UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS:	Edith Ramirez, Chairwoma Julie Brill Maureen K. Ohlhausen Joshua D. Wright Terrell McSweeny	n
In the Matter of		
NOVARTIS AG, a corporation.) Docket No. C-4510

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Novartis AG ("Novartis" or "Respondent") of certain assets related to certain oncology products of GlaxoSmithKline plc, and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of 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; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

- 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 address located at Lichtrasse 35, Basel, Switzerland, V8 CH4056, and the address of its United States subsidiary, Novartis Corporation, located at 230 Park Avenue, New York, New York.
- 2. GlaxoSmithKline plc 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 address located at 980 Great West Road, Brentford Middlesex TW8 9FS, United Kingdom.
- 3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and, when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. "Novartis" or "Respondent" means the following: Novartis AG, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Novartis AG, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "Glaxo" means the following: GlaxoSmithKline plc, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Glaxo SmithKline plc, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. "Commission" means the Federal Trade Commission.
- D. "Decision and Order" means the:
 - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 - 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.

- E. "Oncology Product Assets" means the B-Raf Inhibitor Product Assets and the MEK Inhibitor Product Assets, individually and collectively.
- F. "Oncology Product Business(es)" means the Business of the Respondent related to each of the Oncology Products to the extent that such Business is owned, controlled, or managed by the Respondent and the Oncology Product Assets to the extent such Assets are owned by, controlled by, managed by, or licensed to, the Respondent.
- G. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- H. "Orders" means the Decision and Order and this Order to Maintain Assets.

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondent fully transfers and delivers the Oncology Product Assets to an Acquirer, Respondent shall take such actions with respect to the Oncology Product Assets as are necessary to maintain the full economic viability, marketability and competitiveness of each of the related Oncology Product Businesses, to minimize any risk of loss of competitive potential for such Oncology Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Oncology Product Assets except for ordinary wear and tear. Respondent shall not sell, transfer, encumber or otherwise impair the Oncology Product Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the related Oncology Product Businesses.
- B. Until Respondent fully transfers and delivers the Oncology Product Assets to an Acquirer, Respondent shall maintain the operations of the related Oncology Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic marketability, viability, and competitiveness of such Oncology Product Businesses and shall use its best efforts to preserve the existing relationships with the following: clinical research organizations; suppliers; end-use customers; Agencies; employees; and others having business relations with each of the respective Oncology Product Businesses. Respondent's responsibilities shall include, but are not limited to, the following:
 - 1. providing each of the respective Oncology Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for such Oncology Product Business;

- 2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Oncology Product Businesses authorized prior to the date the Consent Agreement was signed by Respondent including, but not limited to, all research, Development (including ongoing Clinical Trials), manufacturing, distribution, marketing and sales expenditures;
- 3. providing such resources as may be necessary to respond to competition against each of the Oncology Products;
- 4. making available for use by each of the respective Oncology Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Oncology Product Business; and
- 5. providing such support services to each of the respective Oncology Product Businesses as were being provided to such Oncology Product Business by Respondent as of the date the Consent Agreement was signed by Respondent.
- C. Until Respondent fully transfers and delivers each of the respective Oncology Product Assets (including the ongoing Clinical Trials) to an Acquirer, Respondent shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Oncology Products for the relevant Oncology Product's last fiscal year.

D. Respondent shall:

- 1. for a period of two (2) years from the Closing Date, and for the purposes of the Orders, provide the Acquirer, its Manufacturing Designee(s), or its Clinical Research Organization Designee(s) with the opportunity to enter into employment contracts with the Oncology Product Core Employees. Each of these periods is hereinafter referred to as the "Oncology Product Core Employee Access Period(s);"
- 2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide the Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Oncology Product Core Employees unless the Law requires a mandatory notice period prior to the release of such information in which case the information shall be provided not later than ten (10) days after the expiration of the notice period. Failure by Respondent to provide the Product Employee Information for any Oncology Product Core Employee within the time provided herein shall extend the Oncology Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided*,

however, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely to consider whether to provide or continue providing to Oncology Product Core Employees the opportunity to enter into employment contracts during an Oncology Product Core Employee Access Period and not for any other purpose whatsoever, (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use, (iv) destroy or return the information without retaining copies at such time as the specified and permitted use ends and (v) ensure that any Manufacturing Designee(s) or Clinical Research Organization Designee(s) agrees to abide by the preceding conditions, if the Acquirer provides such information to it;

during the Oncology Product Core Employee Access Period(s), not interfere with the hiring or employing by the Acquirer, its Manufacturing Designee(s) or its Clinical Research Organization Designee(s) of the Oncology Product Core Employee, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with the Acquirer, its Manufacturing Designee(s) or its Clinical Research Organization Designee(s), including, but not limited to, any noncompete or nondisclosure provision of employment with respect to an Oncology Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Acquirer, its Manufacturing Designee(s), or its Clinical Research Organization Designee(s). In addition, Respondent shall not make any counteroffer to such an Oncology Product Core Employee who has received a written offer of employment from the Acquirer, its Manufacturing Designee(s) or its Clinical Research Organization Designee(s);

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondent from continuing to employ any Oncology Product Core Employee under the terms of that employee's employment with Respondent prior to the date of the written offer of employment from the Acquirer, its Manufacturing Designee(s), or its Clinical Research Organization Designee(s) to that employee;

4. until the Closing Date, provide all Oncology Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Oncology Products consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Oncology Products and to ensure successful execution of the pre-Acquisition plans for the Oncology Products. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Closing Date(s) has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided further, however, that this Paragraph does not require nor shall be construed to require Respondent to terminate the employment of any employee or to prevent Respondent from continuing to employ the Oncology Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the Closing Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer, its Manufacturing Designee(s), or its Clinical Research Organization Designee(s) with any amount of responsibility related to an Oncology Product ("Oncology Product Employee") to terminate his or her employment relationship with the Acquirer, its Manufacturing Designee(s) or its Clinical Research Organization Designee(s); or hire any Oncology Product Employee;

provided, however, that Respondent may hire any former Oncology Product Employee whose employment has been terminated by the Acquire, its Manufacturing Designee(s), or its Clinical Research Organization Designee(s) or who independently applies for employment with a Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Oncology Product Employees; or (ii) hire an Oncology Product Employee who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent.

- E. Pending divestiture of the Oncology Product Assets, Respondent shall:
 - 1. not use, directly or indirectly, any Confidential Business Information that is exclusively related to the Oncology Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondent's obligations to the Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
 - 2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Oncology Product(s), (ii) other Persons specifically authorized by that Acquirer to receive such information(including, without limitation, those employees of the Respondent authorized to receive such information), (iii) the Commission, (iv) the Interim Monitor (if any has been appointed);

- or (v) Government Entities that have jurisdiction and regulatory authority over the Acquisition or pharmaceutical marketing or manufacturing (including the European Commission and any monitoring trustee appointed or approved by the European Commission, or the EMA);
- 3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information that is exclusively related to the particular research and Development (including, without limitation, the ongoing Clinical Trials) of each respective Oncology Product to the employees of the Respondent that both: (i) are being Developed for the treatment of the identical indication (disease and disease state), and (ii) use the same mechanism of action to treat such disease, other than is necessary to accomplish the requirements of this Order or the related Remedial Agreements, (*e.g.*, providing transitional services to the Acquirer or ongoing Clinical Trial services as agreed to in the Remedial Agreements related to the Oncology Products);
- 4. institute procedures and requirements to ensure that the employees of the Respondent:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information in contravention of the Orders; and,
 - b. do not solicit, access or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose other than as is permitted by the Orders.
- F. Not later than thirty (30) days from the earlier of (i) the Closing Date or (ii) the date this Order to Maintain Assets is issued by the Commission, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information by Respondent's personnel to all of its employees who:
 - 1. has or may have had access to Confidential Business Information; and/or
 - 2. has responsibilities related to the research, Development, marketing or sales of those Retained Products that both: (i) are on the market in the Geographic Territory, or are in Phase II or III Clinical Trials, for the identical indication (disease and disease state) as the Oncology Product(s) as of the Acquisition Date, and (ii) use the same mechanism of action to treat such disease.
- G. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Upon the request of an Acquirer, Respondent shall provide that Acquirer with copies of all such certifications sent to the Commission and all such notifications and reminders sent to

Respondent's personnel.

- H. Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.
- I. After the Closing Date, Respondent's obligations under Paragraphs II.A., II.B., and II.C. of this Order to Maintain Assets shall be as set forth in the Oncology Product Divestiture Agreements referenced in the Decision and Order *unless* the Commission determines not to make the relevant agreement or agreements Remedial Agreements.
- J. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Oncology Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Oncology Product Businesses within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Oncology Product Assets except for ordinary wear and tear.

III.

IT IS FURTHER ORDERED that:

- A. At any time after Respondent sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.

- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
 - 1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
 - 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 - 3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Oncology Product Assets and the transfer and delivery of the related Product Manufacturing Technology and related ongoing Clinical Trials in a manner that fully satisfies the requirements of the Orders and, with respect to each Oncology Product, until the earliest of: (i) the date the Acquirer (or the Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture that Oncology Product and able to manufacture that Oncology Product in commercial quantities, in a manner consistent with cGMP, independently of the Respondent; (ii) the date the Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture that Oncology Product; (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Oncology Product;

provided, however, that, with respect to each Oncology Product, the Interim Monitor's service shall not exceed five (5) years from the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Orders.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

- G. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
- H. Respondent shall report to the Interim Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Orders; *provided, however*, that, beginning one hundred twenty (120) days after Respondent has filed its final report pursuant to Paragraph VII.B. of the Decision and Order, and one hundred twenty (120) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture each Oncology Product and obtaining the ability to manufacture each Oncology Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent.
- I. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided*, *however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondent has fully complied with this Order to Maintain Assets and the Paragraphs that are enumerated in Paragraph VII.B. of the related Decision and Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the Orders. Respondent shall submit at the same time a copy of its report concerning compliance with the Orders to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a detailed description of its efforts to comply with the relevant paragraphs of the Orders, including:

- A. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
- B. a detailed description of the timing for the completion of such obligations.

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph VII of the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on:

A. the later of:

- 1. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- 2. the day after the completion of all of the following: (i) the divestiture of all of the Oncology Product Assets to an Acquirer, (ii) the transfer of the Product Manufacturing Technology related to each of the Oncology Products to an Acquirer, and (iii) the transfer of the Clinical Trials related to each of the Oncology Products to an Acquirer, as required by and described in the Decision and Order; and, the Interim Monitor, in

consultation with Commission staff and the Acquirer, notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures and technology and clinical transfers are complete; or,

B. the date the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

Donald S. Clark Secretary

SEAL:

ISSUED: February 20, 2015