbitration to result from the gross negligence or the willful misconduct of the Monitor.

17. The Monitor's maximum liability to the Merging Parties relating to services rendered pursuant to this Monitor Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the lesser of \$75,000 or the total sum of the fees paid to the Monitor by the Mylan, except to the extent resulting from the gross negligence or the willful misconduct of the Monitor determined by final arbitration. IN NO CIRCUMSTANCES WHATSOEVER SHALL THE MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES.
18. The Merging Parties agrees that Mylan's obligations to indemnify the Monitor extend to any agreement that is entered between the Monitor and Prasco and relates to the Monitor's responsibilities under this Monitor Agreement and/or the Orders.

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19. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Mylan shall be required, to notify Prasco and potential future Acquirers with respect to its appointment as the Monitor.
20. In the event of a disagreement or dispute between the Merging Parties and the Monitor concerning the Merging Parties' obligations under the Orders and, in the event that such disagreement or dispute cannot be resolved by the parties, either party may seek the assistance of the individual in charge of the Commission's Compliance Division to resolve this issue. In the case of any disagreement or dispute between the Merging Parties and the Monitor not relating to the Merging Parties' obligations under the Orders, and in the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Merging Parties' obligations pursuant to the Orders. Any fees and expenses of the arbitration shall be split between the parties.
21. This Monitor Agreement shall be subject to the substantive law of the Commonwealth of Pennsylvania (regardless of any other jurisdiction's choice of law principles).
22. This Monitor Agreement shall terminate no later than: (i) the date set forth in the relevant provision of the Orders; or (ii) on the date on which the Commission has appointed a substitute monitor pursuant to the Orders. The Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Orders. The confidentiality, indemnity and limitation of liability provisions of this Monitor Agreement shall survive its termination.
23. In the event that, during the term of this Monitor Agreement, the Monitor becomes aware that it has a conflict of interest that could adversely affect the performance by the designated lead monitor for the Monitor, of any duty under this Monitor Agreement, the Monitor shall promptly inform both the Merging Parties and the Commission of such conflict.
24. It is understood that the Monitor will be serving under this Monitor Agreement as an independent contractor and that the relationship of employer and employee shall not exist between Monitor and the Merging Parties.
25. This Monitor Agreement is for the sole benefit of the parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.
26. This Monitor Agreement and the Orders contains the entire agreement between the parties hereto with respect to the matters described herein and

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replaces and supersedes any and all prior agreements or understandings, whether written or oral. Any amendment, waiver, or modification of this Monitor Agreement shall not be valid unless in writing and signed by the parties, and approved by the Commission. Any such amendment, modification, or waiver may only be made in a manner consistent with the terms of the Orders. Purchase Order terms and conditions shall not be applicable.

27. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail, reputable overnight courier or fax (with acknowledgment of receipt of such fax having been received), to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Monitor, to:

Quantic Regulatory Services, LLC
Bethanne Seel
Office Manager
5N Regents Street
Suite 502
Livingston, NJ 07039

If to Mylan:

Mylan N.V.
Building 4, Trident Place
Mosquito Way, Hatfield
Hertfordshire, United Kingdom, AL10 9UL, or

1000 Mylan Boulevard, Canonsburg, PA 15317

Attention: Global General Counsel

With a copy to:

Cravath, Swaine & Moore LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019

Attention: Margaret D'Amico

If to Pfizer:

Pfizer Inc.
235 East 42nd Street

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New York, New York 10017, USA

Attention: Global General Counsel

With a copy to:

Morgan, Lewis & Bockius LLP
101 Park Ave
New York, NY 10178

Attention: Harry T. Robins

If to the Commission:

Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, DC 20001
Attn.:
Telephone:
Fax:

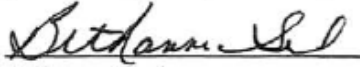
28. This Monitor Agreement shall not become binding until it has been approved by the Commission and the Orders have been accepted for public comment.
29. This Monitor Agreement may be signed in counterparts, each of which shall be deemed an original but when taken together shall constitute one and the same agreement.

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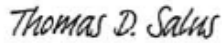
IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 14th of September 2020.

Quantic Regulatory Services, LLC



Bethanne Seel
Office Manager

Mylan N.V.



Thomas D. Salus
Assistant Secretary

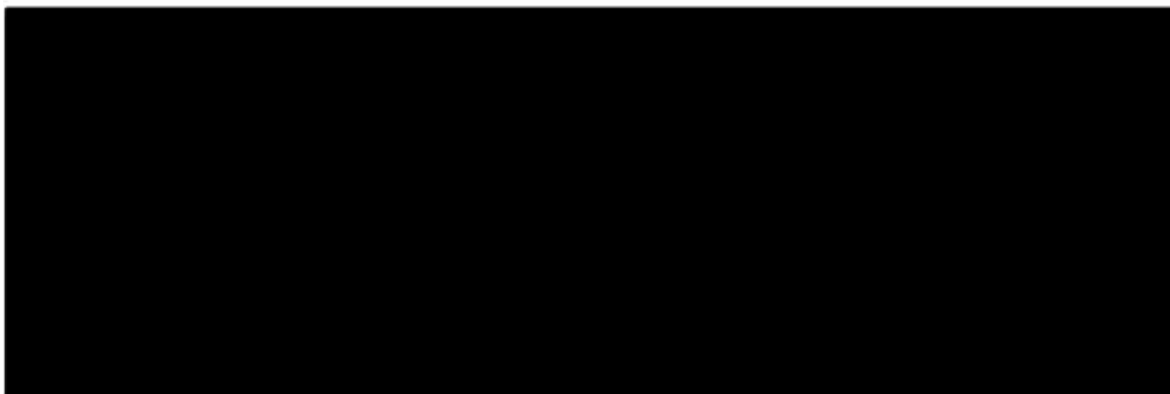
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Marc Brotman
Vice President & Assistant General Counsel Secretary

Order to Maintain Assets

Confidential Appendix A

Decision and Order

DECISION

The Federal Trade Commission initiated an investigation of Respondent Pfizer Inc.'s ("Pfizer") proposal to spin off its Upjohn division and combine it with the assets of Respondent Mylan N.V. Upon consummation, the combination is expected to be renamed Viatriis Inc. and will be comprised of certain legacy Pfizer assets held by Upjohn Inc. and its subsidiaries, Respondent Pfizer's Greenstone LLC business, and all of the assets of Respondent Mylan N.V. The Commission's Bureau of Competition prepared and furnished to each Respondent the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an Agreement Containing Consent Orders ("Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint; (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true; (3) waivers and other provisions as required by the Commission's Rules; and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the said Acts, and that a complaint should issue stating its charges in that respect. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings, and issues the following Decision and Order ("Order"):

1. Respondent Pfizer Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017.
2. Respondent Upjohn Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017. Upon completion of the combination, Upjohn Inc. is expected to be renamed Viatriis Inc. and will become Respondent Viatriis Inc. with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

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3. Respondent Mylan N.V. is a public limited liability company organized, existing, and doing business under and by virtue of the laws of the Kingdom of the Netherlands with its executive offices and principal place of business located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. Mylan N.V.'s United States address for service of process in this matter is as follows: 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.
4. Respondent Utah Acquisition Sub Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017. Upon completion of the combination, Utah Acquisition Sub Inc. will become a subsidiary of Respondent Viatris Inc. with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.
5. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER**I. Definitions**

IT IS ORDERED that, as used in the Order, the following definitions shall apply:

- A. "Pfizer" means Pfizer Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Pfizer Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- B. "Upjohn" means Upjohn Inc., its directors, officers, employees, agents, representatives, successors (including Viatris Inc.), and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Upjohn Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- C. "Viatris" means Viatris Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Viatris Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- D. "Mylan" means Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Mylan N.V., and the

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respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

- E. “Utah Acquisition Sub” means Utah Acquisition Sub Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Utah Acquisition Sub Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- F. “Commission” means the Federal Trade Commission.
- G. “Respondents” means Pfizer, Upjohn, Viatriis, Mylan, and Utah Acquisition Sub.
- H. “Acquirer(s)” means:
 - 1. A Person specified by name in this Order to acquire particular assets or rights pursuant to this Order; or
 - 2. Any other Person that the Commission approves to acquire particular assets or rights pursuant to this Order.
- I. “Acquisition” means the transactions contemplated by *Separation and Distribution Agreement* by and between Pfizer Inc. and Upjohn Inc., dated as of July 29, 2019, and the *Business Combination Agreement* by and among Pfizer Inc., Upjohn Inc., Utah Acquisition Sub Inc., Mylan N.V., Mylan I B.V., and Mylan II B.V. dated as of July 29, 2019, as filed with the Commission.
- J. “Acquisition Date” means the date the parties close on the *Business Combination Agreement* by and among Pfizer Inc., Upjohn Inc., Utah Acquisition Sub Inc., Mylan N.V., Mylan I B.V., and Mylan II B.V. dated as of July 29, 2019.
- K. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes the FDA.
- L. “Authorized Generic Products” mean the authorized generic versions of each of the following products:
 - 1. “Medroxyprogesterone Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorizations: NDA No. 02046 and NDA No. 012541, and any supplements, amendments, or revisions to these NDAs;

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2. “Amlodipine/Atorvastatin Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 021540, and any supplements, amendments, or revisions to this NDA;
 3. “Phenytoin Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: ANDA No. 084427, and any supplements, amendments, or revisions to this ANDA;
 4. “Prazosin Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 017442, and any supplements, amendments, or revisions to this NDA; and
 5. “Spironolactone Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 012616, and any supplements, amendments, or revisions to this NDA.
- M. “Authorized Generic Product License” means an exclusive, royalty-free, fully paid-up right to market, promote, distribute, sell, and offer for sale a non-branded version of each of the Authorized Generic Products in the United States under the applicable FDA Authorization for a term of at least 10 years.
- N. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, advertisement, importation, and sale of a Product.
- O. “Business Information” means all written information, wherever located or stored, relating to or used in a Divestiture Product Business, including documents, graphic materials, and data and information in electronic format. Business Information includes records and information relating to research and development (including copies of Product Development Reports), manufacturing, process technology, engineering, product formulations, production, sales, marketing (including Product Marketing Materials), logistics, advertising, personnel, accounting, business strategy, information technology systems, customers, customer purchasing histories, customer preferences, delivery histories, delivery routing information, suppliers and all other aspects of the Divestiture Product Business. For clarity, Business Information includes any Respondent’s rights and control over information and material provided by that Respondent to any other Person. Business Information includes Confidential Business Information.
- P. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

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- Q. “Confidential Business Information” means all Business Information that is not in the public domain.
- R. “Customer” means any Person that is either a direct purchaser or who negotiates price on behalf of a direct purchaser (*e.g.*, group purchasing organization) of any Divestiture Product from a Respondent or the Acquirer.
- S. “Development” means all new chemical entity research, and all studies of the safety or efficacy of a Product, including test method development and stability testing; toxicology; bioequivalency; bioavailability; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting studies of the safety or efficacy of a Product for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, labeling, and sale of a Product (including any government price or reimbursement approvals); Product Approval and registration; and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- T. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of a Respondent’s employees shall not exceed then-current average hourly wage rate for such employee.
- U. “Divestiture Agreements” mean:
1. Asset Purchase Agreement by and between Mylan Pharmaceuticals Inc. and Prasco, LLC dated as of September 18, 2020; Authorized Generic License, Distribution, and Supply and Product Transfer Agreement by and between Pfizer Inc. and Prasco, LLC, dated as of September 18, 2020; Partial Assignment and Assumption Agreement by and between Upjohn US 2 LLC and Prasco, LLC, dated as of September 18, 2020; Product Transition Agreement by and between Upjohn Inc. and Prasco, LLC, dated as of September 18, 2020; Technology Transfer Agreement by and between Pfizer Inc. and Upjohn Inc. dated as of September 18, 2020; Amendment to the Form of Manufacturing and Supply Agreement between Pfizer Inc., Upjohn Inc., and Mylan N.V. dated as of September 18, 2020; Amendment No. 3 to the Separation and Distribution Agreement by and between Pfizer Inc. and Upjohn Inc. dated as of September 18, 2020; and all amendments, exhibits, attachments, agreements to the above referenced agreements; and
 2. Any other agreement between a Respondent(s) and the Acquirer (or between a Divestiture Trustee and the Acquirer, or between Respondents

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for the benefit of the Acquirer) that has been approved by the Commission to accomplish the requirements of this Order.

- V. “Divestiture Assets” mean Respondents’ equitable and legal right, title, and interests in and to all tangible and intangible assets that are not Excluded Assets, wherever located, relating to a Divestiture Product Business, including the following:
1. All Product Approvals and authorizations for the Divestiture Products, including all FDA Authorizations;
 2. All studies of the safety or efficacy of the Product;
 3. All Product Intellectual Property;
 4. At the option of the Acquirer, Product Manufacturing Equipment;
 5. All technological, scientific, chemical, biological, pharmacological, toxicological, regulatory materials and information, including studies of the safety, efficacy, stability, bioequivalency, bioavailability, and toxicology of a Product;
 6. All website(s), Domain Names, and social media sites related exclusively to the Divestiture Product and the content thereon related exclusively to the Divestiture Product, and the content related exclusively to the Divestiture Product that is displayed on any website that is not dedicated exclusively to the Divestiture Product;
 7. At the option of the Acquirer, Product Contracts;
 8. All Business Information;
 9. At the option of the Acquirer, all inventory and all ingredients, materials, or components used in the manufacture of the specified Divestiture Product in existence as of the Divestiture Date including, the active pharmaceutical ingredient(s), excipient(s), raw materials, packaging materials, work-in-process, and finished goods related to that Divestiture Product; and
 10. At the option of the Acquirer, the right to fill any or all unfilled Customer purchase orders for the specified Divestiture Product as of the Divestiture Date.
- W. “Divestiture Date” means the date on which a Respondent (or a Divestiture Trustee) closes on a transaction to assign, grant, license, divest, transfer, deliver,

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or otherwise convey rights or assets related to a Divestiture Product to the Acquirer as required by Paragraph II of this Order.

- X. “Divestiture Products” means the:
1. Authorized Generic Products;
 2. Eplerenone Products; and
 3. Gatifloxacin Products.
- Y. “Divestiture Product Business” means the Business related to a Divestiture Product.
- Z. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph X of this Order or Paragraph IX of the Order to Maintain Assets.
- AA. “Domain Name” means the domain name(s) and the related uniform resource locator(s) and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration.
- BB. “Employee Information” means the following, for each Relevant Employee, as and to the extent permitted by law:
1. With respect to each such employee, the following information:
 - a. Name, job title or position, date of hire, and effective service date;
 - b. Specific description of the employee’s responsibilities;
 - c. Base salary or current wages;
 - d. Most recent bonus paid, aggregate annual compensation for the relevant Respondent’s last fiscal year, and current target or guaranteed bonus, if any;
 - e. Employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
 - f. All other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
 2. At the option of the Acquirer, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the Relevant Employees.

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- CC. “Eplerenone Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: ANDA 203896, and any supplements, amendments, or revisions to this ANDA.
- DD. “Eplerenone Divestiture Assets” means all rights, title and interest in the Divestiture Product Business related to the Eplerenone Products, including all of the Divestiture Assets related to the Eplerenone Products.
- EE. “Excluded Assets” mean:
1. Any real estate and the buildings and other permanent structures located on such real estate;
 2. Corporate names or corporate trade dress of a Respondent or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by a Respondent or the related corporate logos thereof; or general registered images or symbols by which a Respondent can be identified or defined;
 3. The portion of any Business Information that contains information about any of a Respondent’s business other than a Divestiture Product Business, in those cases in which the redaction does not impair the usefulness of the information related to the Divestiture Product Business;
 4. Any original document that a Respondent has a legal, contractual, or fiduciary obligation to retain the original; *provided, however*, that Respondents shall provide copies of the document to the Acquirer and shall provide that Acquirer access to the original document if copies are insufficient for regulatory or evidentiary purposes;
 5. (i) Any tax asset relating to (a) the Divestiture Assets for pre-Divestiture Date tax periods or (b) any tax liability that any Respondent is responsible for arising out of the divestiture of the Divestiture Assets, (ii) all accounts receivable, notes receivable, rebates receivable and other miscellaneous receivables of any Respondent that are related to the Divestiture Product Business and arising out of the operation of the Divestiture Product Business prior to the Divestiture Date, and (iii) all cash, cash equivalents, credit cards and bank accounts of any Respondent; and
 6. Any records or documents reflecting attorney-client, work product or similar privilege of any Respondent or otherwise relating to the Divestiture Assets as a result of legal counsel representing any Respondent in connection with the divestiture of the Divestiture Assets pursuant to this Order or the Divestiture Agreements.
- FF. “FDA” means the United States Food and Drug Administration.

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- GG. “FDA Authorization(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. “FDA Authorization” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- HH. “Gatifloxacin Product AG Assignment Agreement” means the Partial Assignment and Assumption Agreement by and between Upjohn US 2 LLC and Prasco, LLC, dated as of September 18, 2020.
- II. “Gatifloxacin Products” mean an authorized generic version of the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA #022548, and any supplements, amendments, or revisions to this NDA.
- JJ. “Levothyroxine Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 021301, and any supplements, amendments, or revisions to these NDAs
- KK. “Licensed Intellectual Property” means; (i) all Product Manufacturing Technology that is used (but not exclusively, predominantly, or primarily used) in the manufacture of a Divestiture Product, and (ii) copyrights used (but not exclusively, predominantly, or primarily used), to commercialize, distribute, market, advertise, or sell any Divestiture Product as of the applicable Divestiture Date.
- LL. “Manufacturing Designee” means any Person other than a Respondent that has been designated by the Acquirer to perform any part of the manufacturing process, including the finish or packaging of a Divestiture Product on behalf of that Acquirer.
- MM. “Monitor” means any monitor appointed pursuant to Paragraph IX of this Order or Paragraph VIII of the Order to Maintain Assets, hereinafter, Monitor Paragraphs.

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- NN. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code and package size code for a specific Product.
- OO. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- PP. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.
- QQ. “Orders” means this Decision and Order and the Order to Maintain Assets.
- RR. “Patent(s)” means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the Divestiture Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- SS. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or government entity, and any subsidiaries, divisions, groups, or affiliates thereof.
- TT. “Prasco” means (i) Prasco, LLC, a limited liability company organized, existing and doing business under the laws of the State of Ohio with its executive offices and principal place of business located at 6125 Commerce Court, Mason, Ohio 45040; and (ii) any Person controlled by or under common control of Prasco, LLC.
- UU. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient, or that is the subject of an FDA Authorization.
- VV. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other regulatory approvals, and pending applications and requests therefor, required by applicable Agencies, related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any FDA Authorization related to that Product.

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WW. “Product Contracts” means all contracts, agreements, mutual understandings, arrangements, or commitments related to the Divestiture Product Business, including those:

1. Pursuant to which any third party, including a Customer, purchases, or has the option to purchase, a Product from a Respondent or negotiates the purchase price on behalf of another Customer;
2. Pursuant to which a Respondent had, or has as of the Divestiture Date, the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), from any third party for use in connection with the manufacture of a Product;
3. Relating to any study of the safety or efficacy of a Product;
4. With universities or other research institutions for the use of a Product in scientific research;
5. For the marketing of a Product or educational matters relating solely to the Products;
6. Pursuant to which a third party manufactures or plans to manufacture a Product as a finished dosage form on behalf of a Respondent;
7. Pursuant to which a third party provides or plans to provide any part of the manufacturing process, including, without limitation, the finish or packaging of a Product on behalf of a Respondent;
8. Pursuant to which a third party licenses any Product Intellectual Property or Product Manufacturing Technology related to a Product to a Respondent;
9. Pursuant to which a third party is licensed by a Respondent to use any of the Product Intellectual Property or Product Manufacturing Technology;
10. Constituting confidentiality agreements involving a Product;
11. Involving any royalty, licensing, covenant not to sue, or similar arrangement related to a Product;
12. Pursuant to which a third party provides any specialized services necessary to the research, Development, manufacture, or distribution of a Product to a Respondent including, consultation arrangements; and

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13. Pursuant to which any third party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of a Product.
- XX. “Product Development Reports” means information related to the Development of a Product, including:
1. Pharmacokinetic study reports;
 2. Bioavailability study reports;
 3. Bioequivalence study reports;
 4. All correspondence, submissions, notifications, communications, registrations, or other filings made to, received from, or otherwise conducted with the FDA relating to the FDA Authorization(s);
 5. Annual and periodic reports related to the above-described FDA Authorization(s), including any safety update reports;
 6. FDA approved labeling or other Agency-approved labeling;
 7. Currently used or planned product package inserts (including historical change of controls summaries);
 8. FDA approved patient circulars;
 9. Adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy;
 10. Summaries of complaints from physicians or other health care providers;
 11. Summaries of complaints from ultimate users of the Product;
 12. Summaries of complaints from Customers;
 13. Product recall reports filed with the FDA or any other Agency, and all reports, studies, and other documents related to such recalls;
 14. Investigation reports and other documents related to any out of specification results for any impurities or defects found in any Product;
 15. Reports from any Person (e.g., any consultant or outside contractor) engaged to investigate or perform testing for the purposes of resolving any Product or process issues, including, without limitation, identification and sources of impurities or defects;

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16. Reports from vendors of the component(s), active pharmaceutical ingredient(s), excipient(s), packaging component(s), and detergent(s) used to produce any Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of any Product;
 17. Analytical methods development records;
 18. Manufacturing batch or lot records;
 19. Stability testing records;
 20. Change in control history; and
 21. Executed validation and qualification protocols and reports.
- YY. “Product Intellectual Property” means intellectual property of any kind (other than Licensed Intellectual Property), that is owned, licensed, held, or controlled by a Respondent as of the Divestiture Date, including Patents, patent applications, trademarks, service marks, copyrights, trade dress, commercial names, internet web sites, internet domain names, inventions, discoveries, know-how, trade secrets, and proprietary information.
- ZZ. “Product Manufacturing Equipment” means equipment that is being used, or has been used to manufacture the specified Divestiture Product.
- AAA. “Product Manufacturing Technology” means all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of a Product, including the following: all product specifications, processes, analytical methods, product designs, plans, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the conformance of any Product Approvals, conformance with any Agency requirements, and cGMP compliance, labeling and all other information related to the manufacturing process, and supplier lists.
- BBB. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the United States as of the Divestiture Date that are owned or controlled by a Respondent, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), Customer information (including Customer net purchase information to

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be provided on the basis of dollars and units for each month, quarter or year), sales forecasting models, educational materials, advertising and display materials, speaker lists, promotional and marketing materials, website content, artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.

CCC. “Product Releasee(s)” means any of the following Persons:

1. The Acquirer;
2. Any Person controlled by or under common control with that Acquirer;
3. Any Manufacturing Designee(s); and
4. Any licensees, sublicensees, manufacturers, suppliers, marketers, distributors, and Customers of that Acquirer, or of such Acquirer-affiliated entities, in each such case, as related to each Divestiture Product acquired by that Acquirer.

DDD. “Relevant Employees” includes:

1. Manufacturing Employees means all employees of a Respondent who have participated at any time during the 3-year period immediately prior to the Acquisition Date (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) in any of the following related to the specified Divestiture Product: (i) Developing and validating the commercial manufacturing process, (ii) formulating the manufacturing process performance qualification protocol, (iii) controlling the manufacturing process to assure performance Product quality, (iv) assuring that during routine manufacturing the process remains in a state of control, (v) collecting and evaluating data for the purposes of providing scientific evidence that the manufacturing process is capable of consistently delivering quality Products, (vi) managing the operation of the manufacturing process, or (vii) managing the transfer of the Product Manufacturing Technology to a different facility; and
2. Marketing Employees means all management-level employees of a Respondent who have participated at any time during the 3-year period immediately prior to the Acquisition date (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) in any of the following related to the specified Divestiture Product: sales management, brand management, sales training, market research, or marketing and contracting with any of the following: drug wholesalers or distributors,

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group purchasing organizations, pharmacy benefit organizations, managed care organizations, or hospitals, *excluding* administrative assistants.

- EEE. “Retained Product(s)” means any Product(s) other than a Divestiture Product that is manufactured, in Development, marketed, sold, owned, controlled, or licensed by a Respondent anywhere in the world on or before the Acquisition Date and that has not been discontinued or permanently withdrawn from the market.
- FFF. “Sucralfate Products” mean the Products in Development or manufactured anywhere in the world and authorized for marketing or sale in the United States pursuant to the following FDA Authorization: ANDA No. 074415, and any supplements, amendments, or revisions to this ANDA.
- GGG. “Supply Cost” means the actual cost of materials, ingredients, packaging, direct labor, and direct overhead *excluding* any allocation or absorption of costs for excess or idle capacity, and *excluding* any intracompany transfer profits *plus* the actual cost of shipping and transportation in cases in which those costs are incurred by a Respondent.
- HHH. “Technology Transfer Standards” mean requirements and standards sufficient to ensure that the information and assets required to be transferred and delivered are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, as related to the specified Divestiture Product(s), *inter alia*:
1. Designating employees or other Persons working on behalf of a Respondent knowledgeable about the Product Manufacturing Technology who will be responsible for communicating directly with the receiving Person, and a Monitor, for the purpose of effecting such delivery;
 2. Preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the Product that are acceptable to the receiving Person;
 3. Preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology to the receiving Person;
 4. For any part of the manufacturing process that is performed by a Respondent, permitting employees of the receiving Person to visit the Respondent’s facility where that process occurs for the purposes of evaluating and learning that process or discussing the process with employees of the Respondent involved in that process (including, without

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limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, and methods to ensure batch or lot consistency); and

5. Providing, in a timely manner, assistance and advice to enable the receiving Person to:
 - a. Manufacture the Product in the quality and quantities achieved by a Respondent prior to the Acquisition Date;
 - b. Obtain any Product Approvals necessary for the receiving Person to manufacture the Product for the Acquirer in a manner that allows that Acquirer to distribute, market, and sell the Product in commercial quantities and to meet all Agency-approved specifications for the Product; and
 - c. Receive, integrate, and use all Product Manufacturing Technology used in, and all Product Intellectual Property that is related to, the manufacture of the Product.

III. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product or that otherwise meets the FDA’s criteria for such classification.

JJJ. “Varenicline Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 021928 and any supplements, amendments, or revisions to this NDA.

KKK. “United States” means the United States of America, and its territories, districts, commonwealths, and possessions.

II. Divestitures

IT IS FURTHER ORDERED that:

- A. No later than 10 days after the Acquisition Date, Respondents shall, absolutely and in good faith, pursuant to the Divestiture Agreements:
 1. Divest the Eplerenone Divestiture Assets and grant a perpetual, non-exclusive, fully paid up, fully transferable, and royalty-free license to use the related Licensed Intellectual Property in the related Divestiture Product Business to Prasco;
 2. Grant the Authorized Generic Product License for each of the Authorized Generic Products to Prasco; and

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3. Assign all rights granted to any Respondent to market, promote, distribute, sell, and offer for sale an authorized generic of the Gatifloxacin Products to Prasco; *provided, however* that Respondents may satisfy this requirement by providing an executed copy of a direct agreement between Prasco and the holder of the FDA Authorization of Gatifloxacin Products granting Prasco exclusive rights to market, promote, distribute, sell, and offer for sale an authorized generic of the Gatifloxacin Products;

provided, further, however, that, if within 12 months after the Order Date, the Commission determines, in consultation with the Acquirer and a Monitor, the Acquirer needs one or more Excluded Assets to operate any of the Divestiture Product Businesses in a manner that achieves the purposes of this Order, Respondents shall divest or license (as applicable) absolutely and in good faith, the needed Excluded Assets to that Acquirer.

- B. With respect to the Authorized Generic Product License, Respondents shall:
 1. Permit the Acquirer to terminate the license on a product-by-product basis without penalty;
 2. Not terminate the license due to (i) a breach by the Acquirer, or (ii) the Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;
 3. Not withdraw or discontinue the FDA Authorization for any of the Authorized Generic Products other than as permitted under this Order; and
 4. Permit the Acquirer to acquire the FDA Authorization from the holder at no cost should the holder withdraw or discontinue the FDA Authorization for any reason.
- C. If Respondents have divested any of the Divestiture Assets or granted or assigned rights to the Divestiture Products to the Acquirer who is named in this Order prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that:
 1. The named Acquirer is not an acceptable purchaser of any of the Divestiture Assets or rights related to the Divestiture Products, then Respondents shall immediately rescind the transaction with that Acquirer as directed by the Commission, and shall divest the respective Divestiture Assets or grant or assign the rights related to the Divestiture Products, as applicable, within 180 days after the Order Date, absolutely and in good faith, at no minimum price, to a different Acquirer that receives the prior

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approval of the Commission, and only in a manner that receives the prior approval of the Commission; or

2. The manner in which the divestiture was accomplished is not acceptable, then Respondents shall make such modifications to the manner of divestiture of the Divestiture Assets or the grant or assignment of rights to the Divestiture Products, as applicable, to the Acquirer named in this Order (including, entering into additional agreements or arrangements) as the Commission determines are necessary to satisfy the requirements of this Order.

- D. Prior to the Divestiture Date, Respondents shall provide the Acquirer with the opportunity to review Product Contracts related to each of the Divestiture Products so that the Acquirer can determine whether to assume each Product Contract;

provided, however, that in cases in which any Product Contract also relates to a Retained Product the Respondent shall, at the option of that Acquirer, assign or otherwise make available to that Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product.

- E. Prior to the Divestiture Date, Respondents shall secure all approvals, consents, ratifications, waivers, or other authorizations from all non-governmental third parties that are necessary to permit Respondents to divest the Divestiture Assets and to grant or assign rights to the Divestiture Products to the Acquirer, and to permit that Acquirer to continue in the related Divestiture Product Business in the United States without interruption or impairment.
- F. As related to the Product Manufacturing Technology and any ingredient, material, or component used in the manufacture of the Divestiture Product, Respondents shall not enforce any agreement against a third party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the third party a license or other right to the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product. Such agreements include agreements that might limit the ability of a third party to disclose Confidential Business Information related to such Product Manufacturing Technology to the Acquirer. No later than 10 days after the Divestiture Date, Respondents shall grant a release to each third party that is subject to any such agreement that allows the third party to provide the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product to the Acquirer. Within 5 days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer;

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provided, however, Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant third parties.

- G. Respondents shall transfer the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer, with the consent of the Acquirer, or at the Acquirer's option, to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Respondent Pfizer shall be responsible for validating and qualifying the manufacture of these Products at either a facility that is retained by Respondent Pfizer after the Acquisition Date or at a facility owned or controlled by the Manufacturing Designee in order to obtain FDA Approvals to manufacture these Products from such facilities and Respondents shall bear all costs related to these transfers.
- H. If, at any time during the term of the Authorized Generic Product License, the Acquirer notifies the Respondents that the Acquirer wants to move manufacturing of an Authorized Generic Product out of a facility owned or controlled by a Respondent, then such Respondent shall transfer the Product Manufacturing Technology to that Acquirer, or to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Such Respondent shall be responsible for ensuring the validation and qualification of the manufacture of these Products at the facility chosen by that Acquirer in order to obtain FDA Approvals to manufacture these Products from that facility. Such Respondent shall bear all costs related to this transfer.
- I. No later than 10 days after the Divestiture Date, Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale of each of the Divestiture Products to assist the Acquirer of each of the Divestiture Products to transfer and integrate the related Divestiture Product Business.
- J. No later than 10 days after the Divestiture Date, Respondents shall provide the following to the relevant Acquirer of each of the Divestiture Products:
 - 1. A list of any finished batch or lot of the relevant Divestiture Product that any Respondent, any manufacturer for a Respondent, or regulatory Agency determined to be out-of-specification at any time during the three-year period immediately preceding the Divestiture Date, and, for each such batch or lot: (i) a detailed description of the known deficiencies or defects (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure); (ii) the corrective actions taken to remediate any cGMP deficiencies in that Divestiture Product; and (iii) to the extent known by any Respondent, the employees (whether current or former) responsible for taking such corrective actions;

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2. A list by stock-keeping unit by Customer that contains the current net price per unit as packaged for sale (*i.e.*, the price net of all customer-level discounts, rebates, or promotions) for the relevant Divestiture Product for each order sold to that Customer during the two-year period prior to the Divestiture Date;
 3. A list of the inventory levels (weeks of supply) of the relevant Divestiture Product in the possession of each Customer to the extent known or available to any Respondent, as of the date prior to and closest to the Divestiture Date as is available;
 4. A list of any pending reorder dates for the relevant Divestiture Product by Customer as of the Divestiture Date to the extent known by any Respondent;
 5. A list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by law, to control, prohibit, or otherwise limit the use, including the use in Customer cross-referencing, of such NDC numbers by the Respondents, *unless* that Divestiture Product has not been marketed or sold in the United States prior to the Divestiture Date; and
 6. The quantity and delivery terms in all unfilled Customer purchase orders for the relevant Divestiture Product as of the Divestiture Date.
- K. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Product Releasees under any Patent that was pending or issued on or before the Acquisition Date if such suit would limit or impair the Acquirer's freedom to research and Develop, or manufacture anywhere in the world the Divestiture Product(s), or to distribute, market, sell, or offer for sale within the United States any such Divestiture Product.
- L. Upon reasonable written request from the Acquirer to a Respondent, that Respondent shall provide, in a timely manner, assistance of knowledgeable employees of that Respondent (*i.e.*, employees of that Respondent that were involved in the Development of the Divestiture Products) to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a third party related to the Product Intellectual Property for the Divestiture Products acquired by that Acquirer from a Respondent. A Respondent shall make its employees available to that Acquirer for the fee provided in the relevant Divestiture Agreement, or if no fee is provided, at no greater than Direct Cost.
- M. For any patent infringement suit that is filed or to be filed within the United States that is (i) filed by, or brought against, a Respondent prior to the Divestiture Date related to any Divestiture Product or (ii) any potential patent infringement suit that a Respondent has prepared, or is preparing, to bring or defend against as of

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the Divestiture Date that is related to any Divestiture Product, that Respondent shall:

1. Cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of such patent infringement suit;
2. Waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the Acquirer in any such patent infringement suit; and
3. Permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to such patent infringement suit.

III. Divestiture Agreements

IT IS FURTHER ORDERED that:

- A. The Divestiture Agreements shall be incorporated by reference into this Order and made a part hereof, and any failure by a Respondent to comply with any term of the Divestiture Agreements shall constitute a violation of this Order; *provided however*, that the Divestiture Agreements shall not limit, or be construed to limit, the terms of this Order. To the extent any provision in the Divestiture Agreements varies from or conflicts with any provision in this Order such that the Respondents cannot fully comply with both, Respondents shall comply with this Order.
- B. Respondents shall include in the Divestiture Agreements a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondents' obligations to the Acquirer pursuant to this Order.
- C. Respondents shall not modify or amend any of the terms of any Divestiture Agreement without the prior approval of the Commission, *except* as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5).

IV. Transition Services and Manufacturing by Respondents

IT IS FURTHER ORDERED that:

- A. At the request of the Acquirer, in a timely manner, at no greater than Direct Cost or at such cost as provided in a Divestiture Agreement, Respondents shall provide transition services sufficient to enable the Acquirer of each of the Divestiture Products to operate the related Divestiture Product Business in substantially the

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same manner that Respondents have operated that Business prior to the Acquisition Date.

- B. Upon reasonable written notice and request from the Acquirer of the rights to the Authorized Generic Products, Respondents shall manufacture, deliver and supply, or cause to be manufactured, delivered, and supplied, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, that Acquirer's requested supply of each of the Authorized Generic Products and any of the active pharmaceutical ingredients used in the Authorized Generic Products that are made by a Respondent, as applicable, hereinafter "Supplied Products." For the initial 10-year term of the Authorized Generic Agreement, the requested supply of Supplied Products shall be provided at no greater than Supply Cost or at such cost as provided in a Divestiture Agreement.
- C. The Respondents shall make representations and warranties to the Acquirer that the Supplied Products meet the relevant Agency-approved specifications.
- D. The Respondents shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Supplied Products to meet cGMP, but the Respondents may make this obligation contingent upon the Acquirer giving the Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the Respondents may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondents' responsibilities to supply the Supplied Products in the manner required by this Order;

provided further, however, that this obligation shall not require the Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the Respondents to the Acquirer in a Divestiture Agreement.

- E. The Respondents shall agree to hold harmless and indemnify the Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of the Respondents to deliver the Supplied Products to the Acquirer in a timely manner *unless* (i) Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents, and (ii) Respondents are able to cure the supply failure no later than 30 days after the receipt of notice from that Acquirer of a supply failure.
- F. The Respondents shall give priority to supplying the Acquirer over the supplying of Products for any Respondent's own use or sale.

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- G. During the term of any agreement for a Respondent to supply the Supplied Products, upon written request of the Acquirer or a Monitor, the Respondent shall make available to the supplied Acquirer and a Monitor all records generated or created after the Divestiture Date that relate directly to the manufacture of the applicable Supplied Products.
- H. The Respondents shall provide the Acquirer with the actual costs incurred or the price paid for active ingredients, components, and excipients the Respondents use to manufacture the applicable Supplied Products.
- I. During the term of any agreement for a Respondent to supply the Supplied Products, Respondents shall take all actions as are reasonably necessary to ensure an uninterrupted supply of each of the Supplied Products.
- J. Respondents shall not be entitled to terminate any agreement to supply the Supplied Products due to (i) a breach by the Acquirer of a Divestiture Agreement, or (ii) that Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;

provided, however, that this Paragraph shall not prohibit a Respondent from seeking compensatory damages from the Acquirer for that Acquirer's breach of its payment obligations to the Respondent under the agreement.
- K. The Respondents shall permit the Acquirer to terminate the agreement for the supply of the Supplied Products on a product-by-product basis, at any time, upon commercially reasonable notice, and without cost or penalty (other than costs or penalties due by the Respondent to third parties pursuant to the termination of such agreement, which may be the responsibility of that Acquirer).
- L. In the event that that a Respondent becomes (i) unable to supply or produce a Supplied Product from the facility that has been supplying the Acquirer, and (ii) any Respondent has a different facility that is listed on the FDA Authorization for that Supplied Product and is still suitable for use to manufacture the Supplied Product, or any Respondent has a facility that manufactures the Therapeutic Equivalent of such Supplied Product, then such Respondent shall, at the option of the supplied Acquirer, provide a supply of either the Therapeutic Equivalent or the Supplied Product from the other facility under the same terms and conditions as contained in the Divestiture Agreement to supply.
- M. During the term of any agreement for a Respondent to supply the Supplied Products, the Respondents shall provide consultation with knowledgeable employees of Respondents and training, at the written request of the supplied Acquirer and at a facility chosen by the supplied Acquirer, for the purposes of enabling that Acquirer (or its Manufacturing Designee) to obtain all Product

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Approvals to manufacture the applicable Supplied Products in final form in the same quality achieved by, or on behalf of, Respondents and in commercial quantities, in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of that Acquirer that its personnel (or its Manufacturing Designee's personnel) are adequately trained in the manufacture of the applicable Supplied Products.

- N. For any Supplied Product that, after the Acquisition Date, is made in a facility owned by Respondent Upjohn or Respondent Viatris, Respondents shall transfer such manufacturing to a facility owned, controlled, or operated by Respondent Pfizer or, at the option of the Acquirer, to its Manufacturing Designee. Respondents shall bear all costs for this transfer including the cost to validate the Supplied Products at the changed facility and the costs for any changes in the specifications for any Supplied Product required by the FDA prior to the FDA's granting approval to market such Product from the changed site of manufacture.
- O. For any Authorized Generic Product that, after the Acquisition Date, has as its source of the active pharmaceutical ingredient either Respondent Upjohn or Respondent Viatris: (i) Respondents shall give priority to supplying the active pharmaceutical ingredients for use in such Authorized Generic Product over supplying the active pharmaceutical ingredients for any Product for any Respondent's own use or sale, and (ii) at the Acquirer's option, Respondents shall bear the costs to qualify and obtain FDA regulatory approval to change the source of the active pharmaceutical ingredient(s).

V. Asset Maintenance

IT IS FURTHER ORDERED that, until the Respondents have physically transferred the Eplerenone Divestiture Assets, granted the Authorized Generic Product License and assigned the rights to the Gatifloxacin Products to the Acquirer pursuant to Paragraph II of this Order, Respondents shall operate and maintain each of the respective Divestiture Assets and each of the respective Divestiture Product Businesses in the ordinary course of business consistent with past practices. Included in these obligations, Respondents shall:

- A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses, to minimize the risk of loss of competitive potential of such Divestiture Product Businesses, to operate such Divestiture Product Businesses in a manner consistent with applicable laws and regulations, and to prevent the destruction, removal, wasting, or deterioration of any of the Divestiture Assets, except for ordinary wear and tear.
- B. Not sell, transfer, encumber, or otherwise impair such Divestiture Assets, or terminate any of the operations of such Divestiture Product Businesses, other than in the ordinary course of business consistent with past practice or as prescribed in the Orders.

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- C. Make all payments required to be paid under any contract or lease when due, and pay all liabilities and satisfy all obligations associated with such Divestiture Product Businesses.
- D. Provide such Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls, to perform routine or necessary maintenance, to repair or replace facilities and equipment, and to carry on, at least at their scheduled pace, all capital projects, business plans, promotional plans, capital expenditure plans, research and development plans, and commercial activities for such Divestiture Product Businesses.
- E. Use best efforts to preserve the existing relationships and goodwill with suppliers, customers, employees, vendors, distributors, landlords, licensors, licensees, government entities, brokers, contractors, and others having business relations with such Divestiture Product Businesses.
- F. Maintain the working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with such Divestiture Product Businesses, including by:
 - 1. Filling vacancies that occur in the regular and ordinary course of business consistent with past practice; and
 - 2. Not transferring any employees from such Divestiture Product Businesses to another of Respondents' businesses.
- G. Maintain and preserve the Business Information of such Divestiture Product Businesses.
- H. Provide the resources necessary for such Divestiture Product Businesses to respond to competition, prevent diminution in sales, and maintain its competitive strength.
- I. Continue providing customary levels of support services to such Divestiture Product Businesses.
- J. Maintain all licenses, permits, approvals, authorizations, or certifications used in the operation of such Divestiture Product Businesses, and operate such Divestiture Product Businesses in accordance and compliance with all regulatory obligations and requirements.
- K. Maintain the levels of production, quality, pricing, service, or customer support typically associated with such Divestiture Product Businesses.

Provided, however, Respondents may take actions that the Acquirer has requested or agreed to in writing and that has been approved in advance by a Monitor (in

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consultation with Commission staff), in all cases to facilitate that Acquirer's acquisition of the Divestiture Assets and rights in the Divestiture Products and consistent with the purposes of the Orders.

VI. Employees**IT IS FURTHER ORDERED** that:

- A. Until 2 years after the Divestiture Date, Respondents shall cooperate with and assist the Acquirer to evaluate independently and offer employment to the Relevant Employees for the Divestiture Products acquired by that Acquirer.
- B. Respondents shall:
 - 1. No later than 10 days after a request from the Acquirer, provide to that Acquirer a list of all Relevant Employees and provide Employee Information for each Relevant Employee;
 - 2. No later than 10 days after a request from the Acquirer, provide that Acquirer or its Manufacturing Designee an opportunity to meet individually and outside the presence or hearing of any employee or agent of Respondents with any of the Relevant Employees, and to make offers of employment to any of the Relevant Employees;
 - 3. Remove any impediments within the control of Respondents that may deter Relevant Employees from accepting employment with the Acquirer or its Manufacturing Designee, including, but not limited to, removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee, and shall not make any counteroffer to a Relevant Employee who receives an offer of employment from that Acquirer or its Manufacturing Designee; *provided, however*, that nothing in the Orders shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee; and
 - 4. Not interfere, directly or indirectly, with the hiring or employing by that Acquirer or its Manufacturing Designee of any Relevant Employees, not offer any incentive to such employees to decline employment with that Acquirer or its Manufacturing Designee, and not otherwise interfere with the recruitment of any Relevant Employees by that Acquirer.
- C. Respondents shall continue to provide Relevant Employees compensation and benefits, including regularly scheduled raises and bonuses, until the Divestiture Date or as may be necessary to comply with the provisions of the Orders to

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provide manufacturing and supply of Divestiture Products or transition services to the Acquirer.

- D. Respondents shall provide reasonable financial incentives for Relevant Employees to continue in their positions, and as may be necessary, to facilitate the employment of such Relevant Employees by the Acquirer.
- E. If, at any point within 6 months of the Divestiture Date, the Commission, in consultation with the Acquirer and a Monitor, determines in its sole discretion that the Acquirer or its Manufacturing Designee should have the ability to interview, make offers of employment to, or hire any of Respondents' employees who were not included as Relevant Employees, but who either (i) were involved with any of the Divestiture Products, or (ii) provided manufacturing and supply of Divestiture Products or transition services to the Acquirer, then the Commission may notify Respondents that such employees are to be designated as Relevant Employees, and Paragraph VI of this Order shall apply to such employees as of that notification date.
- F. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any of the Relevant Employees who have accepted offers of employment with the Acquirer or its Manufacturing Designee to terminate his or her employment with the Acquirer or its Manufacturing Designee; *provided, however*, Respondents may:
 - 1. Hire an employee whose employment has been terminated by the Acquirer;
 - 2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more of Relevant Employees; and
 - 3. Hire an employee who has applied for employment with Respondents, as long as such application was not solicited or induced in violation of this Paragraph.

VII. Business Information

IT IS FURTHER ORDERED that:

- A. Respondents shall transfer and deliver all Business Information related to a Divestiture Product Business to the Acquirer pursuant to the following:
 - 1. Respondents shall deliver the Business Information to that Acquirer, at Respondents' expense, in good faith, in a timely manner (*i.e.* as soon as practicable, avoiding any delays in transmission), and in a manner that

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ensures the completeness and accuracy of all information and ensures its usefulness;

2. Pending complete delivery of all Confidential Business Information, Respondents shall provide that Acquirer with access to all Business Information and to employees who possess or are able to locate this information for the purposes of identifying the Business Information that contains Confidential Business Information and facilitating the delivery in a manner consistent with the Orders;
3. Not use, directly or indirectly, any such Confidential Business Information other than as necessary to comply with the following:
 - a. The requirements of the Orders;
 - b. Respondents' obligations to that Acquirer under the terms of the related Divestiture Agreements; or
 - c. Applicable law;
4. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person *except* (i) that Acquirer, (ii) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (*e.g.*, employees of a Respondent providing transition services, manufacturing Divestiture Products, or who are engaged in the transfer and delivery of the Product Manufacturing Technology), (iii) the Commission, or (iv) a Monitor, and *except* to the extent necessary to comply with applicable law;
5. Not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information to the employees associated with the business that is being retained, owned, or controlled by a Respondent, other than those employees specifically authorized as described above;
6. Institute procedures and requirements to ensure that those employees of a Respondent that are authorized by that Acquirer to have access to such Confidential Business information:
 - a. Do not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information in contravention of the Orders; and
 - b. Do not solicit, access, or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose; and

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7. Take all actions necessary and appropriate to prevent access to, and the disclosure or use of, such Confidential Business Information by or to any Person(s) not authorized to access, receive, or use such information pursuant to the terms of the Orders or the Divestiture Agreements, including:
 - a. Establishing and maintaining appropriate firewalls, confidentiality protections, internal practices, training, communications, protocols, and system or network controls and restrictions;
 - b. To the extent practicable, maintaining such Confidential Business Information separate from other data or information of any Respondent; and
 - c. Ensuring by other reasonable and appropriate means that such Confidential Business Information is not shared with a Respondent's personnel engaged in any Business related to the same or substantially the same type of Business as the Divestiture Products, including a Respondent's personnel engaged in the marketing and sale within the United States of Products Developed or in Development for the same or similar indications as the Divestiture Products or that use the same active pharmaceutical ingredients as the Divestiture Products.
- B. As a condition of continued employment after the Divestiture Date, Respondents shall require each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one-year period prior to the Divestiture Date, and each employee that has responsibilities related to the Development, marketing, or sales of those Retained Products that are Developed or in Development for the same or similar indications as the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all such Confidential Business Information as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of any Respondent (other than as necessary to comply with the requirements of the Orders).
- C. No later than 30 days after the Divestiture Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the above-described Confidential Business Information by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for 2

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years after the Divestiture Date. Respondents shall provide a copy of their notifications to the Acquirer. Respondents shall maintain complete records of all such notifications at the respective Respondent's principal executive offices within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide that Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.

D. Each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to the Acquirer or access original documents provided to that Acquirer, except under circumstances in which copies of documents are insufficient or otherwise unavailable, and for the following purposes:

1. To assure such Respondent's compliance with any Divestiture Agreement, the Orders, any law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable government entity, or any taxation requirements; or
2. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of an Divestiture Product, the Divestiture Assets, or the Divestiture Product Business;

provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided further, however, that pursuant to this Paragraph, a Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VIII. Additional Obligations

IT IS FURTHER ORDERED that, during the term of the license of any Authorized Generic Product to the Acquirer pursuant to Paragraph II of this Order, Respondent Pfizer shall retain and maintain each FDA Authorization that is the FDA Authorization for an Authorized Generic Product unless:

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- A. Respondent Pfizer transfers such FDA Authorization to the Acquirer;
- B. The FDA requires the withdrawal of the FDA Authorization for safety or efficacy reasons;
- C. Respondent Pfizer demonstrates, in consultation with that Acquirer and a Monitor, that a withdrawal of the FDA Authorization is necessary due to safety issues based on adverse events, serious adverse events, unexpected adverse events, or other pharmacovigilance reported to the FDA since the Divestiture Date; or
- D. The Acquirer consents to the Respondent Pfizer's withdrawal of the FDA Authorization.

IX. Monitor**IT IS FURTHER ORDERED** that:

- A. The Commission appoints F. William Rahe and William Hitchings of Quantic Regulatory Services Inc. as Monitors to observe and report on Respondents' compliance with the terms of the Orders. The Monitors shall serve pursuant to the agreement contained in the Monitor Agreement Appendix to the Orders, *provided, however*, such agreement shall not limit, or be construed to limit, the terms of the Monitor Paragraphs of the Orders.
- B. No later than one day after the Commission issues the Order to Maintain Assets, Respondents shall:
 - 1. Confer on the Monitors all rights, power, and authorities necessary to permit the Monitors to monitor Respondents' compliance with the terms of the Orders as set forth in the Monitor Paragraphs of the Orders; and
 - 2. Consent to the terms and conditions regarding such rights, powers, and authorities of the Monitors set forth in the Monitor Paragraphs of the Orders.
- C. The Monitors:
 - 1. Shall have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;
 - 2. Shall act in consultation with the Commission or its staff;
 - 3. Shall serve as an independent third party and not as an employee, or agent of the Respondents or of the Commission;
 - 4. Shall serve the expense of Respondents, without bond or other security;

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5. May employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out that Monitor's duties and responsibilities;
 6. Shall enter into a confidentiality agreement related to Commission materials and information received in connection with the performance of that Monitor's duties and each of that Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into such a confidentiality agreement;
 7. Shall notify Respondents and staff of the Commission, in writing, of any potential financial, professional, personal, or other conflicts of interest within 5 days should they arise;
 8. Within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission, shall report in writing to the Commission regarding Respondents' compliance with their obligations under the Orders; and
 9. Shall serve until that Monitor, in conjunction with Commission staff, determines that all obligations for the Respondents to provide manufacturing and supply of Divestiture Products have expired or been terminated and a final report is filed within 30-days after that date or until such other time as may be determined by the Commission or its staff.
- D. Respondents shall (i) provide the Monitors full and complete access to all information and facilities, and, as necessary, make such arrangements with third parties, to allow the Monitors to monitor Respondents' compliance with its obligations under the Orders; and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitors to perform their duties pursuant to the Orders.
- E. Respondents shall indemnify and hold the Monitors harmless against losses, claims, damages, liabilities, or expenses (including attorney's fees and out of pocket costs) that arise out of, or in connection with, any claim concerning the Monitors' performance of the Monitors' duties under the Orders, whether or not such claim results in liability, *except*, to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitors' gross negligence or willful misconduct. For purposes of this Paragraph, the term "Monitor" shall include all persons retained by the Monitors in the performance of their duties under the Orders.
- F. Respondents may require the Monitors and each of the Monitors' consultants, accountants, attorneys, and other representatives and assistants to enter into a

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customary confidentiality agreement; *provided, however*, that such agreement does not restrict the Monitors from providing any information to the Commission.

- G. Respondents shall not require nor compel the Monitors to disclose to Respondents the substance of communications with the Commission, including the Monitors' written reports submitted to the Commission, or any other Person with whom the Monitors communicate in the performance of their duties.
- H. If the Commission determines that the Monitors have ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor and such substitute Monitor shall be afforded all rights, powers, and authorities and subject to all obligations of a Monitor under the Monitor Paragraphs of the Orders:
 - 1. The Commission shall select the substitute Monitor, subject to the consent of Respondents which consent shall not be unreasonably withheld. Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor if, upon notice by staff of the Commission of the identity of the substitute Monitor to Respondents, Respondents have not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within 10 days after such notice; and
 - 2. Not later than 5 days after the Commission appoints a substitute Monitor, Respondents shall enter into an agreement with the substitute Monitor that (i) contains substantially the same terms as the agreement attached as Monitor Agreement Appendix to the Orders or (ii) is approved by the Commission and confers on the substitute Monitor the rights, powers, and authority of a Monitor under the Monitor Paragraphs of the Orders.
- I. The Commission may on its own initiative or at the request of a Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

X. Divestiture Trustee**IT IS FURTHER ORDERED** that:

- A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Assets or the rights to the Divestiture Products as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither

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the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by a Respondent to comply with the Orders.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. No later than 10 days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
 - 2. The Divestiture Trustee shall have one year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one- year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission;

provided, however, the Commission may extend the divestiture period only two (2) times.
 - 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books,

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records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by a Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to the Acquirer that receives the prior approval of the Commission as required by this Order;

provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission;

provided further, however, that Respondents shall select such Person within 5 days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

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6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 30 days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement;

provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

XI. Prior Approvals

IT IS FURTHER ORDERED that,

- A. Each Respondent (other than Respondent Pfizer) shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any rights or interests in

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the Levothyroxine Products, the Sucralfate Products or the Varenicline Products, or the Therapeutic Equivalent of any of these Products without the prior approval of the Commission.

- B. Respondent Pfizer shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any voting or non-voting stock, equity, notes convertible into any voting or non-voting stock rights or interests, or debt in Respondent Viatrix, Respondent Upjohn, or Respondent Mylan without the prior approval of the Commission.

XII. Compliance Reports

IT IS FURTHER ORDERED that:

- A. Respondents shall:
1. Notify Commission staff via email at bccompliance@ftc.gov of the Acquisition Date and the Divestiture Dates no later than 5 days after the occurrence of each; and
 2. Submit the complete copies of each of the Divestiture Agreements to the Commission at ElectronicFilings@ftc.gov and bccompliance@ftc.gov no later than 30 days after the Divestiture Date.
- B. Respondents shall file verified written reports (“Compliance Reports”) in accordance with the following:
1. Respondents shall submit interim Compliance Reports within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter until Respondents have completed all of the following: (i) the transfer and delivery of the Divestiture Assets and the rights to the Divestiture Products to the Acquirer, (ii) the transfer and delivery of all of the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer or to Pfizer’s designated third-party contract manufacturer, (iii) the transfer and delivery of all Business Information to the Acquirer, and (iv) Respondent Pfizer or a third-party contract manufacturer (non-Respondent) designated by Pfizer is FDA approved to manufacture each of the Authorized Generic Products at a facility that is owned or controlled by Pfizer after the Acquisition Date or by Pfizer’s designated third-party contract manufacturer; and Respondents shall submit annual Compliance Reports one year after the Order Date, and annually for the following 9 years on the anniversary of the Order Date; and additional Compliance Reports as the Commission or its staff may request;

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2. Respondent Pfizer shall continue to submit interim Compliance Reports every 6 months regarding Respondent Pfizer's provision of manufacturing and supply of the Authorized Generic Products to the Acquirer, including a detailed explanation of any manufacturing disruptions or any failures to supply the quantity of ordered Product to that Acquirer, and any other related requirements of the Orders;
3. Each Respondent's Compliance Report shall contain sufficient information and documentation to enable the Commission to determine independently whether the Respondent is in compliance with the Orders. Conclusory statements that the Respondent has complied with its obligations under the Orders are insufficient. Respondents shall include in their Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance:
 - a. A detailed description of all substantive contacts, negotiations, or recommendations related to the transfer and delivery to the Acquirer of (i) the Divestiture Assets and the rights to the Divestiture Products, (ii) the Business Information related to each of the Divestiture Product Businesses, and (iii) the provision of manufacturing and supply of Authorized Generic Products to that Acquirer;
 - b. A detailed description of the transfer of the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer or to Pfizer's designated third-party contract manufacturer and progress toward the manufacturing of these products at a facility retained by Pfizer or Pfizer's designated third-party contract manufacturer; and
 - c. A detailed description of the timing for the completion of such obligations.
4. Each annual Compliance Report shall include the previous year's market information for each market alleged in the Complaint including the aggregate size of the market in units and in dollars; the monthly sales in units and in dollars, separately for each strength, for each market participant; the market share for each market participant calculated based on units and on dollars; and, to the extent known, an explanation of any significant changes in the total size of the market and any significant adverse impacts to the manufacture or supply of competing products to the market;
5. Respondents shall retain all material written communications with each party identified in the Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling

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Respondents' obligations under the Orders and provide copies of these documents to Commission staff upon request.

- C. Respondents shall verify each Compliance Report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or other officer or employee specifically authorized to perform this function. Respondents shall submit an original and 2 copies of each Compliance Report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov. In addition, Respondents shall provide a copy of each Compliance Report to each Monitor.

XIII. Change in Respondents

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least 30 days prior to:

- A. The dissolution of: Pfizer Inc., Upjohn Inc., Viatris Inc., and Mylan N.V.;
- B. Any proposed acquisition, merger, or consolidation of Pfizer Inc., Upjohn Inc., Viatris Inc., and Mylan N.V.; or
- C. Any other change in Respondents including, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

XIV. Access

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with the Orders, subject to any legally recognized privilege, upon written request, and upon 5 days' notice to a Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with the Orders, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and
- B. To interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

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XV. Purpose

IT IS FURTHER ORDERED that the purpose of this Order is to remedy in a timely and sufficient manner the lessening of competition as alleged in the Commission's Complaint by:

- A. Ensuring that the Acquirer can continue to use the Divestiture Assets and rights in the Divestiture Products granted or assigned pursuant to this Order for the purposes of each of the respective Divestiture Product Businesses within the United States; and
- B. Creating a viable and effective competitor in the respective Divestiture Product Businesses within the United States.

XVI. Term

IT IS FURTHER ORDERED that this Order shall terminate on January 25, 2031.

By the Commission, Acting Chairwoman Slaughter and Commissioner Chopra dissenting.

NON-PUBLIC APPENDIX I**AGREEMENTS RELATED TO THE DIVESTITURES**

[cover page]

NON-PUBLIC APPENDIX**MONITOR COMPENSATION**

[cover page]

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PUBLIC APPENDIX**MONITOR AGREEMENT**

This Monitor Agreement (“Monitor Agreement”) entered into among Quantic Regulatory Services, LLC (“Quantic”), and Mylan N.V. (“Mylan”) and Pfizer Inc. (“Pfizer”) (together with Mylan, the “Merging Parties”), provides as follows:

WHEREAS, the United States Federal Trade Commission (the “Commission”), in *In the Matter of Mylan N.V.*, has accepted or will shortly accept for Public Comment an *Agreement Containing Consent Orders* (the “Consent Agreement”), incorporating a Decision and Order (“Decision and Order”) and an Order to Maintain Assets, with the Merging Parties (collectively, the “Orders”), which, among other things, require the Merging Parties to divest or transfer certain defined assets and maintain those assets pending such divestiture or transfer, and provide for the appointment of one or more Monitors to ensure that the Merging Parties comply with their obligations under the Orders;

WHEREAS, the Commission may appoint Quantic, and in particular William Hitchings and William Rahe, as such monitor (the “Monitor”) pursuant to the Orders to monitor the Merging Parties’ compliance with the terms of the Consent Agreement and Orders and with the Remedial (Divestiture) Agreement referenced in the Orders, and to monitor the efforts of the Commission-approved Acquirers (as defined in the Orders) to obtain all necessary FDA approvals, as applicable, and Quantic has consented to such appointment;

WHEREAS, the Orders further provide or will provide that the Merging Parties shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Monitor to carry out such duties and responsibilities pursuant to the Orders;

WHEREAS, this Monitor Agreement, although executed by the Monitor and the Merging Parties, is not effective for any purpose, including but not limited to imposing rights and responsibilities on the Merging Parties or the Monitor under the Orders, until it has been approved by the Commission; and

WHEREAS, the parties to this Monitor Agreement intend to be

legally bound; NOW, THEREFORE, the parties agree as follows:

1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Orders. The term “Divestiture Products” means, individually and collectively, amlodipine besylate/atorvastatin calcium tablets, eplerenone tablets, gatifloxacin ophthalmic solution, medroxyprogesterone acetate injectable suspension, phenytoin chewable tablets, prazosin hydrochloride capsules, spironolactone/hydrochlorothiazide tablets, and mesalamine delayed release capsules, and any other Divestiture Product as required in the Orders.

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2. The Monitor shall have all of the powers and responsibilities conferred upon the Monitor by the Orders, including but not limited to:
 - a. supervising the transfer of the Divestiture Products, including tangible assets, contracts, Product Intellectual Property and Confidential Business Information to Commission-approved Acquirers;
 - b. supervising any redaction of Confidential Business Information retained by the Merging Parties as required by the Orders; and
 - c. supervising the performance of any transition services, including Contract Manufacture, required by the Orders.
3. The Merging Parties hereby agrees that it will fully and promptly comply with all terms of the Orders requiring it to confer all rights, powers, authority and privileges upon the Monitor, or to impose upon itself any duties or obligations with respect to the Monitor, to enable the Monitor to perform the duties and responsibilities of the Monitor thereunder.
4. The Merging Parties further agrees that:
 - a. it will use its best efforts to ensure that Prasco LLC ("Prasco") or any other Commission-approved Acquirer enters into an agreement with the Monitor at or about the Closing Date governing the facilitation of the Monitor's duties under the Orders and the exchange of information between Prasco or any other Commission-approved Acquirer and the Monitor;
 - b. no later than ten (10) business days after the Commission approves this Monitor Agreement, it will provide the Monitor with the following, as applicable:
 - (1) a complete inventory and description of the Divestiture Products, identifying, in particular, those Divestiture Products which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;
 - (2) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Divestiture Products identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;
 - (3) a complete inventory of all activities or operations worldwide that relate to the manufacture of the Products relating to the Divestiture Products, and which relate to the Merging Parties' compliance with the Orders, including processes and process

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- validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture;
- (4) full and complete details of all dealings with any future Commission-approved Acquirer of the Divestiture Products (other than Prasco or any other entity accepted by the Commission), including copies of all correspondence and written reports of all contacts and discussions with any such future Commission-approved Acquirer and any draft and/or executed complete agreements, including any attached exhibits, schedules and appendices;
 - (5) a complete inventory of all Patents included in the Divestiture Products related to the manufacture or sale of the Divestiture Products in the United States, identifying actions needed to maintain such Patents and the person(s) responsible for such actions; and
 - (6) such other information as reasonably requested by the Monitor in order to carry out its duties and responsibilities under the Orders and Consent Agreement.
- c. it will designate a senior individual as a primary contact for the Monitor and provide a written list of the principal individuals to be involved in the transitioning of the Divestiture Products to Prasco, together with their locations, telephone numbers, electronic mail addresses (if available), and responsibilities, and will provide the Monitor with written notice of any changes in such personnel occurring thereafter;
 - d. it will provide the Monitor with prompt notification of significant meetings, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the development, manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Divestiture Products, and such meetings may be attended by the Monitor or its representative, at the Monitor's option or at the request of the Commission or staff of the Commission;
 - e. it will provide the Monitor with the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Merging Parties;
 - f. it will provide the Monitor with all correspondence, meeting minutes, telephone summaries, and reports, sent to or received from

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the FDA relating to the Divestiture Products;

- g. it will provide the Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Consent Agreement and the Orders, simultaneous with the submission of such reports to the Commission;
- h. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Orders, it will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as reasonably requested by the Monitor, electronic or hard copy reports to the Monitor reasonably describing the Merging Parties' activities and obligations under the Orders concerning the Divestiture Products including, without limitation to the extent applicable:
 - (1) all significant activities concerned with the manufacture, supply and technology transfer of the relevant Products that are identified in the Divestiture Products, including, without limitation, negotiation and operation of supply agreements, actual supply and inventory;
 - (2) all minutes and records of significant meetings, action plans, and follow-ups to action plans and meetings with Prasco related to the manufacture, supply, and technology transfer of the Divestiture Products;
 - (3) all significant activities concerning the assistance, advice and consultation provided to Prasco generally as provided in the Decision and Order; and
 - (4) on request, the Merging Parties will provide the Monitor with any and all records that relate to the manufacture of the Products identified in the Divestiture Products with the right to use them to achieve the purposes of the Orders;

provided, however, that, at the time the Decision and Order becomes final, the reports described in this paragraph shall be due to the Monitor either as requested by the Monitor or within five (5) business days of the date that the Merging Parties files the Merging Parties' reports with the Commission as required pursuant to the Decision and Order;

- i. it will comply with the Monitor's reasonable requests for onsite visits and audits of the Merging Parties' facilities (or any Respondent's or contract manufacturer's facility, to the extent within the Merging Parties' control) used to manufacture the Products identified in the

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Divestiture Products;

- j. it will comply with the Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to this Monitor Agreement, including, as applicable, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale and/or divestiture of any Divestiture Product(s) and, further including, actions necessary to maintain all necessary FDA approvals to manufacture and sell any of the Divestiture Products, to maintain the viability and marketability of the Divestiture Products, as well as the tangible assets of the facilities used to manufacture and sell all of the Divestiture Products (to the extent within the Merging Parties' control), and to prevent the destruction, removal, wasting, deterioration or impairment of the Divestiture Products, and will provide the Monitor with access to and hard copies of all other data, records or other information that the Monitor reasonably believes are necessary to the proper discharge of its responsibilities under the Orders; and
 - k. it will provide prompt notice of any meetings or events affecting or likely to affect the maintenance of the Divestiture Products, including, but not limited to, any and all meetings or communications with the FDA.
- 5. The Merging Parties shall promptly notify the Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and the Merging Parties related to the Orders or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be requested by the Monitor, of such communications.
 - 6. The Merging Parties agrees that to the extent authorized by the Orders, the Monitor shall have the authority to employ, at the expense of the Merging Parties, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information.
 - 7. The Merging Parties and the Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Orders, that the Monitor investigate and/or audit the Merging Parties' compliance with the Merging Parties' obligations to maintain assets pursuant to the Orders, and submit such additional written or oral reports, under applicable confidentiality restrictions, to the Commission as the Commission or its staff may at any time request concerning the Merging Parties' compliance with the Merging Parties' obligations to maintain assets pursuant

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to the Orders.

8. The Monitor shall maintain the confidentiality of all information provided to the Monitor by the Merging Parties. Such information shall be used by the Monitor only in connection with the performance of the Monitor's duties pursuant to this Monitor Agreement and the Orders. Such information shall not be disclosed by the Monitor to any third party other than:
 - a. persons employed by, or working with, the Monitor under this Monitor Agreement; or
 - b. persons employed at the Commission and working on this matter.
9. Upon written request, the Monitor will inform the Commission and the Merging Parties of all persons employed by, or working with, the Monitor under this Monitor Agreement (other than, for the avoidance of doubt, representatives of the Commission, the Merging Parties or Prasco) to whom confidential information related to this Monitor Agreement has been disclosed.
10. Upon (i) termination of the Monitor's duties under this Monitor Agreement and the Orders, and (ii) written request by the Merging Parties, the Monitor shall promptly return to the Merging Parties all material provided to the Monitor by the Merging Parties that is confidential to the Merging Parties and that it is entitled to have returned to it under the Orders, and shall destroy any written material prepared by the Monitor that contains or reflects any confidential information of the Merging Parties, provided, that, notwithstanding the foregoing, the Monitor shall be entitled to keep one copy of such information in its confidential files and all electronic records thereof. Nothing herein shall abrogate the Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of ten (10) years after the termination of this Monitor Agreement;
11. To the extent that the Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Monitor in accordance with the Orders, the Monitor shall ensure that, prior to being retained, such persons agree to confidentiality restrictions consistent with those set forth herein.

For the purposes of this Section and Sections 8, 9 and 10, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known to the recipient at the time of receipt or becomes known to the recipient from a source other than the Merging Parties,

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or any director, officer, employee, agent, consultant or affiliate of the Merging Parties, when such source is entitled to make such disclosure to such recipient or such information was independently developed by the Monitor as evidenced by written records.

12. Nothing in this Monitor Agreement shall require the Merging Parties to disclose any material or information that is subject to a legally recognized privilege or that the Merging Parties is prohibited from disclosing by reason of law.
13. The Monitor shall be responsible for monitoring Respondents' compliance with their obligations as set forth in the Orders and the Divestiture Agreements (Remedial Agreements). In doing so, the Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or the Commission. The Monitor shall have all rights, duties, powers and authorities as required by the Orders, and nothing in the Monitor Agreement shall change, amend, modify, or otherwise limits those rights, duties, powers, and authorities. .
14. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Orders as it relates to the Merging Parties.
15. Mylan will pay the Monitor within thirty (30) days of receipt of an invoice in accordance with the fee schedule attached hereto as Confidential Exhibit A for all time spent in the performance of the Monitor's duties including all monitoring activities related to the efforts of Prasco with respect to the Divestiture Products (including any and all such activities performed prior to the date of this Monitor Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time. Every six months such hourly rates should be reviewed and may be adjusted by agreement with the Merging Parties.
 - a. In addition, Mylan will pay within thirty days of receipt of an invoice (i) all reasonable and customary out-of-pocket expenses incurred by the Monitor in the performance of the Monitor's duties, including any auto, train or air travel in the performance of the Monitor's duties, and international telephone calls, and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties.
 - b. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense reimbursement purposes at the exchange rate used for said credit card transaction and

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any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.

- c. The Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.
 - d. To the extent that the Monitor is requested to travel in the performance of the Monitor's duties, the Monitor shall use such travel time, to the extent practicable, to work on the FTC monitor process.
16. Mylan hereby confirms its obligation to indemnify the Monitor and hold the Monitor harmless in accordance with and to the extent required by the Orders (and, upon direction by the Commission to the Monitor to divest any Divestiture Products).

Without in any way limiting the generality of the foregoing, Mylan shall indemnify the Monitor and any subcontractor and their respective consultants, agents, partners, principals, directors, officers, members, managers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses arising out of or in connection with, the performance of the Monitor's duties and obligations including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses are determined by final arbitration to result from the gross negligence or the willful misconduct of the Monitor.

17. The Monitor's maximum liability to the Merging Parties relating to services rendered pursuant to this Monitor Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the lesser of \$75,000 or the total sum of the fees paid to the Monitor by the Mylan, except to the extent resulting from the gross negligence or the willful misconduct of the Monitor determined by final arbitration. IN NO CIRCUMSTANCES WHATSOEVER SHALL THE MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES.
18. The Merging Parties agrees that Mylan's obligations to indemnify the Monitor extend to any agreement that is entered between the Monitor and Prasco and relates to the Monitor's responsibilities under this Monitor Agreement and/or the Orders.

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19. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Mylan shall be required, to notify Prasco and potential future Acquirers with respect to its appointment as the Monitor.
20. In the event of a disagreement or dispute between the Merging Parties and the Monitor concerning the Merging Parties' obligations under the Orders and, in the event that such disagreement or dispute cannot be resolved by the parties, either party may seek the assistance of the individual in charge of the Commission's Compliance Division to resolve this issue. In the case of any disagreement or dispute between the Merging Parties and the Monitor not relating to the Merging Parties' obligations under the Orders, and in the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Merging Parties' obligations pursuant to the Orders. Any fees and expenses of the arbitration shall be split between the parties.
21. This Monitor Agreement shall be subject to the substantive law of the Commonwealth of Pennsylvania (regardless of any other jurisdiction's choice of law principles).
22. This Monitor Agreement shall terminate no later than: (i) the date set forth in the relevant provision of the Orders; or (ii) on the date on which the Commission has appointed a substitute monitor pursuant to the Orders. The Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Orders. The confidentiality, indemnity and limitation of liability provisions of this Monitor Agreement shall survive its termination.
23. In the event that, during the term of this Monitor Agreement, the Monitor becomes aware that it has a conflict of interest that could adversely affect the performance by the designated lead monitor for the Monitor, of any duty under this Monitor Agreement, the Monitor shall promptly inform both the Merging Parties and the Commission of such conflict.
24. It is understood that the Monitor will be serving under this Monitor Agreement as an independent contractor and that the relationship of employer and employee shall not exist between Monitor and the Merging Parties.
25. This Monitor Agreement is for the sole benefit of the parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.
26. This Monitor Agreement and the Orders contains the entire agreement between the parties hereto with respect to the matters described herein and

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replaces and supersedes any and all prior agreements or understandings, whether written or oral. Any amendment, waiver, or modification of this Monitor Agreement shall not be valid unless in writing and signed by the parties, and approved by the Commission. Any such amendment, modification, or waiver may only be made in a manner consistent with the terms of the Orders. Purchase Order terms and conditions shall not be applicable.

27. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail, reputable overnight courier or fax (with acknowledgment of receipt of such fax having been received), to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Monitor, to:

Quantic Regulatory Services, LLC
Bethanne Seel
Office Manager
5N Regents Street
Suite 502
Livingston, NJ 07039

If to Mylan:

Mylan N.V.
Building 4, Trident Place
Mosquito Way, Hatfield
Hertfordshire, United Kingdom, AL10 9UL, or

1000 Mylan Boulevard, Canonsburg, PA 15317

Attention: Global General Counsel

With a copy to:

Cravath, Swaine & Moore LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019

Attention: Margaret D'Amico

If to Pfizer:

Pfizer Inc.
235 East 42nd Street

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New York, New York 10017, USA

Attention: Global General Counsel

With a copy to:

Morgan, Lewis & Bockius LLP
101 Park Ave
New York, NY 10178

Attention: Harry T. Robins

If to the Commission:

Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, DC 20001
Attn.:
Telephone:
Fax:

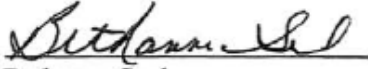
28. This Monitor Agreement shall not become binding until it has been approved by the Commission and the Orders have been accepted for public comment.
29. This Monitor Agreement may be signed in counterparts, each of which shall be deemed an original but when taken together shall constitute one and the same agreement.

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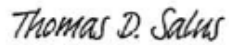
IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 14th of September 2020.

Quantic Regulatory Services, LLC



Bethanne Seel
Office Manager

Mylan N.V.



Thomas D. Salus
Assistant Secretary

~~Bfizer Inc.~~

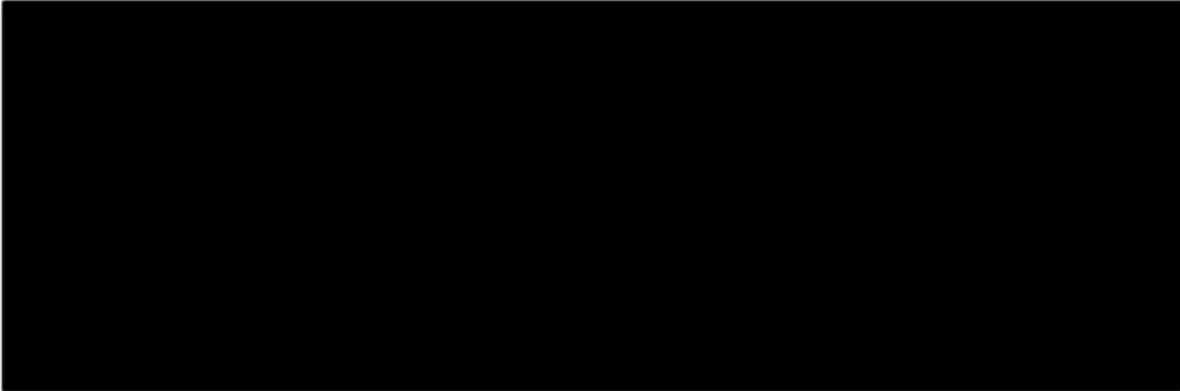


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Marc Brotman
Vice President & Assistant General Counsel Secretary

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Confidential Appendix A



Concurring Statement

STATEMENT OF COMMISSIONER CHRISTINE S. WILSON

Today, the Commission announces that it has voted 3-2 to issue a complaint and accept a settlement to remedy the threats to competition arising from Mylan's proposed acquisition of Pfizer's off-patent drug business.

The experienced staff of the Federal Trade Commission thoroughly investigated all cognizable theories of harm to competition during more than a year of review. Their extensive investigation put to rest some concerns and produced grounds for other concerns. Staff negotiated comprehensive remedies to address the potential anticompetitive effects identified during their exhaustive investigation – as they have done in many transactions in the pharmaceutical sector, including *Bristol-Myers Squibb/Celgene* and *AbbVie/Allergan*. Yet, as Commissioners Slaughter and Chopra did in those merger reviews, they are again opposing the settlement of this enforcement action.

Prices for pharmaceuticals and biologics deserve the attention of the American public and the federal government. As I stated in connection with the announcement of the FTC's settlement with Bristol-Myers and Celgene, within its limited *civil* authority as a competition agency, the Commission vigorously pursues a comprehensive agenda to address anticompetitive mergers and unlawful conduct in the pharmaceutical industry.¹ I continue to encourage those government entities with the appropriate mandates to fix the many problems in this sector that lie beyond our jurisdiction.

¹ Statement of Commissioner Christine S. Wilson, *In the Matter of Bristol-Myers Squibb Company / Celgene Corporation*, File No. 191-0061, Nov. 15, 2019, available at https://www.ftc.gov/system/files/documents/public_statements/1554278/bms-celgene - wilson statement.pdf.

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**STATEMENT OF COMMISSIONER ROHIT CHOPRA
JOINED BY COMMISSIONER REBECCA KELLY SLAUGHTER**

Summary

- The FTC's record when it comes to reviewing pharmaceutical mergers suggests that the agency will simply never seek to block a merger. Instead, the agency's approach is to strike narrow settlements. This encourages market actors to propose even more unlawful mergers.
- Both Pfizer and Mylan have been accused of collusion in the generic drug business. We must assess whether this merger will enhance their ability to conspire and collude.
- Rajiv Malik, who will be president of the merged entity, is currently a defendant charged with antitrust misconduct. The Commission's silence about his role is deeply problematic.

Drug prices are out of control, and in too many instances, are out of reach for patients who depend on them. Competition from generic drugs pushes down high prices. That's why it's critical to combat abuse of intellectual property that allows branded drug makers to block generic entry. But we should also be deeply concerned that patients can't reap the full benefits from generic competition, given the alleged collusion in the generic drug industry to drive up prices.

Any investigation of massive mergers in the generic business must take this into account.

Today, the Federal Trade Commission has voted to settle allegations that Mylan's (NASDAQ: MYL) proposed \$12 billion acquisition of Pfizer's (NYSE: PFE) generic drug business is unlawful.¹ The combined firm would become the largest generic pharmaceutical firm in the world and offer approximately 3,000 drug products that treat a broad range of diseases and conditions.² The FTC's proposed settlement requires divestiture of seven individual products, as well as other provisions.

When it comes to pharmaceutical mergers, I am unable to identify a single instance in recent history where the agency has filed a complaint in federal court seeking to halt a prescription drug company merger. This lack of litigation creates the strong impression that the FTC simply looks to strike settlement deals involving individual product divestitures. Virtually

1 Pfizer, Press Release, Mylan and Upjohn, a Division of Pfizer, to Combine, Creating a New Champion for Global Health Uniquely Positioned to Fulfill the World's Need for Medicine (July 29, 2019, 2:45AM), <https://www.pfizer.com/news/press-release/press-release-detail/mylan-and-upjohn-a-division-of-pfizer-to-combine-creating-a-new-champion-for-global-health-uniquely-positioned-to-fulfill-the-world-s-need-for-medicine>.

2 See Mylan & Upjohn Investor Presentation, A New Champion for Global Health at 17 (July 29, 2019), <https://www.championforglobalhealth.com/-/media/championforglobalhealth/pdf/mylanupjohninvestorpresentation072919.pdf>; see also Mylan & Upjohn Fact Sheet, A New Champion for Global Health (n.d.a.), <https://www.championforglobalhealth.com/-/media/championforglobalhealth/pdf/MylanUpjohnFactsheet072919.pdf>

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every market participant I have spoken to in this industry believes that there is simply no risk of the FTC blocking an unlawful pharmaceutical merger outright.

I respectfully disagree with the status quo approach the Commission applied to this pharmaceutical merger. The use here is especially concerning, since both firms and two of Mylan's top executives have been accused of a wide-ranging price fixing and market allocation conspiracy in the generic drug industry.³ With an expanded empire of generic drug products, these alleged antitrust crimes may be even easier to perpetrate by the new entity.⁴

In this statement, I focus on how mergers involving companies competing across a large number of product lines can exacerbate the risk of collusive conspiracies, particularly in industries where middlemen may not have an incentive to keep prices low.⁵ I also focus on issues we must always confront. For example, the Commission should always look to testimony from top executives at companies proposing to merge in order to fully understand the range of potential effects on competition. The Commission can only make a conclusion about the risk of collusion and any impacts on competition when it has a full range of data and evidence.

Conditions for Collusion

When competitors enter into agreements to fix prices, rig bids, and divvy up markets, they can face civil and criminal charges. Pfizer and Mylan are defendants in several state attorneys general and private plaintiff lawsuits alleging market allocation and price fixing in the generic drug industry.⁶ They are also under investigation for criminal market allocation and price fixing by the Department of Justice.⁷ Over thirty additional generic drug companies are defendants in the same state attorneys general suits, including well-known drug firms Sandoz, Actavis, Teva, and Allergan, among others. Patients have allegedly paid many billions of dollars

3 See Compl., *Connecticut v. Teva Pharms. USA, Inc.*, Case No. 3:19-cv-00710 (D. Conn. filed May 10, 2019) ¶ 50; *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34, Civ. Action No. 17-3768 (E.D. Pa. filed June 15, 2018).

4 The Department of Justice also charged Teva with criminally conspiring to fix prices, rig bids, and allocate customers for generic drugs. Five previous corporate cases were resolved by deferred prosecution agreements; Teva and its co-conspirator Glenmark are awaiting trial. Four executives have also been charged; three have entered guilty pleas, and one is awaiting trial. See Press Release, Dep't. of Just., Seventh Generic Drug Manufacturer Is Charged In Ongoing Criminal Antitrust Investigation (Aug. 25, 2020), <https://www.justice.gov/opa/pr/seventh-generic-drug-manufacturer-charged-ongoing-criminal-antitrust-investigation>.

5 Most generic drugs are sold by their manufacturers to group purchasing organizations and large retail purchasers, who negotiate pricing contracts for their members that ultimately purchase the products. These contracts typically have inflation-based provisions that allow for potentially greater compensation when prices are higher. See *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 74.

6 See e.g., Pl. States' Consol. Am. Compl., *In re Generic Pharms. Pricing Antitrust Litig.*; Compl., *Connecticut v. Teva Pharms.*; Compl., *Connecticut v. Sandoz, Inc.*, Civ. Action No. 3:20-cv-802 (D. Conn. filed June 10, 2020).

7 See Pfizer Inc., Current Report (Form 8-K) (Aug. 6, 2020) at 175; Mylan N.V., Annual Report (Form 10-K) (Dec. 31, 2019) at 153.

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in overcharges for the generic drugs involved, causing a significant negative impact on our national health and economy.⁸

Typically, collusion is easier to pull off when a market has only a few big players, since coordination is more difficult with more actors.⁹ However, there are many generic drug companies that operate in the United States. So why might there be widespread misconduct?

One potential explanation is that these companies compete with each other in multiple different product markets. The enormous profit potential for these firms from collusion likely contributes to their incentives to engage in mutually beneficial coordination. By trading favorable competitive terms in one market for favorable competitive terms in another market, it may be easier for competing firms to reach mutually beneficial terms of trade and punish each other for any deviations.¹⁰

Pfizer and Mylan allegedly did just that.¹¹ In addition to colluding within individual generic drug product markets, Pfizer's Greenstone division, Mylan, and others are charged with trading customers across *different* drug markets.¹² They allegedly allowed price increases on generic drugs without competing, based on a quid pro quo from competitors on different drug products.¹³ Given these allegations, it is important that we closely investigate how this transaction could increase the ability of the merged entity to engage in similar – or even more harmful – collusive conduct.

For example, the merged entity would become the top supplier of generic drugs by global revenues, with an enormous number of products and a broad range of competitors with which to engage in quid pro quo collusive arrangements.¹⁴ With more generic drugs in the hands of one competitor, it may be easier to form a cartel and punish those who don't adhere to its terms.

8 Compl., *Connecticut v. Teva Pharms. USA, Inc.* ¶ 5.

9 This concept is reflected in the FTC's Horizontal Merger Guidelines. U.S. DEP'T OF JUST. & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 7.2 (Aug. 19, 2010), <https://www.justice.gov/sites/default/files/atr/legacy/2010/08/19/hmg-2010.pdf>.

10 See Federico Ciliberto & Jonathan W. Williams, *Does multimarket contact facilitate tacit collusion? Inference on conduct parameters in the airline industry*, 45 RAND J. OF ECON. 764 – 791 (2014) (noting that such multimarket contact facilitates tacit collusion in the U.S. airline industry).

11 Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶¶ 103 – 105 (describing Defendant Malik's willingness to "play fair" and give up two large customers to Heritage because Heritage had previously allowed Mylan to enter another market without competition); see also Compl., *Connecticut v. Sandoz, Inc.* ¶ 1299.

12 *Id.*

13 Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 101; see also Compl., *Connecticut v. Teva Pharms* ¶ 12.

14 Beth Snyder Bulik, *Mylan and Pfizer roll out tricolor branding for their giant generics combo, Viatrix*, FIERCEPHARMA (July 9, 2020, 10:06 AM), <https://www.fiercepharma.com/marketing/mylan-and-pfizer-debuts-new-viatrix-generics-merged-brand-unveils-tri-color-logo-for>.

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Despite this risk, the Commission's analysis is silent with respect to the alleged price fixing conduct.¹⁵

The FTC often acts without the benefit of the experience of other law enforcement partners.¹⁶ In all matters the Commission should avoid a go-it-alone approach and collaborate with other agencies to help shed light on the mechanisms involved in the allegations. Together, we should closely assess whether the likelihood of harm increases post-merger.

Investigating Executives

In any matter where a company has a history of potential wrongdoing, a key method to determine the motivations for a merger and to predict how it will affect competition is to seek sworn testimony from key executives. This is especially critical to understand how sales, pricing, and market forces are working. This evidence is also helpful if the agency must prepare a lawsuit.

While filings submitted by merging parties shed light on many aspects of a transaction, they do not always provide a complete picture of the deal rationale, pricing models, and boardroom behavior. The state allegations of price fixing and market allocation make clear that individual executives play a key role in sales and price setting, so it is critical that we fully understand this element of the competitive process.

For example, what is their involvement in developing a pricing model? Do they approve deviations from this pricing model? How do they decide which new markets to enter? In what contexts do they interact with their competitors? There are a long list of questions that are absolutely essential in an inquiry like this.

In this transaction, one of the alleged masterminds of the ongoing price fixing and market allocation schemes is Rajiv Malik, Mylan's current president, who is a named defendant in one of the state lawsuits.¹⁷ A second Mylan executive, Vice President of Sales James Nesta, is also a named defendant in one of the cases.¹⁸ The merging parties have publicly announced that Mr. Malik will retain the top executive role in the expanded generic drug empire, if the transaction

15 See, e.g., Analysis Of Agreement Containing Consent Orders To Aid Public Comment, *In the Matter of Pfizer Inc./Mylan N.V.*, File No. 1910182 (Oct. 29, 2020).

16 See Statement of Commissioner Rohit Chopra In the Matter of AbbVie, Inc./Allergan plc, Comm'n File No. 1910169, 2, 19 (May 5, 2020), https://www.ftc.gov/system/files/documents/public_statements/1574583/191-0169_dissenting_statement_of_commissioner_rohit_chopra_in_the_matter_of_abbvie-allergan_redacted.pdf; see also Statement of Commissioner Rohit Chopra In the Matter of Social Finance, Inc., Comm'n File No. 1623917 (Oct. 29, 2018), https://www.ftc.gov/system/files/documents/public_statements/1418711/162_3197_statement_of_commissioner_chopra_on_sofi_10-29-18.pdf.

17 Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34.

18 See Compl., *Connecticut v. Teva Pharms. USA, Inc.* ¶ 50.

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closes.¹⁹ As president, he will be in charge of the merged entity's sales and marketing operations.²⁰ He will also serve on the merged company's board.²¹

Mr. Malik's role in the alleged price fixing scheme is significant. He allegedly conceived and directed many of the schemes.²² In one example, he is alleged to have agreed to cede market share in one market to a specific competitor in exchange for an agreement from that competitor to allow Mylan to enter a different market without competition.²³

Despite the obvious alarm bells raised by Mr. Malik's planned role in the merged firm, the Commission's analysis does not discuss his involvement in the ongoing price fixing and market allocation allegations in the industry or his future plans for the company. In my view, the Commission owes the public a clear explanation about Mr. Malik's role.

In matters like this, it is critical that the Commission rely on a wide range of data and evidence, including testimony from key executives.²⁴

Conclusion

I am concerned that executives in the pharmaceutical industry routinely propose anticompetitive mergers without any fear that their transactions will ever be blocked. In my view, the status quo approach of seeking settlements through divestitures of individual products is myopic and misses some of the fundamental elements of how firms compete in this industry. I am also not aware of any instance where the Commission publicly relied on the testimony under oath of a pharmaceutical executive in approving a pharmaceutical divestiture settlement.

Unless we change our approach, anticompetitive mergers in the pharmaceutical industry will continue unabated, and we will all suffer for it. I appreciate the diligence of our staff, who work at the direction of the Commission. Unfortunately, the directives of the Commission are deeply flawed, favoring routine over rigor. For all these reasons, I respectfully dissent.

¹⁹ See Pfizer Press Release, *supra* note 1.

²⁰ Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34.

²¹ See Pfizer Press Release, *supra* note 1.

²² Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 10.

²³ *Id.* ¶ 188.

²⁴ This is particularly important in industries where the Commission cannot rely on evidence and testimony from customers who act as middlemen. We know from the allegations in the state attorneys general lawsuits that drug wholesalers and large retailers allegedly benefit when generic drug prices are higher. These firms have contractual provisions allowing for potentially greater compensation when prices are higher. *Id.* ¶¶ 71 – 75.

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ANALYSIS OF CONSENT ORDERS TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Pfizer Inc., Upjohn Inc., Viatriis Inc., Mylan N.V., and Utah Acquisition Sub Inc., that is designed to remedy the anticompetitive effects resulting from the proposed combination of Upjohn and Mylan. Under the terms of the Consent Agreement, the parties are required to divest Upjohn’s generic drug rights and assets related to six products to Prasco, LLC. The Consent Agreement also requires the parties to divest Mylan’s rights and assets related to eplerenone tablets to Prasco. Further, the Consent Agreement requires prior Commission approval before Upjohn, Mylan, or Viatriis may gain an interest in or exercise control over any third party’s rights to (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets.

The Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw the Consent Agreement, modify it, or make final the proposed Decision and Order (“Order”).

Pursuant to agreements dated July 29, 2019, Pfizer proposes to spin off its Upjohn business, which includes legacy Pfizer branded products and the authorized generic business, Greenstone, LLC. Upjohn will combine with Mylan to form a new entity, Viatriis (“Proposed Combination”). The Commission alleges in its Complaint that the Proposed Combination, if consummated, would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, as amended, and Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended, by lessening current competition in the following seven U.S. markets: (1) amlodipine besylate/atorvastatin calcium tablets, (2) eplerenone tablets, (3) gatifloxacin ophthalmic solution, (4) medroxyprogesterone acetate injectable solution, (5) phenytoin chewable tablets, (6) prazosin hydrochloride (“HCl”) capsules, and (7) spironolactone hydrochlorothiazide (“HCTZ”) tablets. The Commission also alleges that the Proposed Combination would violate the aforementioned statutes by lessening future competition in the markets for: (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Combination.

I. The Products and Structure of the Markets

In human pharmaceutical markets, price generally decreases as the number of generic competitors increases. Prices continue to decrease incrementally with the entry of the second, third, fourth, and even fifth generic competitor. And in markets prone to supply shortages, additional entry after the fifth generic competitor continues to affect price and ensures more stable supply. Accordingly, the reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Combination would reduce current competition in the markets for seven products where Greenstone distributes the authorized generic version of the branded drug:

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- Amlodipine besylate/atorvastatin calcium tablets combine a calcium channel blocker to treat hypertension with a lipid-lowering agent to treat high cholesterol. Only four companies sell generic amlodipine besylate/atorvastatin calcium tablets: Greenstone, Mylan, Dr. Reddy's Laboratories Ltd., and Apotex Inc.
- Eplerenone is a diuretic that is prescribed as an adjunctive therapy when treating hypertension or congestive heart failure after a heart attack. Significant sellers of eplerenone include Greenstone, Mylan, Breckenridge Pharmaceutical, Inc., and Accord Healthcare Inc.
- Gatifloxacin ophthalmic solution is an eye drop that treats bacterial conjunctivitis caused by susceptible strains of certain bacteria. The market for gatifloxacin has faced historical supply disruptions. Five companies supply this product today: Greenstone, Mylan, Sandoz International GmbH, Akorn, Inc., and Lupin Ltd.
- Medroxyprogesterone acetate is an injectable solution used to treat certain types of dysfunctional uterine bleeding. Injectable products, such as medroxyprogesterone acetate, have recently experienced shortages and supply disruptions. Greenstone, Mylan, Amphastar Pharmaceuticals, Inc., Teva Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Ltd. currently supply medroxyprogesterone acetate.
- Phenytoin chewable tablets are an anti-epileptic drug that slows down impulses in the brain that cause seizures. Only three suppliers provide phenytoin chewable tablets today: Greenstone, Mylan, and Taro Pharmaceutical Industries Ltd.
- Prazosin HCl capsules are an alpha-adrenergic blocker that treats hypertension by relaxing the veins and arteries so that blood can more easily pass. The market for prazosin HCl capsules is supplied by four companies: Greenstone, Mylan, Teva, and Novitium Pharma LLC.
- Spironolactone HCTZ tablets are a diuretic used to treat hypertension. Only three suppliers provide spironolactone HCTZ tablets: Greenstone, Mylan, and Sun.

The Proposed Combination also would reduce future competition in the following generic markets:

- Levothyroxine sodium tablets are offered in a host of strengths and are prescribed to treat hypothyroidism or as an adjunct therapy for patients undergoing treatment for thyroid cancer. Suppliers for levothyroxine sodium tablets vary by strength. Should Upjohn or Greenstone launch an authorized generic of Pfizer's levothyroxine sodium branded product (Levoxyl®), the Proposed Combination likely would reduce the number of independent suppliers from three to two in some strengths.

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- Sucralfate tablets are used to treat and prevent ulcers in the small intestines. Only three companies sold sucralfate tablets historically: Greenstone, Mylan, and Teva. More recently, Mylan discontinued sales of sucralfate. The Proposed Combination likely alters Mylan's incentives to relaunch sucralfate tablets and would reduce the number of firms capable of selling sucralfate tablets from three to two.
- Varenicline tartrate tablets are a smoking cessation aid offered under Pfizer's brand Chantix®. Currently, only branded Chantix® is available in the market. Mylan is one of a limited number of companies likely to share the Hatch-Waxman 180-day exclusivity period when the generic market forms. Should Upjohn or Greenstone launch an authorized generic of Pfizer's Chantix®, the Proposed Combination would significantly reduce the number of independent generic suppliers.

II. Entry

Entry into the markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Combination. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and time-consuming.

III. Competitive Effects

The Proposed Combination would likely cause significant anticompetitive harm to consumers in the relevant generic pharmaceutical markets by eliminating current and/or future competition in concentrated existing generic markets or in future generic markets. In generic pharmaceuticals markets, price is heavily influenced by the number of participants with sufficient supply. Market participants consistently characterize generic drug markets as commodity markets in which the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the prices of the generic pharmaceutical products at issue continue to decrease with new entry even after a number of suppliers have entered these generic markets.

The evidence shows that anticompetitive effects are likely to result from the Proposed Combination due to a decrease in the number of independent competitors in the markets at issue. In each of the current generic drug markets, industry participants have indicated that the presence of Greenstone and Mylan as independent competitors has allowed them to negotiate lower prices and, in some markets, has improved surety of supply.

In five of the markets where Upjohn and Mylan currently compete (amlodipine besylate/atorvastatin calcium tablets, eplerenone tablets, phenytoin chewable tablets, prazosin HCl capsules, and spironolactone HCTZ tablets), the Proposed Combination likely would reduce competition by combining two of only four or fewer current suppliers, likely leading to higher prices. In two of the markets where Upjohn and Mylan currently compete and where significant product shortages have occurred (gatifloxacin ophthalmic solution and medroxyprogesterone

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acetate injectable solution), the Proposed Combination would eliminate an independent supplier. Customers have indicated that preserving competition between Upjohn and Mylan, particularly in markets prone to shortages, is important to maintaining adequate supplies and competitive prices.

In addition, the Proposed Combination likely would delay or forego the introduction of beneficial competition, and subsequent price decreases, by eliminating future competition in the markets for generic levothyroxine sodium tablets, sucralfate tablets, and varenicline tartrate tablets.

Absent the Consent Agreement, the Proposed Combination would eliminate significant current and future competition between the parties and likely cause U.S. consumers to pay higher prices for the aforementioned generic pharmaceutical products.

IV. The Consent Agreement and Order

The proposed Order effectively remedies the competitive concerns raised by the Proposed Combination for the ten generic pharmaceutical product areas at issue. Pursuant to the proposed Order, the parties are required to divest to Prasco Upjohn's authorized generic rights and assets related to six products. The proposed Order also requires the parties to divest Mylan's rights and assets related to eplerenone tablets to Prasco. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Combination is consummated. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

Further, the proposed Order requires prior Commission approval before Upjohn, Mylan, or Viatriis may gain an interest in or exercise control over any third party's rights to the following products: (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Combination. Prasco is a capable purchaser with management and employees who have experience marketing and distributing generic pharmaceutical products. It will be able to replicate the competition otherwise lost from the Proposed Combination.

The proposed Order contains several provisions to help ensure that the divestitures are successful. As to the products and rights being divested to Prasco, generic drug manufacturing will continue to be performed by the same entity as prior to the Proposed Combination, reducing the risk of any interruption in supply to Prasco. In some instances, Pfizer—which will be an independent entity, separate from Viatriis after the Proposed Combination—will serve as Prasco's contract manufacturer, allowing Prasco to step into the shoes of Upjohn/Greenstone. Should Prasco decide to move manufacturing to another contract manufacturer, the proposed Order requires the parties to provide transitional services to assist Prasco or its designated contract manufacturer in establishing manufacturing capabilities and securing all necessary FDA approvals. These transitional services include technical assistance to manufacture the currently

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marketed products in substantially the same manner and quality employed or achieved by the parties. To the extent that Pfizer will manufacture relevant products on behalf of both Viartis and Prasco, the proposed Order requires that supply to Prasco is provided at a pre-determined cost and is prioritized over supply to Viartis. For amlodipine besylate/atorvastatin calcium tablets, Viartis will provide the active pharmaceutical ingredient (“API”) used in Prasco’s product. The proposed Order requires that Viartis provide Prasco with API at a pre-determined cost and that it prioritizes Prasco’s use of API over its own. Moreover, the proposed Order requires a firewall between Viartis’s API business and its commercial business to prevent the sharing of commercially sensitive information. Under the proposed Order, the Commission also will appoint two Monitors.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

SKYMED INTERNATIONAL, INC.**D/B/A****SKYMED TRAVEL AND CAR RENTAL PRO**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT*Docket No. C-4732; File No. 192 3140**Complaint, January 26, 2021 – Decision, January 26, 2021*

This consent order addresses SkyMed International, Inc.’s information security practices and notifications. The complaint alleges that SkyMed violated Section 5 of the Federal Trade Commission Act by using unreasonable security practices that led to the exposure of a cloud database containing approximately 130,000 membership records with consumers’ personal information stored in plain text. The complaint further alleges that SkyMed engaged in deceptive acts when it notified current and former members about the database exposure, and when displaying a seal on every page of its website that attested to its purported compliance with the Health Insurance Portability and Accountability Act. The consent order prohibits SkyMed from making false or deceptive statements regarding: (1) the extent to which it is a member of, complies with, is endorsed by, or otherwise participates in any privacy or security program sponsored by a government or third party; (2) the extent of any data security incident involving consumers’ personal information; (3) the extent of any investigation, and the results thereof, relating to a data security incident; (4) the extent to which SkyMed collects, maintains, uses, discloses, deletes, or permits or denies access to consumers’ personal information; and (5) the extent to which SkyMed otherwise protects the privacy, security, availability, confidentiality, or integrity of consumers’ personal information.

Participants

For the *Commission*: *Brian Berggren* and *Miles Plant*.

For the *Respondents*: *Andrea Bland*, *Russell Duncan*, and *Melissa Ventrone*, *Clark Hill PLC*.

COMPLAINT

The Federal Trade Commission (“Commission”), having reason to believe that SkyMed International, Inc., a Nevada corporation, has violated the provisions of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent SkyMed International, Inc. (“Respondent”), also doing business as SkyMed Travel and as Car Rental Pro, is a Nevada corporation with its principal office or place of business at 9089 E. Bahia Drive, Suite 100, Scottsdale, Arizona 85260.

2. The acts and practices of Respondent, as alleged in this Complaint, have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.