

UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman  
Julie Brill  
Maureen K. Ohlhausen  
Joshua D. Wright

<p><b>In the Matter of</b></p> <p style="padding-left: 40px;"><b>ACTAVIS, INC.,</b> a corporation;</p> <p style="padding-left: 40px;"><b>and</b></p> <p style="padding-left: 40px;"><b>WARNER CHILCOTT PLC,</b> a public limited company.</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p><b>Docket No. C-4414</b></p>
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**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Actavis, Inc. (“Actavis”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Warner Chilcott plc (“Warner Chilcott”), a public limited company subject to the jurisdiction of the Commission, in violation of Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, that such acquisition, 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. RESPONDENT**

1. Respondent Actavis is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Nevada, with its corporate head office and principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

2. Respondent Warner Chilcott is a public limited company organized, existing, and doing business under and by virtue of the laws of Ireland, with its corporate head office and principal place of business located at 1 Grand Canal Square, Docklands, Dublin 2, Ireland.

3. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business 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 ACQUISITION**

4. Pursuant to a Transaction Agreement dated May 19, 2013, Actavis proposes to acquire Warner Chilcott for approximately \$8.5 billion (the “Acquisition”).

## **III. THE RELEVANT MARKETS**

5. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the manufacture and sale of:

- a. generic human pharmaceutical oral contraceptive products containing 21 active chewable tablets with 0.4 mg norethindrone progestin and 0.035 mg ethinyl estradiol estrogen, and seven inactive chewable tablets with ferrous fumarate (“generic Femcon FE”);
- b. human pharmaceutical oral contraceptive products containing 24 active tablets with 1 mg norethindrone progestin and 0.02 mg ethinyl estradiol estrogen, and four inactive tablets with ferrous fumarate, a version of which is currently marketed under the brand name Loestrin 24 FE;
- c. human pharmaceutical oral contraceptive products containing 24 active tablets with 1 mg norethindrone progestin and 0.01 mg ethinyl estradiol estrogen, two active tablets with 0.01 mg ethinyl estradiol estrogen only, and four inactive iron supplement tablets, a version of which is currently marketed under the brand name Lo Loestrin FE; and

- d. human pharmaceutical products containing delayed-release risedronate sodium, a version of which is currently marketed under the brand name Atelvia.

6. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

#### **IV. THE STRUCTURE OF THE MARKETS**

7. Warner Chilcott developed and markets the branded formulation of Femcon FE. Only Actavis and Lupin Limited (“Lupin”) currently sell significant volumes of generic Femcon FE in the United States. Lupin’s product is supplied by Warner Chilcott as an authorized generic version of the drug. Teva Pharmaceutical Industries Ltd. has an approved ANDA to sell generic Femcon FE, but has only *de minimis* sales at this time. Among the generic competitors, Actavis is the leader with a 70.2% share, and Warner Chilcott / Lupin has a 29.7% share.

8. Warner Chilcott manufactures and markets the branded formulation of the oral contraceptive Loestrin 24 FE. No company currently markets a generic version in the United States. Actavis holds an approved ANDA to market generic Loestrin 24 FE in the United States and, in the near future, is likely to be the first generic competitor to the Warner Chilcott branded product. No other suppliers are expected to enter this market in time to prevent the competitive harm likely to result from the Acquisition.

9. Warner Chilcott manufactures and markets the branded formulation of Lo Loestrin FE. No company currently markets a generic version in the United States. Actavis is one of a limited number of suppliers capable of entering the generic Lo Loestrin FE market in the near future and may be the first and only generic competitor to the Warner Chilcott branded product for a period of 180 days.

10. Warner Chilcott’s branded risedronate sodium product, Atelvia, is a delayed-release tablet used to treat postmenopausal osteoporosis. No company currently markets a generic version in the United States. Actavis is one of a limited number of suppliers capable of entering the market for generic Atelvia in the near future and may be the first and only generic competitor to the Warner Chilcott branded product for a period of 180 days.

#### **V. ENTRY CONDITIONS**

11. Entry into the relevant markets described in Paragraphs 5 and 6 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 U.S. Food and Drug Administration (“FDA”) approval requirements take at least two years. In addition, no other

entry by firms for which the FDA approval process is already underway would be sufficient to prevent the competitive harm likely to result from the Acquisition.

## **VI. EFFECTS OF THE ACQUISITION**

12. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets 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 Actavis and Warner Chilcott and reducing the number of significant competitors in the market for generic Femcon FE from two to one thereby: (1) increasing the likelihood that Actavis will be able to unilaterally exercise market power in this market; and (2) increasing the likelihood that customers would be forced to pay higher prices;
- b. by eliminating potential competition between Actavis and Warner Chilcott and reducing the number of competitors in the future thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of Actavis's generic version of Loestrin 24 FE; and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from an independent Actavis supplying a generic version of Loestrin 24 FE;
- c. by eliminating potential competition between Actavis and Warner Chilcott and reducing the number of competitors in the future thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of Actavis's generic version of Lo Loestrin FE; and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from an independent Actavis supplying a generic version of Lo Loestrin FE; and
- d. by eliminating potential competition between Actavis and Warner Chilcott and reducing the number of competitors in the future thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of Actavis's generic version of Atelvia; and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from an independent Actavis supplying a generic version of Atelvia.

## VII. VIOLATIONS CHARGED

13. The Transaction Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

14. The Acquisition described in Paragraph 4, 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 twenty-seventh day of September, 2013 issues its Complaint against said Respondent.

By the Commission.

Donald S. Clark  
Secretary

SEAL: