

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS
TO AID PUBLIC COMMENT**

*In the Matter of Watson Pharmaceuticals, Inc., Actavis Inc.,
Actavis Pharma Holding 4 ehf., and Actavis S.a.r.l., File No. 121-0132*

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Watson Pharmaceuticals, Inc. (“Watson”) and Actavis Inc., Actavis Pharma Holding 4 ehf., and Actavis S.à.r.l. (together, “Actavis”) that is designed to remedy the anticompetitive effects in twenty-one pharmaceutical markets resulting from Watson’s acquisition of Actavis. Under the terms of the proposed Consent Agreement, the companies would be required to divest to Par Pharmaceutical, Inc. (“Par”) all of Watson’s rights and assets relating to (1) generic adapalene and benzoyl peroxide topical gel; (2) generic extended release morphine sulfate capsules; (3) generic extended release oxymorphone non-tamper resistant tablets; and (4) generic extended release amphetamine salts capsules; as well as all of Actavis’s rights and assets relating to the following generic products: (1) extended release diltiazem hydrochloride capsules (generic Cardizem CD); (2) fentanyl transdermal system; (3) extended release glipizide tablets; (4) extended release methylphenidate hydrochloride tablets; (5) ursodiol tablets; (6) metoclopramide hydrochloride tablets; (7) extended release oxycodone tamper resistant tablets; (8) extended release nifedipine tablets; (9) extended release rivastigmine film; and (10) varenicline tartrate tablets. The companies would also be required to divest to Sandoz International GmbH (“Sandoz”), a subsidiary of Novartis AG (“Novartis”), all of Watson’s rights and assets relating to generic dextromethorphan hydrobromide and quinidine sulfate capsules, as well as all of Actavis’s rights and assets to (1) generic extended release bupropion hydrochloride tablets; (2) generic extended release diltiazem hydrochloride capsules (generic Tiazac); and (3) generic lorazepam tablets. The companies would also be required to waive all of Actavis’s rights in generic isradipine capsules and generic loxapine succinate capsules. In addition, the proposed Consent Agreement requires Watson to amend a Development and Manufacturing Agreement with Pfizer, Inc. (“Pfizer”) relating to the manufacture of extended release morphine sulfate and naltrexone combination capsules.

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 Sale and Purchase Agreement dated as of April 25, 2012, Watson proposes to acquire Actavis in a transaction valued at approximately \$5.9 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 current and future competition in U.S. markets for the following generic pharmaceutical products: (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; (7) extended release nifedipine tablets; (8) extended release amphetamine salts capsules; (9) extended release diltiazem hydrochloride capsules (generic Tiazac); (10) extended release oxymorphone non-tamper resistant tablets; (11) extended release glipizide tablets; (12) isradipine capsules; (13) loxapine succinate capsules; (14) extended release methylphenidate hydrochloride tablets; (15) ursodiol tablets; (16) adapalene and benzoyl peroxide topical gel; (17) dextromethorphan hydrobromide and quinidine sulfate capsules; (18) extended release morphine sulfate and naltrexone combination capsules; (19) extended release oxycodone tamper resistant tablets; (20) extended release rivastigmine film; and (21) varenicline tartrate tablets (collectively, the “Products”). The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the acquisition.

The Products and Structure of the Markets

The Proposed Acquisition would reduce the number of suppliers in each of the relevant markets. In human pharmaceutical product markets with generic competition, 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.

The Proposed Acquisition would reduce current competition in the markets for each of the following generic products: (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. The structure of these markets is as follows:

- 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, four firms market generic Zyban – Watson, Actavis, Teva Pharmaceutical Industries Ltd. (“Teva”), and Mylan, Inc. (“Mylan”). Thus, the Proposed Acquisition would reduce the number of competitors for generic Zyban from four to three and result in a 45% market share for the combined entity based on 2011 sales. Teva and Mylan had 2011 shares of 53% and 2%, respectively.
- Extended release diltiazem hydrochloride capsules (generic Cardizem CD) are used to treat hypertension, angina, and certain heart rhythm disorders. Currently, four firms market generic Cardizem CD – Watson, Actavis, Teva and Sun Pharmaceutical Industries, Ltd. (“Sun”), which entered in late 2011. Thus, the Proposed Acquisition would reduce the number of competitors for generic Cardizem CD from four to three and result in a 55% market share for the combined entity.
- Fentanyl transdermal system is a patch that releases fentanyl to ease chronic pain and is the generic equivalent of Janssen Pharmaceuticals, Inc.’s (“Janssen’s”) branded product, Duragesic. Currently, five firms market generic fentanyl transdermal system – Watson, Actavis, Mylan, Apotex, Inc., and Mallinckrodt, LLC (a division of Covidien plc). Thus,

the Proposed Acquisition would reduce the number of competitors for generic Duragesic from five to four and give the combined entity a market share of 34%. Mylan is the market leader with 51% and the remaining two suppliers combined had slightly more than a 10% share.

- Lorazepam, the generic of Ativan by Valeant Pharmaceuticals International, Inc. (“Valeant”), is used to treat anxiety disorders. Currently, five firms market generic lorazepam – Watson, Actavis, Excellium Pharmaceutical, Ltd. (“Excellium”), Mylan, and Ranbaxy Laboratories, Ltd. (“Ranbaxy”). The proposed transaction would reduce the number of competitors for lorazepam from five to four and result in a market share for the combined entity of 53%. Mylan and Ranbaxy had 21% and 16% market shares, respectively, while Excellium had a 1% market share. The remainder of the market is split by repackagers of these competitors’ product.
- Metoclopramide hydrochloride is the generic version of Reglan, which is used to treat nausea and is marketed by Ani Pharmaceuticals, Inc. In 2011, Watson, Actavis, and Teva shared approximately 61% of sales. While other suppliers have U.S. Food and Drug Administration (“FDA”) approval to market the drug, they have been exiting the market over the last several years for a variety of reasons, including product liability issues associated with the branded product. Accounting for recent exit, the proposed transaction would reduce the number of competitively significant suppliers of metoclopramide hydrochloride from three to two and give the combined entity a 34% market share.
- Extended release morphine sulfate capsules are the generic equivalent of Actavis’s Kadian, which is used to treat acute pain. In addition to owning the branded Kadian product, Actavis also markets an authorized generic version of Kadian. Watson markets the only other generic Kadian available. Thus, absent a remedy, the proposed transaction would create a monopoly in generic extended release morphine sulfate capsules.
- Extended release nifedipine tablets are the generic version of Adalat CC, which is marketed by Bayer AG, and used to treat hypertension and angina. Currently, there are four suppliers of extended release nifedipine tablets in the United States – Watson, Actavis, Mylan, and Valeant, whose product is sold by Teva. Thus, the proposed transaction would reduce the number of suppliers of extended release nifedipine tablets from four to three and result in a combined entity with 31% market share.

In addition to reducing current competition in the seven above-identified markets, the Proposed Acquisition would significantly reduce competition in the markets for each of the following generic products: (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; and (8) ursodiol tablets. Either Watson or Actavis currently markets each of these products, and the other is likely to enter, significantly increasing competition and likely causing price reductions

when entry occurs. The structure of each of these markets is as follows:

- 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 eliminate a likely potential supplier in the concentrated market for generic Adderall XR.
- 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 eliminate a likely potential supplier in the concentrated market for generic Tiazac.
- 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 proposed transaction would eliminate a likely potential supplier in the concentrated market for generic Opana ER.
- 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 proposed transaction would eliminate a likely potential supplier in the concentrated market for extended release glipizide.
- 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 a likely potential supplier in the concentrated market for isradipine capsules.
- 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 available today. Actavis has a profit-sharing arrangement with a best-positioned entrant for this product, which is a likely potential supplier in the concentrated market for generic Loxatine.
- Extended release methylphenidate hydrochloride tablets are the generic equivalent of Concerta, which is manufactured by Janssen and 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 proposed transaction would eliminate a likely potential supplier in the concentrated market for extended release methylphenidate hydrochloride tablets.

- 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 proposed transaction would eliminate a likely potential supplier in the concentrated market for ursodiol tablets for a significant period of time.

The transaction will also reduce future competition in generic markets that do not yet exist, but will be highly concentrated when Watson and Actavis enter. These markets include: (1) adapalene and benzoyl peroxide topical gel; (2) dextromethorphan hydrobromide and quinidine sulfate capsules; (3) extended release morphine sulfate and naltrexone combination capsules; (4) extended release oxycodone tamper resistant tablets; (5) extended release rivastigmine film; and (6) varenicline tartrate tablets. The structure of each of these markets is as follows:

- 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. The proposed transaction would eliminate a likely entrant into what will be a concentrated market for generic Epiduo.
- 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. The proposed transaction would eliminate a likely entrant into what will be a concentrated market for generic Nuedexta.
- 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 are no generic versions of Embeda available in the United States. Pfizer recalled the branded product, but plans to return it to market in the near future. Actavis and Pfizer have entered into an exclusive Development and Manufacturing Agreement to manufacture Embeda, and that agreement grants Actavis competitively significant rights (including authorized generic marketing rights). Watson is one of a limited number of likely potential suppliers of generic Embeda. The proposed transaction would eliminate a likely entrant into what will be a concentrated market for generic Embeda.

- 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. The proposed transaction would eliminate a likely entrant into what will be a concentrated market for generic OxyContin.
- 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 markets branded Exelon in the United States. Currently, there are no generic versions of this product in the United States. Watson and Actavis are among a limited number of likely potential suppliers of generic Exelon. The proposed transaction would eliminate a likely entrant into what will be a concentrated market for generic Exelon.
- Varenicline tartrate tablets are the generic version of Pfizer's Chantix, which is a smoking cessation medicine. Currently, 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. The proposed transaction would eliminate a likely entrant into what will be a concentrated market for generic Chantix.

Entry

Entry into the markets for the Products would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. The combination of drug development times and regulatory requirements, including FDA approval, takes well in excess of two years. And even companies for whom the FDA approval process is well underway face other regulatory barriers, including Hatch-Waxman regulatory exclusivity and pending patent litigation, that limit their ability to enter these markets in a timely manner.

Effects

The Proposed Acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the Products, either by eliminating significant current or potential competition in concentrated existing markets, or by eliminating significant potential competition among a limited number of competitors in future markets. In pharmaceutical markets with generic competition, price generally decreases as the second, third, fourth, and frequently fifth competitors enter. Although in certain of the markets, neither Watson nor Actavis yet have a marketed product, and in other of the markets, all generic products have yet to be approved, the FDA approval process provides extensive information about the timeliness and likelihood of entry by firms that market generic pharmaceuticals. In addition, substantial experience and empirical evidence of the impact of multiple generic suppliers on prices for other drugs demonstrate that the likely effects of the Proposed Acquisition in the markets for these products would be substantial. The Proposed Acquisition, by reducing an already limited number of

competitors or likely potential competitors in each of these markets, would cause anticompetitive harm to U.S. consumers by increasing the likelihood of higher post-acquisition prices.

The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant markets. Pursuant to the Consent Agreement, Watson and Actavis are required to divest either Watson's or Actavis's rights and assets related to eighteen of the twenty-one Products (all but extended release morphine sulfate and naltrexone combination capsules, isradipine capsules, and loxapine succinate capsules) to a Commission-approved acquirer no later than ten days after the acquisition. To remedy the concerns with the three remaining products, the combined entity would also be required to amend Actavis's existing Development and Manufacturing Agreement with Pfizer to eliminate Actavis' right of first refusal to market a potential authorized generic, to allow the relationship to end, and to transfer manufacturing rights back to Pfizer. In addition, the companies are required to waive Actavis's rights related to isradipine capsules and loxapine succinate capsules.

The proposed Consent Agreement requires Watson or Actavis to divest assets related to four of the markets (generic extended release bupropion hydrochloride tablets, generic extended release diltiazem hydrochloride capsules, generic lorazepam tablets, and generic dextromethorphan hydrobromide and quinidine sulfate capsules) to Sandoz, and the rest of the Products (all but extended release morphine sulfate and naltrexone combination capsules, isradipine capsules, and loxapine succinate capsules) to Par. Par is a New Jersey-based generic pharmaceutical company selling over 60 prescription drug product families and has an active product development pipeline. Sandoz is based in Germany and has approximately 200 generic product families in the United States and an active product development pipeline. With their experience in generic markets, Par and Sandoz are expected to replicate the competition that would otherwise be lost with the Proposed Acquisition. Further, the amended supply agreement with Pfizer concerning Embeda will ensure that Pfizer's plans to re-launch Embeda and the ensuing generic competition for that product will remain intact after the Proposed Acquisition. The renunciations of the combined entity's interest in the isradipine and loxapine succinate agreements will similarly preserve competition in each of those markets.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the acquisition. If the Commission determines that Par and/or Sandoz are not acceptable acquirers of the assets to be divested, or that the manner of the divestitures is not acceptable, the parties must unwind the sale to Par and/or Sandoz and divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the products if the parties fail to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Watson and Actavis to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time as they are transferred to a Commission-approved acquirer. Watson and Actavis must

transfer the manufacturing technology for generic (1) adapalene and benzoyl peroxide topical gel; (2) extended release morphine sulfate capsules; (3) generic extended release oxycodone tamper resistant tablets; (4) extended release amphetamine salts capsules; (5) extended release diltiazem hydrochloride capsules (generic Cardizem CD); (6) fentanyl transdermal system; (7) extended release glipizide tablets; (8) extended release methylphenidate hydrochloride tablets; (9) ursodiol tablets; (10) metoclopramide hydrochloride tablets; (11) extended release oxycodone tamper resistant tablets; (12) extended release nifedipine tablets; (13) extended release rivastigmine film; and (14) varenicline tartrate tablets to Par and must supply Par with extended release morphine sulphate capsules, extended release nifedipine tablets, ursodiol tablets, extended release glipizide tablets, metoclopramide hydrochloride tablets, and extended release diltiazem hydrochloride capsules (generic Cardizem CD). Watson and Actavis must also transfer to Sandoz the manufacturing technology for generic (1) dextromethorphan hydrobromide and quinidine sulfate capsules; (2) extended release bupropion hydrochloride tablets; (3) extended release diltiazem hydrochloride capsules (generic Tiazac); and (4) lorazepam tablets and must supply Sandoz with extended release diltiazem hydrochloride capsules (generic Tiazac) and lorazepam tablets during the transition period.

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.