

**UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION**

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

In the Matter of )  
ACTAVIS PLC, )  
a corporation; )  
and )  
FOREST LABORATORIES, INC., )  
a corporation. )

Docket No. C-4474

## **COMPLAINT**

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

1. Respondent Actavis is a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland, with its headquarters address located at 1 Grand Canal Square, Docklands, Dublin 2, Ireland.

2. Respondent Forest is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its headquarters address located at 909 Third Avenue, New York, New York 10022-4731.

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 an Agreement and Plan of Merger dated February 17, 2014, Actavis proposes to acquire 100% of the voting securities of Forest for approximately \$25 billion (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

## **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 development, license, manufacture, marketing, distribution, and sale of the following pharmaceutical products:

- a. generic diltiazem hydrochloride extended release capsules (AB4) (generic Tiazac) (“generic diltiazem hydrochloride (AB4)");
- b. generic ursodiol tablets (“generic ursodiol");
- c. generic propranolol hydrochloride extended release capsules (“generic propranolol hydrochloride"); and
- d. lamotrigine orally disintegrating tablets, a version of which is currently marketed under the brand name Lamictal ODT.

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

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

7. Generic diltiazem hydrochloride (AB4) is used to treat hypertension and chronic stable angina. The market for generic diltiazem hydrochloride (AB4) is highly concentrated with only three current suppliers—Actavis, Forest, and Sun Pharmaceutical Industries, Ltd. The Acquisition would reduce the number of suppliers of generic diltiazem hydrochloride (AB4) from three to two and increase the Herfindahl-Hirschman Index concentration (“HHI”) by 2700, from 3550 to a post-merger total of 6250.

8. Generic ursodiol tablets are used to treat primary biliary cirrhosis of the liver. Four firms—Actavis, Forest, which distributes its product pursuant to an authorized generic arrangement with Prasco Laboratories, Par Pharmaceutical Companies, and Glenmark Pharmaceuticals, Ltd.—currently supply generic ursodiol in this highly concentrated market, which has an HHI in excess of 5000. The Acquisition would reduce the number of suppliers of generic ursodiol from four to three and increase the HHI by 342, from 5416 to a post-merger total of 5758.

9. Generic propranolol hydrochloride is an extended release capsule indicated for the treatment of hypertension. The market for generic propranolol hydrochloride is highly concentrated with only four current suppliers—Actavis, Forest, which distributes its product through Breckenridge Pharmaceutical LLC (“Breckenridge”), Rouses Point Pharmaceuticals, and Upsher-Smith Laboratories. The Acquisition would reduce the number of suppliers of generic propranolol hydrochloride from four to three and increase the HHI by 1408, from 4523 to a post-merger total of 5931.

10. 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. No companies currently market a generic version in the United States. Actavis holds the only approved Abbreviated New Drug Application to market generic Lamictal ODT. Thus, absent the Acquisition, Actavis is 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 Proposed Acquisition would likely delay or preclude the entry of Actavis’ generic product.

## **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 FDA approval requirements would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract 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 Forest and reducing the number of significant competitors in the markets for (1) generic diltiazem hydrochloride (AB4); (2) generic ursodiol; and (3) generic propranolol hydrochloride, thereby increasing the likelihood that: (a) Actavis would be able to unilaterally exercise market power in these markets; (b) the remaining competitors would engage in coordinated interaction between or among each other; and (c) customers would be forced to pay higher prices; and
- b. by eliminating future competition between Actavis and Forest in the market for lamotrigine orally disintegrating tablets, thereby (a) increasing the likelihood that the combined entity would forego or delay the launch of this product and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of this product.

## **VII. VIOLATIONS CHARGED**

13. The Agreement and Plan of Merger 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 thirtieth day of June, 2014 issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark  
Secretary

SEAL: