

UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman  
Julie Brill  
Maureen K. Ohlhausen  
Joshua D. Wright  
Terrell McSweeney

_____	)	
In the Matter of	)	
	)	
NOVARTIS AG,	)	
a corporation;	)	
	)	
and	)	Docket No. C-4510
	)	
GLAXOSMITHKLINE, PLC,	)	
a corporation.	)	
	)	
_____	)	

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Novartis AG (“Novartis”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire oncology assets from Respondent GlaxoSmithKline, PLC (“GSK”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Novartis is a corporation organized, existing, and doing business under and by virtue of the laws of the Swiss Confederation, with its headquarters located at Lichtstrasse 35, Basel, Switzerland CH 4056 and the address of its U.S. subsidiary, Novartis Corporation, located at 230 Park Avenue, New York, NY 10169.

2. Respondent GSK is a corporation organized, existing, and doing business under and by virtue of the laws of the United Kingdom of Great Britain and Northern Ireland, with its headquarters located at 980 Great West Road, Brentford Middlesex, TW8 9GS, England. GSK’s U.S. headquarters are located at Philadelphia Navy Yard, 5 Crescent Drive, Philadelphia, PA, 19112.

3. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

## **II. THE PROPOSED TRANSACTION**

4. Pursuant to an agreement executed on April 22, 2014 (the “Agreement”), Novartis intends to acquire GSK’s marketed oncology products and two pipeline products for approximately \$16 billion (the “Transaction”). The Transaction is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

## **III. THE RELEVANT MARKETS**

5. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Transaction are:

- a. the development and sale of BRAF inhibitors used to treat cancer (“BRAF inhibitors”); and
- b. development and sale of MEK inhibitors used to treat cancer (“MEK inhibitors”).

6. For the purposes of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Transaction in the relevant lines of commerce.

## **IV. THE STRUCTURE OF THE MARKETS**

7. There are currently only two BRAF-inhibitors approved by the U.S. Food and Drug Administration (“FDA”) and sold in the United States: (1) Zelboraf®, sold by F. Hoffman-La Roche Ltd. (“Roche”); and (2) Tafinlar®, sold by GSK. Novartis is the only other firm likely to begin competing with a BRAF inhibitor in the near future.

8. GSK currently sells the only FDA-approved MEK inhibitor, Mekinist®. Roche and Novartis are two of only a small number of companies with MEK inhibitors in late-stage clinical development.

9. The near-term application of BRAF and MEK inhibitors is primarily as a combination product to treat melanoma. GSK sells the only FDA-approved BRAF/MEK combination, which consists of Tafinlar and Mekinist. Roche and Novartis have BRAF/MEK combinations in clinical development and likely will be the only other firms to compete against GSK’s combination in the near future.

## V. ENTRY CONDITIONS

10. Entry into the relevant lines of commerce described in Paragraphs 5 and 6 would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of the Transaction. Development of a BRAF inhibitor and MEK-inhibitor by a new entrant would be difficult, expensive, and time-consuming, in large part because new oncology medicines must complete clinical trials and receive FDA approval before they can be sold in the United States. No firms have products in development which are likely to enter the relevant markets and prevent the competitive harm from the transaction.

## VI. EFFECTS OF THE TRANSACTION

11. The effects of the Transaction, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant lines of commerce, in violation of 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, by:

- a. Eliminating substantial future competition between GSK and Novartis in the development and sale of BRAF-inhibitors; and
- b. Eliminating substantial future competition between GSK and Novartis in the development and sale of MEK-inhibitors.

## VII. VIOLATIONS CHARGED

12. The Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

13. The Transaction described in Paragraph 4, if consummated, would constitute a violation of 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.

**WHEREFORE, THE PREMISES CONSIDERED,** the Federal Trade Commission on this twentieth day of February, 2015, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark  
Secretary

SEAL: