UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

Rebecca Kelly Slaughter, A Joseph J. Simons Noah Joshua Phillips Rohit Chopra Christine S. Wilson	cting Chair.
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) DECISION AND ORDER
)) Docket No. C-4727
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ability company;)
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SUB INC.,)
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	Joseph J. Simons Noah Joshua Phillips Rohit Chopra Christine S. Wilson

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 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.

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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 Viatris Inc. and will become Respondent Viatris 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 Viatris Inc. with its

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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 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, Viatris, Mylan, and Utah Acquisition Sub.
- H. "Acquirer(s)" means:

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- 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;
 - 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;
 - "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;
 - "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
 - "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.

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- 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.
- 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:

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1. Asset Purchase Agreement by and between Mylan Pharmaceuticals Inc. and Prasco, LLC dated as of September 18, 2020; Authorized Generic License,

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