1210132

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

In the Matter of	)	
WATSON PHARMACEUTICALS INC., **a corporation;**	)	
ACTAVIS INC., **a corporation;**	)	
ACTAVIS PHARMA HOLDING 4 EHF., **a private limited liability company;**	)	**Docket No. C-4373**
and	)	
ACTAVIS S.Á.R.L. **a limited liability corporate entity.**	)	

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, Inc. ("Watson"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Actavis Inc., Actavis Pharma Holding 4 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, 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 Watson 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 Actavis includes three entities. Actavis Inc. 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 60 Columbia Road, Building B, Morristown, New Jersey 07960. Actavis Pharma Holding 4 ehf. is a private limited liability company organized, existing, and doing business under and by virtue of the laws of the Republic of Iceland, with its headquarters address located at Reykjavikurvegi 76-78, 220 Hafnarfirdi, Iceland. Actavis S.á.r.l. is a limited liability corporate entity organized, existing, and doing business under and by virtue of the laws of the Grand Duchy of Luxemburg, with its headquarters address located at 6c, Rue Gabriel Lippmann, L 5365 Munsbach, Luxembourg.

3. Respondents are, and at all times relevant herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and 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 Sale and Purchase Agreement ("Purchase Agreement") dated as of April 25, 2012, Watson proposes to acquire 100% of the voting securities of Actavis Group for approximately $5.9 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 the following generic pharmaceutical products:

a. extended release bupropion hydrochloride tablets (generic Zyban);

b. extended release diltiazem hydrochloride capsules (generic Cardizem CD);

c. fentanyl transdermal system;

d. lorazepam tablets;

e. metoclopramide hydrochloride tablets;

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 Tiazac);

j. extended release oxymorphone 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 rivastigmine 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

7. Extended release bupropion hydrochloride tablets, the generic of Zyban by GlaxoSmithKline plc, are designed to help people quit smoking by reducing cravings and other side effects of withdrawal. Currently, Teva Pharmaceutical Industries Ltd. ("Teva"), Mylan, Inc. ("Mylan"), Watson, and Actavis market generic Zyban. Thus, the Acquisition would reduce the number of suppliers from four to three. A combination of Watson and Actavis would create a firm that would supply 45% of the market and increase the Herfindahl-Hirschman Index ("HHI") by 700 points, from 4,138 points to 4,838 points.

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 Mallinckrodt, 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.

15. Extended release diltiazem hydrochloride capsules (generic Tiazac) are used to treat hypertension and angina. Three companies currently market generic Tiazac – Sun, Inwood Laboratories (a wholly-owned subsidiary of Forest Pharmaceuticals, Inc.), and Watson. Actavis is one of a limited number of firms that has a generic extended release diltiazem hydrochloride capsule in development. The proposed transaction would reduce the number of current and likely potential suppliers of generic Tiazac.

16. Extended release oxymorphone non-tamper resistant tablets are the generic version of Opana ER, which is used to treat chronic pain. Opana ER is marketed by Endo Health Solutions, Inc. Actavis markets the only generic version of Opana ER in two strengths and is developing additional strengths. Watson is also one of a limited number of firms developing this product. The Acquisition would reduce the number of current and likely potential suppliers of generic Opana ER.

17. Extended release glipizide is an oral diabetes medicine that boosts insulin production to control blood sugar levels. Watson's product and Pfizer, Inc.'s ("Pfizer's") authorized generic are the only generic versions of the product currently available. Actavis is one of a limited number of firms that has extended release glipizide in development and the Acquisition would reduce the number of current and likely potential suppliers of extended release glipizide.

18. Isradipine capsules are used to treat high blood pressure and are the generic version of Dynacirc. Branded Dynacirc has been discontinued and Watson manufactures the only generic product available today. Actavis has a marketing and profit-sharing arrangement with the best-positioned entrant, which is one of a limited number of likely potential suppliers of isradipine capsules.

19. Loxapine capsules are used to treat the symptoms of schizophrenia and are the generic version of branded Loxatine, which is no longer on the market. Watson manufactures the only generic product currently on market. As with generic isradipine capsules, Actavis has a marketing and profit-sharing arrangement with the best-positioned entrant, which is one of a limited number of likely potential suppliers of generic Loxatine.

20. Extended release methylphenidate hydrochloride tablets are used in the treatment of ADHD in people over the age of six. Watson markets the only generic product as the authorized generic and Actavis is one of a limited number of firms that has an extended release methylphenidate hydrochloride tablet in development. The Acquisition would reduce the number of current and likely potential suppliers of extended release methylphenidate hydrochloride tablets.

21. Depending on the strength, generic ursodiol tablets are the generic version of Urso 250 or Urso Forte and are used to treat primary biliary cirrhosis. Watson currently markets both strengths of generic ursodiol and Actavis is one of a limited number of likely potential suppliers of each of these strengths of ursodiol tablets. The Acquisition would reduce the number of current and likely potential suppliers for a significant period of time.

22. The combination of adapalene and benzoyl peroxide is a topical treatment for acne. It is marketed by Galderma Laboratories L.P. 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 tamper resistant tablets are the generic version of tamper 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 yet 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 yet 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 yet 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 or counteract 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 FDA approval requirements, which delay entry by at least two years.

VI. EFFECTS OF THE ACQUISITION

29. 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:

- 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) metoclopramide 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 unilaterally 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; and

- 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 oxymorphone non-tamper resistant tablets; (4) extended release glipizide tablets; (5) isradipine capsules; (6) loxapine succinate capsules; (7) extended release methylphenidate hydrochloride tablets; (8) ursodiol tablets; (9) adapalene 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 tamper resistant tablets; (13) extended release rivastigmine film; and (14) varenicline tartrate tablets, and thereby: (a) increasing the likelihood that the combined entity would forego or delay the launch of these products, 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 these products.

VII. VIOLATIONS CHARGED

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

29. 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 fifteenth day of October, 2012 issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: