

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS
TO AID PUBLIC COMMENT**

*In the Matter of Pfizer Inc., Upjohn Inc., Viatrix Inc., Mylan N.V., Utah Acquisition Sub Inc.
File No. 191-1082, Docket No. C-4727*

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Pfizer Inc., Upjohn Inc., Viatrix 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 Viatrix 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, Viatrix (“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:

- 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.

- 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 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 Viartis 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 Viartis 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 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 Viatrix and Prasco, the proposed Order requires that supply to Prasco is provided at a pre-determined cost and is prioritized over supply to Viatrix. For amlodipine besylate/atorvastatin calcium tablets, Viatrix will provide the active pharmaceutical ingredient (“API”) used in Prasco’s product. The proposed Order requires that Viatrix 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 Viatrix’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.