

UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman  
J. Thomas Rosb  
Edith Ramirez  
Julie Brill  
Maureen K. Ohlhausen

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In the Matter of )  
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 )  
 WATSON PHARMACEUTICALS INC., )  
 a corporation; )  
 )

ACTAVIS PHARMA HOLDING 4 EHF., )  
 a private limited liability company; )  
 )  
 and )  
 )  
 ACTAVIS S.ÁR.L. )  
 a limited liability corporat e entity. )

) Docket No. C-4373

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 Watson Pharmaceuticals, hc. ("Watson"), a orporation subject to the jurisdiction of the Commission, has agreed to acquire Actavis hc., Adavis Pharma Holding ehf., and Actavis S.à.r.l. together, "Actavis Group" or "Actavis"), entities controlled by Björgólfur Thor Björgólfsson and subject to the jurisdiction of the Commission, 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 Watson is a corporation org

- f. extended release morphine sulfate capsules;
- g. extended release nifedipine tablets (generic Adalat CC);
- h. extended release amphetamine salts capsules;
- i. extended release diltiazem hydrochloride capsules (generic Tiazad);
- j. extended release oxycodone non-tamper resistant tablets;
- k. extended release glipizide tablets;
- l. isradipine capsules;
- m. loxapine succinate capsules;
- n. extended release methylphenidate hydrochloride tablets;
- o. ursodiol tablets;
- p. adapalene and benzoyl peroxide topical gel;
- q. dextromethorphan hydrobromide and quinidine sulfate capsules;
- r. extended release morphine sulfate and naltrexone combination capsules;
- s. extended release oxycodone tamper resistant tablets;
- t. extended release ivastigmine film; and
- u. varenicline tartrate tablets.

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 each of the relevant lines of commerce.

#### IV. THE STRUCTURE OF THE MARKETS

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8. Extended release diltiazem hydrochloride capsules (generic Cardizem CD) are used to treat hypertension, angina, and certain heart rhythm disorders. The proposed transaction would result in a 55% market share for the combined entity. There are two other suppliers – Teva and Sun Pharmaceutical Industries, Ltd. (“Sun”). Thus, the Acquisition would reduce the number of suppliers from four to three and increase the HHI by 1,488 points, from 3,474 points to 4,962 points.

9. Fentanyl transdermal system is a patch that releases fentanyl to ease chronic pain. There are currently five suppliers of generic fentanyl transdermal system – Watson, Actavis, Mylan, Apotex, Inc., and Mainckrodt, LLC (a division of Covidien plc). Thus, the Acquisition would reduce the number of competitors from five to four, give the combined entity a market share of 34%, and increase the HHI by 378 points, from 3,460 points to 3,838 points.

10. Lorazepam is used to treat anxiety disorders. Currently, there are five suppliers of generic lorazepam – Excellium Pharmaceutical, Ltd., Mylan, Ranbaxy Laboratories, Ltd., Watson, and Actavis. The proposed transaction would reduce the number of competitors from five to four and result in a market share for the combined entity of 53%. The Acquisition would increase the HHI by 1,380 points, from 2,208 points to 3,588 points.

11. Metoclopramide hydrochloride is used to treat nausea. Teva, Watson, and Actavis share approximately 61% of the market for this product. Accounting for recent exit, the proposed transaction would reduce the number of competitively significant suppliers from three to two, give the combined entity a 34% market share, and increase the HHI by 560 points, from 1,618 points to 2,178 points.

12. Extended release morphine sulfate capsules are used to treat acute pain. Actavis owns the branded product Kadian, and markets the authorized generic. Watson markets the only other generic Kadian available. Thus, the proposed transaction would create a monopoly in generic extended release morphine sulfate capsules.

13. Extended release nifedipine tablets are used to treat hypertension and angina. Watson, Actavis, Mylan, and Valeant Pharmaceuticals International, Inc., whose product is sold by Teva currently market extended release nifedipine tablets in the United States. The proposed transaction would reduce the number of suppliers from four to three and result in a combined entity with 31% market share. The Acquisition would increase the HHI by 456 points, from 4,746 points to 5,202 points.

14. Extended release amphetamine salts capsules are the generic version of Adderall XR, manufactured by Shire plc, which is a treatment for attention deficit hyperactivity disorder (“ADHD”). Actavis recently entered this market, joining Teva and Impax Laboratories, Inc., who are marketing authorized generics. Watson is one of a limited number of firms that has an extended release amphetamine salts capsule in development. The proposed transaction would reduce the number of current and likely potential suppliers of generic Adderall XR.



22. The combination of adapalene and benzoylperoxide is a topical treatment for acne. It is marketed by Galderma Laboratories LP. under the brand Epiduo. Currently, there are no AB-rated generic versions of Epiduo available in the United States, but Watson and Actavis are two of a limited number of likely potential suppliers of generic Epiduo.

23. Dextromethorphan hydrobromide and quinidine sulfate capsules are the generic version of Nuedexta and are used to treat pseudobulbar affect, i.e., uncontrolled episodes of crying and/or laughing in people with multiple sclerosis and other neurological diseases. Currently, there are no generic versions of Nuedexta available in the United States. Watson and Actavis are two of a limited number of likely potential suppliers of generic Nuedexta.

24. Extended release morphine sulfate and naltrexone combination capsules are the generic equivalent of Pfizer's Embeda, a product used to treat acute pain. Currently, there is no generic market for Embeda in the United States and Pfizer has recalled the branded product, which should return to market in the foreseeable future. Actavis and Pfizer have entered into an exclusive Development and Manufacturing Agreement to manufacture Embeda, while Watson is one of a limited number of likely potential suppliers of generic Embeda.

25. Extended release oxycodone taper resistant tablets are the generic version of taper resistant OxyContin, which is used to treat moderate to severe pain that is expected to last for an extended period of time. No generic versions of this product are available in the United States. Watson and Actavis are among a limited number of likely potential suppliers of generic OxyContin.

26. Extended release rivastigmine film is the generic equivalent of Exelon, a patch used to treat Alzheimer's disease and dementia resulting from Parkinson's disease. Novartis AG markets branded Exelon in the United States. No generic versions of this product are available in the United States. Watson and Actavis are among a limited number of likely potential suppliers of generic Exelon.

27. Varenicline tartrate tablets are the generic version of Pfizer's Chantix, which is a smoking cessation medicine. No generic versions of this product are available in the United States. Watson and Actavis are among a limited number of likely potential suppliers of generic Chantix.

## V. ENTRY CONDITIONS

28. 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 counter the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because of the combination of drug development times, U.S. Drug Enforcement Administration restrictions and quotas on controlled substances, and other barriers to entry.

## VI. EFFECTS OF THE ACQUISITION

The effects of this 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:

- by eliminating actual, direct, and substantial competition between Watson and Actavis and reducing the number of competitors in the markets for (1) extended release bupropion hydrochloride tablets; (2) extended release diltiazem hydrochloride capsules (generic Cardizem CD); (3) fentanyl transdermal system; (4) lorazepam tablets; (5) metoprolol hydrochloride tablets; (6) extended release morphine sulfate capsules; and (7) extended release nifedipine tablets, and thereby (a) increasing the likelihood that Watson will be able to exercise market power in these markets; (b) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (c) increasing the likelihood that customers would be forced to pay higher prices for these products;
- by eliminating future competition between Watson and Actavis and reducing the number of generic competitors in the future in the markets for (1) extended release amphetamine salts capsules; (2) extended release diltiazem hydrochloride capsules (generic Tiazac); (3) extended release oxycodone non-taper resistant tablets; (4) extended release dipizide tablets; (5) isradipine capsules; (6) loxapine succinate capsules; (7) extended release methylphenidate hydrochloride tablets; (8) ursodiol tablets; (9) clonidine and benzoyl peroxide topical gel; (10) dextromethorphan hydrobromide and quinidine sulfate capsules; (11) extended release morphine sulfate and naltrexone combination capsules; (12) extended release oxycodone taper resistant tablets; (13) extended release ivastigmine film; and (14) venidine tartrate tablets, and thereby (a) increasing the likelihood that the combined entity will be able to exercise market power in these markets; (b) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (c) increasing the likelihood that customers would be forced to pay higher prices for these products.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fifteenth day of October, 2012 issues its Complaint against said Respondents

By the Commission.

Donald S. Clark  
Secretary

SEAL: