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FEDERAL TRADE COMMISSION

[File No. 131 0152]

Actavis, Inc. a corporation, and Warner Chilott PLC; Analysis of Agreement Containing Consent Orders 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 or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent orders -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before November 12, 2013.

ADDRESSES: Interested parties may file a comment at https://ftcpublic.commentworks.com/ftc/activiswarnerconsent online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Actavis Warner, File No. 131 0152" on your comment and file your comment online at https://ftcpublic.commentworks.com/ftc/actaviswarnerconsent following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex D), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Keri Wallace (202-326-3085), FTC, Bureau

of Competition, 600 Pennsylvania Avenue, NW, Washington, D.C. 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 a 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 September 27, 2013), on the World Wide Web, at http://www.ftc.gov/os/actions.shtm. A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, either in person or by calling (202) 326-2222.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before November 12, 2013. Write "Actavis Warner, File No. 131 0152" 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/actaviswarnerconsent 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 Warner, File No. 131 0152" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade

[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).

Commission, Office of the Secretary, Room H-113 (Annex D), 600 Pennsylvania Avenue, NW, Washington, DC 20580. 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 November 12, 2013. 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 Agreement Containing 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, Inc. ("Actavis") and Warner Chilcott plc ("Warner Chilcott") that is designed to remedy the anticompetitive effects of Actavis's proposed acquisition of Warner Chilcott. Under the terms of the proposed Consent Agreement, Actavis would be required to divest to Amneal Pharmaceuticals L.L.C. ("Amneal") all of Actavis's rights and assets relating to generic versions of the drugs Femcon FE, Loestrin 24 FE, Lo Loestrin FE, and Atelvia. Actavis will also enter into an agreement to supply generic versions of the Femcon FE and Loestrin 24 FE products to Amneal for a period of two years, which Amneal has the option to extend for up to two additional one-year terms if it chooses.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed

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

Pursuant to a Transaction Agreement dated May 19, 2013, Actavis proposes to acquire Warner Chilcott in a transaction valued at approximately $8.5 billion ("Proposed Acquisition"). The Commission's Complaint alleges 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 the U.S. markets for (1) generic Femcon FE, (2) Loestrin 24 FE and its generic equivalents, (3) Lo Loestrin FE and its generic equivalents, and (4) Atelvia and its generic equivalents. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the Proposed Acquisition.

The Impact of Generics in Pharmaceutical Markets

In human 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 has a direct and substantial effect on pricing. When the first generic version of a drug enters the market, it typically competes by selling at a discount to the branded drug. At that point, the brand typically loses most of its sales to the generic version. During the period in which only one generic product is available, the price for the branded product acts as a ceiling above which the generic manufacturer cannot price its product. In most cases, once additional generic versions of the drug enter the market, competition among the generic competitors drives generic pricing down further. Prices continue to decrease incrementally with the entry of the second, third, fourth, and even fifth generic oral pharmaceutical competitor.

Generic drugs are typically launched upon the expiration of the branded product's patents. If the generic company intends to launch its product before the expiration of the branded product's patents, it must notify the FDA and certify that its product does not infringe the branded company's patent or that the branded company's patents are invalid. This is referred to as a Paragraph IV certification. A Paragraph IV certification typically leads to patent infringement litigation between the generic company and branded company. The first company to file a Paragraph IV ANDA has the right to market its generic drug exclusively for a period of 180 days if it is successful in its litigation against the branded drug manufacturer.2 No other firm, even those that subsequently submit Paragraph IV ANDAs, may enter the generic market until after the conclusion of this marketing exclusivity period. The prospect of earning higher profits as the only firm marketing a generic version of a drug for 180 days provides an incentive to defend against the patent infringement claims brought by the brand drug manufacturer. Thus, the firm with exclusivity usually takes the leading role, and invests the greatest resources, in these cases.

The Proposed Acquisition Would Reduce the Number of Suppliers in the Four Relevant Markets

Femcon FE is a chewable oral contraceptive tablet that contains progestin and estrogen. Warner Chilcott manufactures and markets the branded version of the drug. Only two companies—Warner Chilcott (via an authorized generic it supplies to Lupin Ltd.3) and

2 Uncertainty occasionally exists regarding whether a Paragraph IV ANDA has been filed properly, which creates uncertainty about whether a company is eligible to receive marketing exclusivity rights from the FDA. In addition, the FDA sometimes determines that more than one company is eligible for market exclusivity rights based on the timing of their filings.

3 Branded pharmaceutical companies, such as Warner Chilcott, manufacture authorized generic products for sale under a non-brand label at generic prices. In this case, Warner Chilcott has contracted with Lupin

Actavis—currently sell significant volumes of generic Femcon FE in the United States. Teva Pharmaceutical Industries Ltd. ("Teva") also has approval from the FDA to sell generic Femcon FE, but it has made only *de minimis* sales of this product since 2011. In 2012, Actavis had approximately 70 percent of generic sales, while Warner Chilcott had approximately 30 percent. Therefore, the proposed acquisition combines two of the three firms approved to supply generic Femcon FE, and the only two significant suppliers of this drug today.

Loestrin 24 FE is a low-dose progestin/estrogen combination oral contraceptive product. Warner Chilcott manufactures and markets the branded version of the drug. No companies currently market a generic version of Loestrin 24 FE. Actavis is likely to be the first generic supplier to compete against Warner Chilcott and no other firm is likely to enter the market for generic Loestrin 24 FE in time to prevent the anticompetitive effects from the Proposed Acquisition.

Lo Loestrin FE is another low-dose progestin/estrogen combination oral contraceptive product. Warner Chilcott manufactures and markets the branded version of the drug. No companies currently market a generic version of Lo Loestrin FE, but Lupin and Actavis each plan to launch a generic product. Both companies are currently engaged in patent litigation with the brand drug manufacturer, but it remains uncertain which firm would receive marketing exclusivity rights from the FDA if it succeeded in defending against Warner Chilcott's claims. Thus, absent the acquisition, Actavis may be the first and only generic competitor to the Warner Chilcott branded product for a period of 180 days.

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to market the authorized generic version of Femcon FE, though in other markets a branded drug company may market its own generic product.

Atelvia is a delayed-release tablet containing risedronate sodium that is used to treat postmenopausal osteoporosis. Warner Chilcott markets the branded version of the drug. No generic version of the product is currently available in the United States. Actavis, Teva, and Ranbaxy Laboratories Limited all plan to market generic versions of Atelvia, and all three companies are currently engaged in patent litigation with Warner Chilcott. However, uncertainty remains about which one will have marketing exclusivity rights if successful in the litigation. Thus, absent the acquisition, Actavis may be the first and only generic competitor to Warner Chilcott's branded product for a period of 180 days.

Entry into the Relevant Markets

Entry into the markets for generic Femcon FE, Lo Loestrin 24 and its generic equivalents, Loestrin 24 FE and its generic equivalents, and Atelvia and its generic equivalents would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. *De novo* entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would delay entry by at least two years. Even companies for which the FDA approval process is well underway face additional barriers, including Hatch-Waxman regulatory exclusivity and pending patent litigation, that prevent them from entering these markets in time to deter the price increases that would occur after consummation of the Proposed Acquisition.

The Anticompetitive Effects of the Acquisition

The Proposed Acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for generic Femcon FE, Lo Loestrin 24 and its generic equivalents, Lo Loestrin FE and its generic equivalents, and Atelvia and its generic equivalents. The Proposed Acquisition would eliminate the current competition between the only two significant suppliers

of generic Femcon FE, leading to significantly higher prices for this drug. The acquisition may also delay the onset of beneficial generic competition in the markets for Loestrin 24 FE, Lo Loestrin FE, and Atelvia. Evidence, including information regarding the status of the FDA approval process for potential suppliers of generic Loestrin 24 FE, suggests that Actavis will be the first generic supplier to compete against Warner Chilcott's branded product. Moreover, no other generic supplier is likely to enter the market for a significant period of time. Thus, the combined firm would likely delay the entry of Actavis's generic version of Loestrin 24 FE or, at a minimum, cause Actavis's generic drug to compete less vigorously against Warner Chilcott's branded product, resulting in higher prices for consumers. Similarly, in the markets for Lo Loestrin FE and Atelvia, Actavis may be the first and only generic competitor to Warner Chilcott's branded products for a significant period absent the Proposed Acquisition. By eliminating this potential competition between Warner Chilcott and Actavis in each of these markets, the Proposed Acquisition would harm U.S. consumers by substantially increasing the likelihood of higher post-acquisition prices for Lo Loestrin FE and Atelvia.

The Proposed Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant markets by requiring Actavis to divest to Amneal certain rights and assets related to generic Femcon FE, generic Loestrin 24 FE, generic Lo Loestrin FE, and generic Atelvia no later than ten days after consummating the acquisition. In addition, the Consent Agreement requires Actavis to enter into a supply agreement to provide Amneal with generic versions of the Femcon FE and Loestrin 24 FE products to sell in the United States for up to four years. Amneal is a New Jersey-based generic pharmaceutical company that currently markets 65 products and maintains an active product development pipeline. With its experience

in generic markets, Amneal is well positioned to replicate the competition that would otherwise be lost as a result of the Proposed Acquisition.

If the Commission determines that Amneal is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, Actavis must unwind the sale to Amneal and divest the products within six months of the date the Order becomes final, to a Commission-approved acquirer. If Actavis fails to divest the products as required, the Commission may appoint a trustee to divest the products.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Actavis to maintain the economic viability, marketability, and competitiveness of the divestiture products until such time as they are transferred to Amneal or another Commission-approved acquirer. Actavis must also transfer the manufacturing technology for the divestiture products to Amneal and supply Amneal with the generic Femcon FE and Loestrin 24 FE products during the transition period. In addition, the Consent Agreement requires Actavis to relinquish any claim to marketing exclusivity for generic Lo Loestrin FE and Atelvia products to ensure that the incentives of the companies currently leading the patent litigations relating to those products do not change.

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.

[FR Doc. 2013-25847 Filed 10/30/2013 at 8:45 am; Publication Date: 10/31/2013]