FEDERAL TRADE COMMISSION

[File No. 101 0068]

Novartis AG; Analysis of Proposed Agreement Containing Consent Orders to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order — embodied in the consent agreement — that would settle these allegations.

DATES: Comments must be received on or before September 16, 2010.

ADDRESSES: Interested parties are invited to submit written comments electronically or in paper form. Comments should refer to "Norvartis AG, File No. 101 0068" to facilitate the organization of comments. Please note that your comment — including your name and your state — will be placed on the public record of this proceeding, including on the publicly accessible FTC website, at (*http://www.ftc.gov/os/publiccomments.shtm*).

Because comments will be made public, they should not include any sensitive personal information, such as an individual's Social Security Number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, comments should not include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential. . . .," as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and Commission Rule 4.10(a)(2), 16 CFR 4.10(a)(2). Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c).[1]

Because paper mail addressed to the FTC is subject to delay due to heightened security screening, please consider submitting your comments in electronic form. Comments filed in electronic form should be submitted by using the following weblink: (*https://ftcpublic.commentworks.com/ftc/novartis*) and following the instructions on the web-based form. To ensure that the Commission considers an electronic comment, you must file it on the web-based form at the weblink: (*https://ftcpublic.commentworks.com/ftc/novartis*). If this Notice appears at (*http://www.regulations.gov/search/index.jsp*), you may also file an electronic comment through that website. The Commission will consider all comments that regulations.gov forwards to it. You may also visit the FTC website at (*http://www.ftc.gov/*) to read the Notice and the news release describing it.

A comment filed in paper form should include the "Norvartis AG, File No. 101 0068" reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex D), 600 Pennsylvania Avenue, NW, Washington, DC 20580. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions.

The Federal Trade Commission Act ("FTC Act") and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC website, to the extent practicable, at (*http://www.ftc.gov/os/publiccomments.shtm*). As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at (*http://www.ftc.gov/ftc/privacy.shtm*).

FOR FURTHER INFORMATION CONTACT: Kari A. Wallace (202-326-3085), Bureau of Consumer Protection, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for August 16, 2010), on the World Wide Web, at (*http://www.ftc.gov/os/actions.shtm*). A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before the date specified in the **DATES** section.

Analysis of Agreement Containing Consent Order to Aid Public Comment

I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Novartis AG ("Novartis") that is designed to remedy the anticompetitive effects of Novartis' acquisition of a controlling interest in Alcon, Inc. ("Alcon") from Nestle, S.A. The proposed Consent Agreement requires Novartis to divest its rights and assets in its injectable miotics product, Miochol-E, to Bausch & Lomb, Inc. ("B&L").

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 Purchase and Option Agreement dated April 6, 2008, and the

[1] The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

execution of the call option on January 4, 2010, Novartis proposes to acquire all of the outstanding shares of Alcon held by Nestle in a transaction valued at approximately $28.1 billion. After consummating the transaction, Novartis will hold 77 percent of Alcon. Novartis also proposes to acquire the remaining 23 percent of Alcon held by public shareholders. 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 competition in the U.S. market for the research, development, marketing, manufacture and sale of injectable miotics. The proposed Consent Agreement will remedy the alleged violations by replacing the lost competition that would result from the acquisition in this market.

Novartis is a global manufacturer and supplier of numerous branded and generic pharmaceuticals headquartered in Basel, Switzerland. Nestle is the world's largest food company, and is headquartered in Vevey, Switzerland. Among Nestle's holdings is a 52 percent stake in Alcon, which provides Nestle with a controlling interest in the company. Alcon, a global medical specialty company focused on eye care, is also a Swiss corporation, based in Hünenberg. Alcon develops, manufactures, and sells surgical devices used in surgical eye procedures, branded and generic pharmaceuticals, and over-the-counter consumer eye care products.

II. Injectable Miotics

Injectable miotics are a class of prescription pharmaceutical products that are used to induce miosis, or constriction of the pupil. Injectable miotics are used in a variety of applications, most commonly during cataract surgery. Novartis introduced its product, Miochol-E, in 1993; Alcon's product, Miostat, was launched in 1972. Though patents no longer cover the formulation of the active ingredient of either Miostat or Miochol-E, no generic versions of either product have been launched. For years, Novartis and Alcon have been the only suppliers of injectable miotics in the United States, with respective market shares of approximately 67 and 33 percent. U.S. sales of injectable miotic products in 2009 totaled $12.4 million.

Entry into the market for the research, development, manufacture and sale of injectable miotics would not be timely, likely or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry would not take place in a timely manner because the combination of branded drug development times and U.S. Food and Drug Administration ("FDA") approval requirements takes at least two years. Entry would not be likely because the relevant market is relatively small and in decline, so the limited sales opportunities available to a new entrant are likely insufficient to warrant the time and investment necessary to enter.

In sum, the proposed acquisition of Alcon by Novartis would create a monopoly in the market for injectable miotics. The evidence indicates that customers have benefitted from direct pricing competition between the two companies, and that the price of Miostat-E is currently constrained by Miostat pricing. The reduction in the number of competitors in this market from two to one would allow the merged entity to unilaterally exercise market power and result in an increase in prices to consumers.

III. The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the relevant product market. Pursuant to the Consent Agreement, Novartis is required to divest certain rights and assets related to its injectable miotics product to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically, the proposed Consent Agreement requires that Novartis divest its rights and assets related to Miochol-E to B&L.

Pursuant to the Consent Agreement, the acquirer of divested assets must receive the prior approval of the Commission. As always, the Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not itself present competitive problems.

B&L is an eye-health company that develops, sells, and distributes products in over 100 countries. B&L is particularly well-positioned to manufacture and market Miochol-E and compete effectively in the injectable miotics market. The acquisition by B&L does not create a competitive problem in the injectable miotics market because B&L does not participate in the market. With its resources, capabilities, strong reputation, and experience marketing eye care products, specifically other cataract surgery products, B&L is expected to replicate the competition that would be lost if the proposed transaction were to proceed unremedied.

If the Commission ultimately determines after the public comment period that B&L is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, the parties must unwind the sale and divest the assets within six months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six months, the Commission may appoint a trustee to accomplish the divestiture.

The proposed remedy contains several provisions to ensure that the divestiture is successful. The Order requires Novartis to provide transitional services to enable the Commission-approved acquirer to successfully transfer the manufacturing from Novartis. Much of the manufacturing process for Miochol-E is performed for Novartis by third-party manufacturers. As part of the divestiture, Novartis will transfer its manufacturing arrangements to B&L. Additionally, Novartis will provide technical assistance to help B&L manufacture Miochol-E.

The Commission has appointed Karl L. Hoffman Jr. of Rondaxe Pharma ("Rondaxe") to oversee the asset transfer and to ensure Novartis' compliance with all of the provisions of the proposed Consent Agreement. Mr. Hoffman is a Quality Systems and Support Director at Rondaxe and has an extensive background in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Rondaxe clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestiture and the transfers of assets, the proposed Consent Agreement requires Novartis and Alcon to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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.

By direction of the Commission, Commissioner William E. Kovacic recused.

Richard C. Donohue

Acting Secretary.

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