UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Joseph J. Simons, Chairman**
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter
Christine S. Wilson

In the Matter of	)	
PFIZER INC., **a corporation;**	)	
UPJOHN INC., **a corporation;**	)	
	)	**Docket No. C-4727**
VIATRIS INC., **a corporation;**	)	
MYLAN N.V., **a corporation;**	)	
and	)	
UTAH ACQUISITION SUB INC., **a corporation.**	)	

COMPLAINT

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 Viatris 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 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 gain an interest in Respondent Viatris. 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.

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.

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.

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.

April J. Tabor
Acting Secretary

SEAL: