

**ANALYSIS OF PROPOSED CONSENT ORDER  
TO AID PUBLIC COMMENT  
*In the Matter of Novartis AG, File No. 051-0106***

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Novartis AG (“Novartis”), which is designed to remedy the anticompetitive effects of the acquisition of Eon Labs, Inc. (“Eon”) by Novartis. Under the terms of the proposed Consent Agreement, Novartis, including its generic pharmaceuticals division Sandoz, Inc. (“Sandoz”), would be required to divest to Amide Pharmaceutical, Inc. (“Amide”) the Eon assets necessary to manufacture and market generic desipramine hydrochloride tablets, and the Sandoz assets necessary to manufacture and market orphenadrine citrate ER tablets and rifampin oral capsules in the United States. Further, Novartis, through Sandoz, has agreed to enter into a supply agreement with Amide to enable Amide to market these products until Amide obtains Food and Drug Administration (“FDA”) approval to manufacture the products itself. Further, Novartis is required to provide technology transfer assistance to enable Amide to obtain all necessary FDA approvals as soon as possible.

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 an Agreement for Purchase and Sale of Stock dated February 20, 2005, Novartis agreed to purchase 60 million shares of Eon from Santo Holding AG (“Santo”) for \$1.72 billion in cash. These shares represent approximately 67% of the outstanding stock of Eon. Further, Novartis has made a definitive agreement, approved by the Eon Board of Directors, to offer to acquire the remaining 31.9 million fully diluted shares of Eon for \$31.00 per share cash. 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 FTC Act, as amended, 15 U.S.C. § 45, in the markets for the manufacture and sale of: (1) generic desipramine hydrochloride tablets, (2) generic orphenadrine citrate ER tablets, and (3) generic rifampin oral capsules. The proposed Consent Agreement will remedy the alleged violations by replacing in each of these markets the lost competition that would result from the acquisition.

Desipramine hydrochloride is a tricyclic antidepressant. The branded desipramine product, Norpramin, does not offer any significant price pressure in the generic desipramine market other than setting a price ceiling that is currently many times higher than the generic pricing level. The brand price is essentially irrelevant with respect to the pricing of generic desipramine tablets. In contrast, the competition between producers of generic desipramine tablets has a direct and substantial effect on generic desipramine pricing. Annual U.S. sales of generic desipramine hydrochloride tablets are reported to be less than \$6 million. The U.S. market for the manufacture and sale of generic desipramine hydrochloride tablets is highly

concentrated. Only Novartis and Eon make all six strengths of generic desipramine hydrochloride tablets. Watson Pharmaceuticals, Inc., the only other firm supplying generic desipramine hydrochloride tablets, sells only three of the six strengths. The acquisition of Eon by Novartis would increase significantly the concentration in the generic desipramine hydrochloride market. Post-acquisition, only Novartis would supply the full line, accounting for more than 95% of U.S. generic desipramine hydrochloride sales.

Orphenadrine citrate is a muscle relaxant. The branded orphenadrine citrate product, Norflex, does not impact the pricing of generic orphenadrine citrate other than setting a price ceiling that is currently many times higher than the generic pricing level. In contrast, the competition between producers of generic orphenadrine citrate tablets has a direct and substantial effect on generic orphenadrine citrate pricing. Annual U.S. sales of generic orphenadrine citrate ER tablets is slightly under \$10 million. The U.S. market for the manufacture and sale of generic orphenadrine citrate ER tablets is highly concentrated. Only Eon, Novartis, and Impax Laboratories, Inc. (through its generic marketing division, Global Pharmaceuticals) manufacture and market generic orphenadrine citrate ER tablets in the United States. The acquisition would result in a duopoly with Novartis accounting for approximately 70% of all prescriptions of generic orphenadrine citrate. The acquisition of Eon by Novartis would increase the concentration in the market significantly.

Rifampin is one of several drugs used in a multi-drug cocktail for the treatment of tuberculosis. Rifampin is indicated for the treatment of tuberculosis. The branded rifampin product, Rifadin, does not offer any significant price pressure in the generic rifampin oral capsule market other than setting a price ceiling that is currently many times higher than the generic pricing level. In contrast, the competition between producers of generic rifampin capsules has a direct and substantial effect on generic rifampin pricing. Annual U.S. sales of generic rifampin oral capsules is about \$14.5 million. The U.S. market for the manufacture and sale of generic rifampin oral capsules is highly concentrated. Only Eon, Novartis, and VersaPharm, Incorporated market generic rifampin oral capsules in the United States. The acquisition would result in a duopoly with Novartis accounting for more than 70% of sales of generic rifampin in the United States. The acquisition of Eon by Novartis would increase the concentration in the market significantly.

Entry into manufacture and sale of: (1) generic desipramine hydrochloride tablets, (2) generic orphenadrine citrate ER tablets, and (3) generic rifampin oral capsules would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Developing and obtaining FDA approval for the manufacture and sale of generic desipramine hydrochloride tablets, generic orphenadrine citrate ER tablets, and generic rifampin oral capsules takes at least two years due to substantial regulatory, technological, and intellectual property barriers.

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for generic desipramine hydrochloride tablets, generic orphenadrine citrate ER tablets, and generic rifampin oral capsules by eliminating actual, direct, and substantial competition between Novartis and Eon; by increasing the likelihood that Novartis will be able to unilaterally exercise market power; by increasing the likelihood and degree of coordinated interaction between the few remaining competitors; and by increasing the likelihood that consumers will pay higher prices.

The proposed Consent Agreement preserves competition in the generic desipramine hydrochloride tablets, generic orphenadrine citrate ER tablets, and generic rifampin oral capsules markets by requiring that Novartis divest all of the Sandoz orphenadrine citrate ER and rifampin assets and all of Eon's desipramine hydrochloride assets to Amide no later than ten days after the acquisition. Amide, a reputable generic manufacturer, is particularly well-positioned to manufacture and market generic rifampin, because Amide already currently contract manufactures generic rifampin capsules for Novartis. Amide is also well-positioned to obtain FDA approval to manufacture and market generic desipramine hydrochloride and orphenadrine citrate ER in the near future. If the Commission determines that Amide is not an acceptable purchaser, or that the manner of the divestiture is not acceptable, Novartis must rescind the transaction with Amide and divest the assets to a Commission-approved buyer not later than six months from the date the Order becomes final. If Novartis fails to divest within the six months, the Commission may appoint a trustee to divest the desipramine hydrochloride, rifampin, and orphenadrine citrate ER assets.

The proposed remedy contains several provisions designed to ensure the successful divestiture of the desipramine hydrochloride, rifampin, and orphenadrine citrate ER assets to Amide. Novartis must provide various transitional services to enable Amide to compete against Novartis immediately following the divestiture. Novartis is obligated to provide Amide with all inventory of the three divested products and to supply Amide the two products that Amide does not currently manufacture – desipramine hydrochloride and orphenadrine citrate ER – while Amide attempts to obtain FDA approval to manufacture the products for itself in its own facility. Novartis will supply Amide with desipramine hydrochloride for two years, and Amide will have options to extend that supply for two additional one-year periods if Amide is making progress toward approval and needs the additional time to obtain FDA approval. Novartis will supply Amide with orphenadrine citrate ER for four years, and Amide will again have options to extend the supply up to two additional one-year periods as it seeks FDA approval to manufacture orphenadrine citrate for itself. Novartis is also required to provide technology transfer assistance to enable Amide to obtain all necessary FDA approvals to manufacture and sell desipramine hydrochloride, rifampin, and orphenadrine citrate for itself.

The proposed remedy does not provide for a technology transfer or supply obligation for rifampin because Amide is already in possession of the manufacturing technology, having contract manufactured generic rifampin for Novartis for several years.

The proposed remedy also incorporates the use of an Interim Trustee, experienced in obtaining regulatory approval and the manufacture of pharmaceuticals, to oversee the technology transfer and to assist Amide and the Commission in the event of difficulties with supply or delays in obtaining approval. As part of the proposed remedy, Novartis is required to execute an agreement conferring all rights and powers necessary for the Interim Trustee to satisfy his responsibilities under the Order to assure successful divestitures of the desipramine hydrochloride, rifampin, and orphenadrine citrate assets. Novartis has selected Francis J. Civile to be the Interim Monitor and Amide has consented to his selection. The monitor will ensure that the Commission remains informed about the status of the proposed divestitures and asset transfers.

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 Consent Agreement or to modify its terms in any way.