

ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS

tablets; (5) metoprolol 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 oxycodone non-taper resistant tablets; (11) extended release dipizide 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 naloxone combination capsules; (19) extended release oxycodone taper resistant tablets; (20) extended release rivastigmine film; and (21) varenicline tartrate tablets (collectively, the "Products"). The proposed Consent Agreement will remedy the alleged

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 has 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 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 oxycodone non-tamper resistant tablets; (4) extended release dipizide tablets; (5) isradipine capsules; (6) loxapine succinate capsules; (7) extended release methphenidate 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

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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 naraxone combination capsules, isradipine ca

transfer the manufacturing technology for generic (1) adapalene and benzoyl peroxide topical gel; (2) extended release morphine sulfate capsules; (3) generic extended release oxycodone non-tamper resistant tablets; (4) extended release amphetamine salts capsule; (5) extended release diltiazem hydrochloride capsule (generic Cardizem CD); (6)entanyl transdermal system; (7) extended release glipizide tablets; (8) extended release methylphenidate hydrochloride tablets; (9) ursodiol tablets; (10) tetracycline 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 sulfate capsules, extended release nifedipine tablets, ursodiol tablets, extended release glipizide tablets, metoclopramide hydrochloride tablets, and extended release diltiazem hydrochloride capsule (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 capsule (generic Tiazac) and (4) lorazepam tablet 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.