ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS

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

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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 have 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

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- Extended release oxycodone tamper resistant tablets are the generic version of tamper resistant Oxy

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 renouncements 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 oxymorphone non-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.