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FEDERAL TRADE COMMISSION

[File No. 141 0098]

Actavis plc and Forest Laboratories; Analysis of Proposed Consent Order to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis of Agreement Containing Consent Order to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before July 30, 2014.

ADDRESSES: Interested parties may file a comment at https://ftcpublic.commentworks.com/ftc/actavisdivestapp online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Actavis plc and Forest Laboratories - Consent Agreement; File No. 141 0098" on your comment and file your comment online at https://ftcpublic.commentworks.com/ftc/actavisdivestapp by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the

Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Christine Tasso, Bureau of Competition, (202-326-2232), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for June 30, 2014), on the World Wide Web, at http://www.ftc.gov/os/actions.shtm.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before July 30, 2014. Write "Actavis plc and Forest Laboratories - Consent Agreement; File No. 141 0098" on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at http://www.ftc.gov/os/publiccomments.shtm. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card

number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR § 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR § 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at https://ftcpublic.commentworks.com/ftc/actavisdivestapp by following the instructions on the web-based form. If this Notice appears at http://www.regulations.gov/#!home, you also may file a comment through that website.

If you file your comment on paper, write "Actavis plc and Forest Laboratories - Consent Agreement; File No. 141 0098" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR § 4.9(c).

the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at http://www.ftc.gov to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before July 30, 2014. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at http://www.ftc.gov/ftc/privacy.htm.

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Actavis plc ("Actavis") that is designed to remedy the anticompetitive effects in three current generic pharmaceutical markets and two future markets resulting from Actavis' acquisition of Forest Laboratories, Inc. ("Forest"). Under the terms of the proposed Consent Agreement, the parties are required to: (1) return all of Forest's rights and assets related to generic diltiazem hydrochloride (AB4) to Valeant Pharmaceuticals International, Inc. ("Valeant"), (2) divest all of Actavis' rights and assets to generic ursodiol and generic lamotrigine ODT to Impax Laboratories, Inc. ("Impax"), and (3) divest all of Forest's rights and assets to generic propranolol hydrochloride to Catalent Pharma Solutions, Inc. ("Catalent").

The proposed 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 proposed Consent Agreement, along with the comments received, in order to make a final decision as to

whether it should withdraw from the proposed Consent Agreement, or make final the Decision and Order ("Order").

Pursuant to an Agreement and Plan of Merger dated February 17, 2014, Actavis plans to acquire, 100% of the voting securities of Forest for a total value of approximately $25 billion (the "Proposed Acquisition"). The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate 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, by lessening competition in three current relevant product markets: (1) generic diltiazem hydrochloride extended release capsules (AB4) (generic Tiazac) ("generic diltiazem hydrochloride (AB4)"; (2) generic ursodiol tablets ("generic ursodiol"); and (3) generic propranolol hydrochloride extended release capsules ("generic propranolol hydrochloride"), and the future relevant market of lamotrigine orally disintegrating tablets ("ODT") and its generic equivalent. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

The Products and Structure of the Markets

The Proposed Acquisition would reduce the number of suppliers in three current relevant markets, each of which has only a limited number of market participants. It would also likely delay the introduction of generic competition against Lamictal ODT, the branded lamotrigine orally disintegrating tablets marketed by Forest.

Generic versions of drugs are usually launched after a branded product's patents expire, or a generic supplier successfully challenges such patents in court or reaches a legal settlement with the branded manufacturer. When only one generic product is available, the price for the 2 branded product acts as a ceiling above which the generic manufacturer cannot price its product. During this period, the branded product competes directly with the generic. Once multiple

generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, the generic suppliers compete only against each other. In generic pharmaceutical product markets, price generally decreases as the number of generic competitors increases. Accordingly, the reduction in the number of suppliers within each relevant market would likely have a direct and substantial anticompetitive effect on pricing.

The Proposed Acquisition would reduce current competition in markets for three currently marketed generic prescription drugs—generic diltiazem hydrochloride (AB4), which is used to treat hypertension and chronic stable angina, generic ursodiol, which is used to treat primary biliary cirrhosis of the liver, and generic propranolol hydrochloride, an extended release drug indicated for the treatment of hypertension. The structure of these markets is as follows:

• The generic diltiazem hydrochloride (AB4) market currently has three suppliers: Actavis, Forest, and Sun Pharmaceutical Industries, Ltd. The Proposed Acquisition would reduce the number of suppliers in this market from three to two.

• The generic ursodiol market currently has four suppliers: Actavis, Forest, which distributes its product through Prasco Laboratories, Glenmark Pharmaceuticals, Ltd., and Par Pharmaceutical Companies. The Proposed Acquisition would reduce the number of suppliers in this market from four to three.

• The generic propranolol hydrochloride market currently has four suppliers: Actavis, Forest, which distributes its product through Breckenridge Pharmaceutical, LLC, Rouses Point Pharmaceuticals, and Upsher-Smith Laboratories. The Proposed Acquisition would reduce the number of suppliers in this market from four to three.

In addition to reducing current competition in three generic prescription markets, the proposed transaction would significantly reduce competition in the future market of lamotrigine orally disintegrating tablets:

• Lamictal ODT is a lamotrigine orally disintegrating tablet indicated for seizures. Forest currently manufactures Lamictal ODT for GlaxoSmithKline plc ("GSK"). GSK owns the New Drug Application for Lamictal ODT and markets the product. Actavis holds the only approved Abbreviated New Drug Application to market generic lamotrigine ODT. Thus, Actavis appears likely to be the first generic entrant and would be the sole competitor to Forest/GSK's branded Lamictal ODT product for a significant period of time. The Acquisition would likely delay or preclude the entry of Actavis' generic product.

Entry

Entry into the markets for the Products would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. The combination of drug development times and regulatory requirements, including U.S. Food and Drug Administration ("FDA") approval, is costly and lengthy. Industry participants also note that expertise and facilities associated with manufacturing extended release products and orally disintegrating tablets is sufficiently specialized that a relatively small number of firms participate in such markets.

Effects

The Proposed Acquisition 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. Further, customers generally believe that having at least four suppliers in a generic pharmaceutical market produces more competitive prices than if fewer suppliers are available to them.

The evidence shows that anticompetitive effects are likely to result from the Proposed Acquisition due to a decrease in the number of independent competitors in the markets at issue. In each of the current generic prescription markets, industry participants have indicated that the presence of Forest as a competitor has allowed them to negotiate lower prices from other suppliers, including Actavis, and has allowed them to locate additional supply in times of product shortages from their existing suppliers.

The evidence also shows that the Proposed Acquisition would eliminate significant future competition between Actavis and Forest in the market for lamotrigine orally disintegrating tablets because, absent the Proposed Acquisition, Actavis likely would have been the first generic supplier to enter the market.

By eliminating the significant current and future competition between the parties, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic drugs, absent a remedy.

The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in each of the relevant product markets. Pursuant to the Consent Agreement, the parties are required to return all of Forest's rights and assets related to generic

diltiazem hydrochloride (AB4) to Valeant, divest all of Actavis' rights and assets to generic ursodiol and generic lamotrigine ODT to Impax, and provide all of Forest's rights and assets to 4 generic propranolol hydrochloride to Catalent. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Acquisition is consummated.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that Valeant, Impax, or Catalent is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the proposed D&O requires the parties to unwind the sale and then divest the products within six months of the date the D&O becomes final to another Commission-approved acquirer or acquirers. The proposed D&O further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. With regard to generic diltiazem hydrochloride (AB4), the proposed Consent Agreement requires that Forest transfer to Valeant all confidential business information and requires that Actavis and Forest take all actions that are necessary to maintain the full viability and marketability of the product until Valeant commences the distribution, marketing, and sale of the product. With regard to generic ursodiol, generic lamotrigine ODT, and generic propranolol hydrochloride (termed "Contract Manufacture Products" in the Consent Agreement), the proposed Consent Agreement requires Actavis and Forest to manufacture and supply generic ursodiol and generic lamotrigine ODT to Impax and generic propranolol to Catalent following the divestiture while they seek the necessary FDA approval.

The Commission has agreed to appoint Frank Civille to act as an interim monitor to assure that Actavis and Forest expeditiously comply with all of their obligations and perform all of their responsibilities pursuant to the Consent Agreement. In order to ensure that the

Commission remains informed about the status of the transfer of rights and assets, the Consent Agreement requires Actavis and Forest to file reports with the interim monitor who will report in writing to the Commission concerning performance by the parties of their obligations under the Consent Agreement.

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

By direction of the Commission.

Donald S. Clark,
Secretary.

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