ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Novartis AG, File No. 141-0141

I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Novartis AG ("Novartis"), which is designed to remedy the anticompetitive effects of Novartis' proposed acquisition of oncology assets from GlaxoSmithKline PLC ("GSK"). The Commission has placed the proposed Consent Agreement on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with any comments received, in order to make a final decision as to whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order ("Order").

Pursuant to an agreement dated April 22, 2014 (the "Agreement"), Novartis proposes to acquire GSK's marketed oncology products and two pipeline oncology compounds for approximately $16 billion (the "Transaction"). GSK currently has a BRAF inhibitor and an MEK inhibitor approved by the FDA, as well as the only BRAF/MEK combination therapy approved for sale in the United States. BRAF and MEK inhibitors are medicines that inhibit molecules associated with the development of cancer. Novartis has BRAF and MEK inhibitors in late-stage development, as well as a BRAF/MEK combination therapy that it expects to launch in the near future.

The Commission alleges in its Complaint that the Transaction, 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 substantially lessening competition in U.S. markets for BRAF inhibitors and MEK inhibitors. The proposed Consent Agreement will remedy the alleged violations by preserving competition that the Transaction would otherwise eliminate. Under the terms of the Consent Agreement, Novartis is required to divest all rights and assets related to LGX818, its BRAF inhibitor, and MEK162, its MEK inhibitor, to Array BioPharma Inc. ("Array").

II. The Relevant Products and Markets

The relevant markets in which to analyze the Transaction are the development and sale of BRAF inhibitors and MEK inhibitors. BRAF and MEK inhibitors are orally administered, targeted oncology products. Physicians currently use BRAF and MEK inhibitors, increasingly in combination, to treat metastatic, late-stage melanoma. Last year in the United States, there were approximately 76,100 new cases of melanoma and 9,710 deaths caused by melanoma.[1] In addition to melanoma, researchers are studying BRAF and MEK inhibitors as potential

[1] U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, "Melanoma," http://www.cancer.gov/cancertopics/types/melanoma.

treatments for a range of cancers, including ovarian cancer, colorectal cancer, and non-small cell lung cancer.

The United States is the relevant geographic market in which to assess the competitive effects of the Transaction because the FDA must approve BRAF and MEK inhibitors, as well as the use of the two inhibitors in combination, for marketing and sale in the United States. Accordingly, products sold outside of the United States, but not approved by the FDA, are not alternatives for U.S. consumers.

The BRAF and MEK inhibitor markets in the United States are highly concentrated. Tafinlar®, sold by GSK, and Zelboraf®, sold by F. Hoffman-La Roche AG ("Roche"), are currently the only FDA-approved BRAF inhibitors. Novartis' BRAF inhibitor in development, LGX818, is the only other product likely to begin competing with GSK and Roche in the near future. GSK's Mekinist® is currently the only FDA-approved MEK inhibitor, while Novartis' MEK162 is one of only a small number of MEK inhibitors in late-stage clinical development. GSK also sells the only FDA-approved BRAF/MEK combination therapy, which is comprised of Tafinlar and Mekinist. Aside from GSK, Roche and Novartis are the only companies with BRAF/MEK combinations in late-stage development.

III. Entry

Entry into U.S. markets for BRAF inhibitors and MEK inhibitors would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Transaction. Like other oncology products, BRAF and MEK inhibitors must complete clinical trials and garner approval by the FDA before they can enter the U.S. markets. Development of new oncology medicines is expensive, time consuming, and has a high rate of failure. The time and resources required to develop and market a new oncology medicine make it unlikely that *de novo* entry into the relevant markets would be sufficient to offset the anticompetitive effects of the Transaction, and no firms currently have products in development that are likely to enter and prevent competitive harm from the Transaction.

IV. Effects of the Acquisition

Without a remedy, the Transaction will eliminate likely future competition between GSK and Novartis in the concentrated markets for BRAF and MEK inhibitors. Absent the acquisition, Novartis likely would have obtained FDA approval for and launched its LGX818 and MEK162 products in the near future in direct competition with GSK's combination offering for treating metastatic melanoma patients. The Transaction would also likely reduce the development of BRAF and MEK inhibitors to treat other types of cancer, because GSK and Novartis are currently developing their respective BRAF and MEK inhibitors for several of the same indications beyond melanoma. By eliminating the potential head-to-head competition between Novartis and GSK, the Transaction will likely result in higher prices for BRAF and MEK inhibitors and reduced choice for U.S. health care consumers.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the Transaction's anticompetitive effects by requiring Novartis to divest to Array all of its rights and assets related to LGX818 and MEK162. The divestiture will preserve the competition that otherwise would have been lost in the markets for BRAF and MEK inhibitors.

Array is a biopharmaceutical company headquartered in Boulder, Colorado, that focuses on the discovery, development, and commercialization of oncology medicines. Array is well suited to acquire LGX818 and MEK162 because it initially developed MEK162 and is currently a partner with Novartis in the development of both products. Array is a sophisticated company that possesses both the incentive and ability to develop and commercialize LGX818 and MEK162 either independently or with a new partner.

The Order requires Novartis to divest its rights and interests in LGX818 and MEK162 to Array no later than ten days after consummation of the proposed transaction or on the date that the Order becomes final, whichever is earlier. The divestiture includes regulatory approvals, intellectual property, assets related to ongoing clinical trials and manufacturing processes, and other confidential business information related to the divested compounds. To ensure that the divestiture is successful, the Order requires Novartis to provide transitional support to Array and to manufacture and supply the divested compounds while it transfers manufacturing processes to Array.

The Commission has agreed to appoint an Interim Monitor to ensure that Novartis complies with all of its obligations under the Consent Agreement and to keep the Commission informed about the status of the transfer of rights and assets to Array.

The Commission's goal in evaluating possible divestiture purchasers is to maintain the competitive environment that existed prior to the Transaction. If the Commission ultimately determines that Array is not an acceptable acquirer, or that the manner of the divestiture is unacceptable, then the parties must unwind the sale of rights and assets to Array and divest them to a Commission-approved acquirer within six months of the date that the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the rights and assets if the parties fail to divest them as required.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement; it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.