

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, ) Docket No. C-4510  
a corporation. )  
\_\_\_\_\_)

**DECISION AND ORDER**  
**[Public Record Version]**

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 that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed 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 makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

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 the Order, the following definitions 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. “Acquirer(s)” means the following:
  1. a Person specified by name in this Order to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
  2. a Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

- E. “Acquisition” means Novartis’ acquisition of certain assets of Glaxo as described in the Acquisition Agreement.
- F. “Acquisition Agreement” means the *Sale and Purchase Agreement* dated as of April 22, 2014, and the *Deed of Amendment and Restatement* dated as of May 29, 2014, between GlaxoSmithKline plc and Novartis AG that were submitted to the Commission. The Acquisition Agreement is contained in Non-Public Appendix II to this Order.
- G. “Acquisition Date” means the date on which the Acquisition is consummated.
- H. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”) and the European Medicines Agency (“EMA”).
- I. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto. The term “Application” also includes any submissions or applications to the EMA that are similar in content or purpose to the above-described applications to the FDA.
- J. “Array” means Array BioPharma Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its headquarters address located at 3200 Walnut Street, Boulder, Colorado 80301.
- K. “Array License Agreement” means the *License Agreement* by and between Novartis International Pharmaceutical Ltd. and Array BioPharma Inc. dated as of April 19, 2010. The Array License Agreement is contained in Non-Public Appendix II to this Order.
- L. “B-Raf Inhibitor Product(s)” means Novartis’s proprietary compound known as LGX 818 (an inhibitor of mutated B-Raf protein within cells).
- M. “B-Raf Inhibitor Product Assets” means all assets and rights of the Respondent related to the Business of the B-Raf Inhibitor Products, wherever located throughout the world, as such assets and rights are in existence as of the date the Respondent signs the Agreement Containing Consent Orders in this matter (and as are required to be maintained by the Respondent in accordance with the Asset Maintenance Order until the Closing Date) including, without limitation, the Categorized Assets related to the B-Raf Inhibitor

Products.

- N. “Business” means the research, Development, and manufacture of a Product throughout the world for the purposes of the commercialization, distribution, marketing, importation, advertisement and sale of such Product within the Geographic Territory.
- O. “Categorized Assets” means all rights, title and interest in and to the following:
1. all rights to all of the Applications related to the specified Oncology Product(s);
  2. all rights to all of the Clinical Trials related to the specified Oncology Product(s);
  3. all Product Intellectual Property related to the specified Oncology Product(s) that is not Product Licensed Intellectual Property;
  4. all Product Approvals specifically related to the specified Oncology Product(s);
  5. all Product Manufacturing Technology related to the specified Oncology Product(s) that is not Product Licensed Intellectual Property;
  6. all Product Marketing Materials related to the specified Oncology Product(s);
  7. all Product Scientific and Regulatory Material related to the specified Oncology Product(s);
  8. all Website(s) owned, operated, or controlled by the Respondent related exclusively to the specified Oncology Product(s);
  9. the content related exclusively to the specified Oncology Product(s) that is displayed on any Website owned, operated, or controlled by the Respondent that is not dedicated exclusively to the specified Oncology Product(s);
  10. all Product Development Reports specifically related to the specified Oncology Product(s);
  11. all Product Contracts related to the specified Oncology Product(s);
  12. all patient registries specifically related to the specified Oncology Product(s), and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects specifically related to the specified Oncology Product(s);
  13. a list of all targeted customers specifically related to the specified Oncology Product(s) and a listing of the projected sales (in either units or dollars) of the Oncology Product(s) to such customers on either an annual, quarterly, or monthly basis;
  14. all of the Respondent’s books, records, and files directly related to the foregoing; *provided, however*, that the term “Categorized Assets” *excludes*: (i) documents relating to the Respondent’s general business strategies or practices relating to the conduct of its Business of pharmaceutical Products, where such documents do not discuss with particularity the specified Oncology Product(s); (ii) administrative,

financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the Oncology Product(s) by the Interim Monitor or the particular Acquirer of such Oncology Product(s); (iv) rights that are exclusively related to a Retained Product; (v) any real estate and the buildings and other permanent structures located on such real estate; (vi) all Product Licensed Intellectual Property, and (vii) rights that are exclusively related to Products distributed, marketed or sold outside the Geographic Territory;

*provided further, however,* that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Oncology Product(s) and to the Retained Products or Businesses of the Respondent or Oncology Product(s) being acquired by a different Acquirer and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Oncology Product(s) being acquired by the particular Acquirer; or (ii) for which the Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Oncology Product(s), the Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondent provides each Acquirer with the above-described information (as applicable) without requiring the Respondent completely to divest itself of information that, in content, also relates to the Retained Products or is a part of a divestiture to a different Acquirer.

- P. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- Q. “Clinical Plan” means a written clinical plan setting forth the protocol for the conduct of a Clinical Trial, preparation and filing of each Regulatory Package related to such Clinical Trial, and the activities to be conducted by each Person that is a party to conducting such Clinical Trial in support of such Clinical Trial, including the timelines for such Clinical Trial.
- R. “Clinical Research Organization Designee(s)” means any Person other than the Respondent that has been designated by an Acquirer to conduct a Clinical Trial related to an Oncology Product for that Acquirer.
- S. “Clinical Trial(s)” means a controlled study in humans of the safety and/or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.

- T. “Closing Date” means, as to the particular Divestiture Product Assets being divested, the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey such Divestiture Product Assets to an Acquirer pursuant to this Order.
- U. “Confidential Business Information” means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and that is directly related to the conduct of the Business related to an Oncology Product(s), including, without limitation, the Clinical Trials related to an Oncology Product. The term “Confidential Business Information” includes, without limitation, the following information related to the Clinical Trials of each of the Oncology Products: efficacy results (*e.g.* incidence of response, response rate, duration of therapy, progression free survival, overall survival); safety results (*e.g.*, type of adverse events observed, rate of adverse events observed, grade of adverse events observed); dosing (*e.g.*, maximum tolerated dose of combination regimen, incidence of dose reduction, dose interruption, causes of both); protocol specifics (*e.g.*, dosing schedule, specific secondary endpoints included, biomarkers included, any other protocol-related items not included on clinicaltrials.gov posting); site information (*e.g.*, names of investigators, details regarding each site); and collaborators (*e.g.*, involvement of cooperative groups, government organizations, third-party organizations, and contract research organizations). The term “Confidential Business Information” *excludes* the following:
1. information relating to the Respondent’s general business strategies or practices that does not discuss with particularity the Oncology Products;
  2. information specifically excluded from the definition of the assets required to be divested to a particular Acquirer pursuant to this Order;
  3. information that is contained in documents, records or books of the Respondent that is provided to an Acquirer by the Respondent that is unrelated to the Oncology Product(s) acquired by that Acquirer;
  4. information that is exclusively related to the Retained Products;
  5. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition; and,
  6. information that is exclusively related to the particular discussions or negotiations of a potential divestiture of the Divestiture Assets to a Person or Persons other than the Acquirer.
- V. “Contract Manufacture” means the following:
1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer (including, without limitation, for the purposes of Clinical Trials and/or commercial sales); and,
  2. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

- W. “Contract Manufacture Product(s)” means:
1. the Oncology Products; and
  2. any ingredient, material, or component held exclusively for the use for the manufacture of the foregoing Products including the active pharmaceutical ingredient, excipients or packaging materials.
- X. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product Approval(s) and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- Y. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of the Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee; *provided, however*, that, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for an Oncology Product, the term “Direct Cost” means such cost as is provided in such Remedial Agreement for that Oncology Product.
- Z. “Divestiture Product Assets” means the B-Raf Inhibitor Product Assets and the MEK Inhibitor Product Assets, individually and collectively.
- AA. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- BB. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration. The term “Domain Name” excludes any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- CC. “EEA Commitment Agreements” means the following agreements related to certain rights to seek regulatory approvals and to commercialize the Oncology Products within the European Economic Area that were submitted to the Commission:
1. The *Divestiture Commitment Agreement* by and between Novartis Pharma AG and Array BioPharma Inc., dated as of January 19, 2015; and
  2. The *EEA Remedy Conditional License Agreement*.

- DD. “Geographic Territory” shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.
- EE. “Good Clinical Practices” means then-current standards, practices and promulgated or endorsed by (i) International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use; (ii) the FDA; and (iii) any applicable Laws for the country(ies) within which Clinical Trial is being conducted.
- FF. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- GG. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- HH. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- II. “Manufacturing Designee(s)” means any Person other than the Respondent that has been designated by an Acquirer to manufacture an Oncology Product for that Acquirer.
- JJ. “MEK Inhibitor Product(s)” means the Product in Development known as binimetinib (MEK 162), an MEK modulator, that is, a compound that directly binds to MEK (mitogen-activated ERK kinase) and inhibits the activity of MEK (*i.e.*, inhibits the phosphorylation of ERK) and any improvements thereto. This compound is referred to in the Array License Agreement as “ARRY-162” or the “Lead Compound”.
- KK. “MEK Inhibitor Product Assets” means all assets and rights of the Respondent related to the Business of the MEK Inhibitor Products, wherever located throughout the world, as such assets and rights are in existence as of the date the Respondent signs the *Termination and Asset Transfer Agreement* and as are required to be maintained by the Respondent in accordance with the Asset Maintenance Order including, without limitation, the Categorized Assets related to the MEK Inhibitor Products.
- LL. “Oncology Product Core Employees” means the Product Research and Development Employees and the Product Manufacturing Employees related to each specific Oncology Product.
- MM. “Oncology Product Divestiture Agreements” means the following:
1. The *Termination and Asset Transfer Agreement* by and among Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and Array BioPharma Inc., dated as of November 26, 2014 (related to Binimetinib, *i.e.*, MEK 162);
  2. The *First Amendment to the Termination and Asset Transfer Agreement* by and among Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and Array BioPharma Inc., dated as of January 19, 2015 (related to Binimetinib, *i.e.*, MEK 162);



3. The *Cross License Agreement* by and between Novartis AG and Array BioPharma Inc., to be executed as of the Effective Date (as that term is defined in the *Termination and Asset Transfer Agreement*) (related to Binimetinib, *i.e.*, MEK 162);
4. The *Patent Assignment Agreement* by and between Novartis AG and Array BioPharma Inc., to be executed as of the Effective Date (as that term is defined in the *Termination and Asset Transfer Agreement*) (related to Binimetinib, *i.e.*, MEK 162);
5. The *Other Clinical Trial Agreement* by and between Array BioPharma Inc. and Novartis Pharma AG, to be executed as of the Effective Date (as that term is defined in the *Termination and Asset Transfer Agreement*) (related to Binimetinib, *i.e.*, MEK 162);
6. The *Standalone Clinical Trial Agreement* by and between Array BioPharma Inc. and Novartis Pharma AG, to be executed as of the Effective Date (as that term is defined in the *Termination and Asset Transfer Agreement*) (related to Binimetinib, *i.e.*, MEK 162);
7. The *Supply Agreement* by and between Novartis Pharma AG, and Array BioPharma Inc., to be executed as of the Effective Date (as that term is defined in the *Termination and Asset Transfer Agreement*) (related to Binimetinib, *i.e.*, MEK 162);
8. The *Transition Agreement* by and between Novartis Pharma AG, and Array BioPharma Inc., to be executed as of the Effective Date (as that term is defined in the *Termination and Asset Transfer Agreement*) (related to Binimetinib, *i.e.*, MEK 162);
9. The *LGX818 Asset Transfer Agreement* by and between Novartis Pharma AG and Array BioPharma Inc., dated as of January 19, 2015;
10. The *Cross License Agreement* by and between Novartis AG and Array BioPharma Inc., to be executed as of the Effective Date (as that term is defined in the *LGX818 Asset Transfer Agreement*) (related to Encorafenib, *i.e.*, LGX818);
11. The *Patent Assignment Agreement* by and between Novartis AG and Array BioPharma Inc., to be executed as of the Effective Date (as that term is defined in the *LGX818 Asset Transfer Agreement*) (related to Encorafenib, *i.e.*, LGX818);
12. The *Other Clinical Trial Agreement* by and between Array BioPharma Inc., and Novartis Pharma AG to be executed as of the Effective Date (as that term is defined in the *LGX818 Asset Transfer Agreement*) (related to Encorafenib, *i.e.*, LGX818);
13. The *Standalone Clinical Trial Agreement* by and between Array BioPharma Inc., and Novartis Pharma AG to be executed as of the Effective Date (as that term is defined in the *LGX818 Asset Transfer Agreement*) (related to Encorafenib, *i.e.*, LGX818);

14. The *Supply Agreement* by and between Novartis Pharma AG and Array BioPharma Inc., to be executed as of the Effective Date (as that term is defined in the *LGX818 Asset Transfer Agreement*) (related to Encorafenib, *i.e.*, LGX818);
15. The *Transition Agreement* by and between Novartis Pharma AG and Array BioPharma to be executed as of the Effective Date (as that term is defined in the *LGX818 Asset Transfer Agreement*) (related to Encorafenib, *i.e.*, LGX818);
16. The *Amended and Restated Three-Way Clinical Trial Agreement* by and between Array BioPharma Inc., and Novartis Pharma AG to be executed as of the Effective Date (as that term is defined in the *LGX818 Asset Transfer Agreement*) (related to Encorafenib, *i.e.*, LGX818 and to Binimetinib, *i.e.*, MEK 162);
17. The *Amended and Restated Columbus Trial Agreement* by and between Novartis Pharma AG and Array Biopharma Inc., to be executed as of the Effective Date (as that term is defined in the *LGX818 Asset Transfer Agreement*) (related to Encorafenib, *i.e.*, LGX818 and to Binimetinib, *i.e.*, MEK 162); and,

all amendments, exhibits, attachments, agreements, and schedules to the above-referenced agreements, related to the Divestiture Product Assets that have been approved by the Commission to accomplish the requirements of this Order. Such agreements are also subject to the EEA Commitment Agreements. The Oncology Product Divestiture Agreements are contained in Non-Public Appendix I.

NN. “Oncology Product License” means a perpetual, non-exclusive, fully paid-up, transferable license with rights to sublicense under all Product Licensed Intellectual Property and all Product Manufacturing Technology (to the extent any Product Manufacturing Technology is not either licensed or assigned to the Acquirer under another license or assignment pursuant to this Order) related to general manufacturing know-how that was owned, licensed, or controlled by the Respondent:

1. to research and Develop the Oncology Product(s) being acquired by a particular Acquirer for the purposes of the marketing, distribution or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the such Oncology Product(s) within the Geographic Territory;
3. to import or export the applicable Oncology Product(s) within the Geographic Territory; and
4. to have the applicable Oncology Product(s) made anywhere in the world;

*provided, however*, that, for any Product Licensed Intellectual Property that is the subject of a license from a Third Party entered into by the Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to the Respondent.

- OO. “Oncology Product Releasee(s)” means the following Persons:
1. the Acquirer for the assets related to a particular Oncology Product;
  2. any Person controlled by or under common control with that Acquirer; and
  3. any Manufacturing Designee(s), Clinical Trial Research Organization Designee(s), licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities, in each such case, as related to the Oncology Product(s) being acquired by that Acquirer.
- PP. “Oncology Product(s)” means the B-Raf Inhibitor Products, and the MEK Inhibitor Products, individually and collectively.
- QQ. “Orders” means this Decision and Order and the related Order to Maintain Assets.
- RR. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- SS. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- TT. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- UU. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- VV. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- WW. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.
- XX. “Product Contracts” means all of the following contracts or agreements, each to the extent directly related to the Oncology Products being Acquired by the particular Acquirer:

1. that make specific reference to such Oncology Product(s) and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, that Oncology Product(s) from the Respondent unless such contract applies generally to the Respondent's sales of Products to that Third Party;
2. pursuant to which the Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) from any Third Party for use in connection with the manufacture of such Oncology Product(s);
3. pursuant to which the Respondent had or has as of the Closing Date the ability to independently purchase necessary ingredients or components other than the active pharmaceutical ingredient(s) or had planned to purchase such necessary ingredients or components from any Third Party for use in connection with the manufacture of such Oncology Product(s) other than such ingredients or components as are widely available for purchase and use in pharmaceutical preparations;
4. relating to any Clinical Trials involving such Oncology Product(s);
5. with universities or other research institutions for the use of such Oncology Product(s) in scientific research;
6. relating to the particularized marketing of such Oncology Product(s) or educational matters relating solely to that Oncology Product(s);
7. pursuant to which a Third Party manufactures such Oncology Product(s) on behalf of the Respondent;
8. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of such Oncology Product(s) on behalf of the Respondent;
9. pursuant to which a Third Party provides the Product Manufacturing Technology related to such Oncology Product(s) to the Respondent;
10. pursuant to which a Third Party is licensed by the Respondent to use the Product Manufacturing Technology related to such Oncology Product(s);
11. constituting confidentiality agreements involving such Oncology Product(s);
12. involving any royalty, licensing, covenant not to sue, or similar arrangement involving such Oncology Product(s);
13. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of such Oncology Product(s) to the Respondent including, but not limited to, consultation arrangements; and/or
14. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of such Oncology Product(s) or the Business related to that Oncology Product(s);

*provided, however,* that, where any such contract or agreement also relates to a Retained Product(s), the Respondent shall (i) provide to that Acquirer the benefits of use of such contract or agreement (ii) partially assign to that Acquirer or otherwise divide such contract or agreement into one contract or agreement for Acquirer and one contract or agreement for Respondent, and/or (iii) enable that Acquirer to obtain alternative benefits independently.

YY. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the specified Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product’s sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of the Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law) in connection with the acquisition of that Product; all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

ZZ. “Product Development Reports” means:

1. Pharmacokinetic study reports related to the specified Product;
2. Bioavailability study reports (including reference listed drug information) related to the specified Product;
3. Bioequivalence study reports (including reference listed drug information) related to the specified Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with the FDA relating to the Application(s) related to the specified Product;

5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Product;
8. FDA approved patient circulars and information related to the specified Product;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to the specified Product;
10. summary of Product complaints from physicians related to the specified Product;
11. summary of Product complaints from customers related to the specified Product;
12. Product recall reports filed with the FDA related to the specified Product, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Product;
14. reports related to the specified Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Product;
16. analytical methods development records related to the specified Product;
17. manufacturing batch records related to the specified Product;
18. stability testing records related to the specified Product;
19. change in control history related to the specified Product; and
20. executed validation and qualification protocols and reports related to the specified Product.

AAA. “Product Employee Information” means the following, for each Oncology Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Oncology Product Core Employee (including former employees who were employed by the Respondent within ninety (90) days of the execution date of any Remedial Agreement);

2. with respect to each such employee, the following information:
  - a. the date of hire and effective service date;
  - b. job title or position held;
  - c. a specific description of the employee's responsibilities related to the Oncology Product; *provided, however*, that, in lieu of this description, the Respondent may provide the employee's most recent performance appraisal;
  - d. the base salary or current wages;
  - e. the most recent bonus paid, aggregate annual compensation for the Respondent's last fiscal year and current target or guaranteed bonus, if any;
  - f. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
  - g. and any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees;
3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

BBB. "Product Intellectual Property" means all of the following related to an Oncology Product (other than Product Licensed Intellectual Property):

1. Patents;
2. Product Copyrights;
3. Product Trademarks;
4. Product Trade Dress;
5. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
6. rights to obtain and file for patents, trademarks, and copyrights and registrations related to any of the foregoing and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

The term "Product Intellectual Property" *excludes* the corporate names or corporate trade dress of "Novartis" or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Novartis can be identified or defined.

- CCC. “Product Licensed Intellectual Property” means the following:
1. Patents that are related to an Oncology Product that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) Application as of the Acquisition Date;
  2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to an Oncology Product and that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) Application as of the Acquisition Date.
- DDD. “Product Manufacturing Employees” means all salaried employees of the Respondent who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the Oncology Product(s) being acquired by the particular Acquirer (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the twelve (12) month period immediately prior to the Closing Date.
- EEE. “Product Manufacturing Technology” means all of the following related to an Oncology Product:
1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, synthesis schemes, synthesis control forms, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
  2. list of all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients or packaging materials;
  3. copies of master batch record(s) for the regulatory process being used at the filed commercial manufacturing site(s) (as included in the Application related to the Product), complete batch records of all drug substance batches manufactured by the Respondent or its contractor(s) including copies of certificates of analysis/analysis reports for in-process controls test data, intermediates/raw materials/reagents/solvents and final drug substance;



4. campaign experience reports; and,
5. list of all equipment used to manufacture a product.

- FFF. “Product Marketing Materials” means all marketing materials specifically related to the specified Product and used, or intended for use in the marketing or sale of the specified Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Product.
- GGG. “Product Research and Development Employees” means all salaried employees of the Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies of the Oncology Product(s) being acquired by a particular Acquirer (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the twelve (12) month period immediately prior to the Closing Date.
- HHH. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.
- III. “Product Trade Dress” means the current trade dress of a Product, including, but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- JJJ. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- KKK. “Proposed Acquirer” means a Person proposed by the Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to this Order.
- LLL. “Regulatory Package” means, with respect to each Oncology Product, all INDs and other regulatory applications submitted to any Agency, Product Approvals, pre-clinical and clinical data and information, regulatory materials, drug dossiers, master files (including Drug Master Files, as defined in 21 C.F.R. 314.420 (or any non-United States equivalent thereof)), and any other reports, records regulatory correspondence and other materials

relating to Product Approvals of such Oncology Product or required to Develop, manufacture, distribute or otherwise commercialize such Oncology Product, including information that relates to pharmacology, toxicology, chemistry, manufacturing and controls data, batch records, safety and efficacy, and any safety database, in each case that is necessary or reasonably useful to the Clinical Trial(s).

MMM. “Remedial Agreement(s)” means the following:

1. any agreement between the Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;
2. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to an Oncology Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;
3. any agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by the Respondent to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to an Oncology Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

NNN. “Retained Product” means any Product(s) other than an Oncology Product.

OOO. “Right of Reference or Use” means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation for an FDA audit.

PPP. “Supply Cost” means a cost not to exceed the Respondent’s average direct per unit cost in United States dollars of manufacturing any Oncology Product for the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that, in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for an Oncology Product, the term “Supply Cost” means the cost as specified in such Remedial Agreement for that Oncology Product.

QQQ. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

1. designating employees of the Respondent knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Oncology Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee(s), and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to any Oncology Product that are acceptable to the Acquirer;
3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee(s); and
4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee(s) to:
  - a. manufacture any Oncology Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Oncology Product;
  - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee(s), to manufacture, distribute, market, and sell any Oncology Product in commercial quantities and to meet all Agency-approved specifications for such Oncology Product; and
  - c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to any Oncology Product.

RRR. “Third Party(ies)” means any non-governmental Person other than the following: the Respondent; or, the Acquirer of particular assets or rights pursuant to this Order.

SSS. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by the Respondent. The term “Website” *excludes* the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Oncology Products.

## II.

### IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Acquisition Date, Respondent shall divest the B-Raf Inhibitor Product Assets and grant the related Oncology Product License, absolutely and in good faith, to Array pursuant to, and in accordance with, the Oncology Product Divestiture Agreement(s) (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Array or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the B-Raf Inhibitor Product Assets is incorporated by reference into this Order and made a part hereof;

*provided, however,* that if the Respondent has divested the B-Raf Inhibitor Product Assets to Array prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies the Respondent that Array is not an acceptable purchaser of the B-Raf Inhibitor Product Assets, then the Respondent shall immediately rescind the transaction with Array, in whole or in part, as directed by the Commission, and shall divest the B-Raf Inhibitor Product Assets within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further, however,* that if the Respondent has divested the B-Raf Inhibitor Product Assets to Array prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies the Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the B-Raf Inhibitor Product Assets to Array (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order;

*provided further, however,* Respondent may retain such of the above-described assets and rights as are reasonably necessary to provide transitional services to the Acquirer and to Contract Manufacture for the Acquirer, until the conclusion of the Respondent’s

provision of such services or Contract Manufacture, and for use solely for the purposes of Respondent's compliance with this Order or the related Remedial Agreements.

- B. Not later than ten (10) days after the Acquisition Date, Respondent shall divest the MEK Inhibitor Product Assets (to the extent not already owned, controlled or in the possession of Array) and grant the related Oncology Product License, absolutely and in good faith, to Array pursuant to, and in accordance with, the Oncology Product Divestiture Agreement(s) (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Array or to reduce any obligations of the Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the MEK Inhibitor Product Assets is incorporated by reference into this Order and made a part hereof;

*provided, however,* that if the Respondent has divested the MEK Inhibitor Product Assets to Array prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies the Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the MEK Inhibitor Product Assets to Array (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order;

*provided further, however,* Respondent may retain such of the above-described assets and rights as are reasonably necessary to provide transitional services to the Acquirer and to Contract Manufacture for the Acquirer, until the conclusion of the Respondent's provision of such services or Contract Manufacture, and for use solely for the purposes of Respondent's compliance with this Order or the related Remedial Agreements.

- C. Prior to the Closing Date, Respondents shall provide the Acquirer with the opportunity to review all contracts or agreements that are reasonably expected to be Product Contracts for the purposes of the divestitures required by this Order; *provided, however,* that, if after the Closing Date, Respondent notifies Acquirer, or otherwise learns, of any contract or agreement that is a Product Contract but that Acquirer did not have such an opportunity to review, then the Acquirer shall determine whether or not it will assume such contracts or agreements and the extent to which it will assume such contracts or agreements.
- D. Prior to the Order Date, unless specifically agreed otherwise by the Acquirer, the Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit the Respondent to divest the Divestiture Product Assets and grant the related Oncology Product License to an Acquirer, and to permit that Acquirer to continue the Business related to the Oncology Product(s) being acquired by that Acquirer;

*provided, however*, Respondent may satisfy this requirement by certifying that that Acquirer has executed all such agreements directly with each of the relevant Third Parties.

E. Respondent shall:

1. submit to each Acquirer, at Respondent's expense, all Confidential Business Information related to the Oncology Product(s) being acquired by that Acquirer;
2. deliver all Confidential Business Information to that Acquirer:
  - a. in good faith;
  - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
  - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to that Acquirer, upon reasonable written notice and request, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Oncology Products being acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. 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 applicable Remedial Agreement; or
  - c. applicable Law;
5. not disclose or convey any Confidential Business Information that is exclusively related to the Oncology Products, directly or indirectly, to any Person except (i) the Acquirer of the particular Oncology Product(s), (ii) 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);

6. not provide, disclose or otherwise make available, directly or indirectly, any 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 any employee or subcontractor of the Respondent, other than such employee or subcontractor that is directly involved in the research and Development of the Oncology Product and for the purposes of such work as 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); and,
7. 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. Respondent shall provide, or cause to be provided to each Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Product Manufacturing Technology (including all related intellectual property) related to the Oncology Product(s) being acquired by that Acquirer; and
2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to the Respondent related to such Oncology Product(s).

Respondent shall obtain any consents from Third Parties required to comply with this provision. Respondent shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Oncology Product(s) being acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than thirty (30) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to the Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to the Acquirer.

G. For each Acquirer, Respondent shall:

1. upon reasonable written notice and request from an Acquirer to the Respondent, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Supply Cost, for a period of time sufficient to allow that Acquirer (or the Manufacturing Designee(s) of that Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of the Respondent, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) for the applicable Oncology Product(s) from Persons other than the Respondent;
2. make representations and warranties to the Acquirer being supplied by the Respondent that the Contract Manufacture Product(s) supplied by the Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the Respondent shall agree to indemnify, defend and hold that Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to that Acquirer pursuant to a Remedial Agreement by the Respondent to meet cGMP. This obligation may be made contingent upon that Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

*provided, however,* that the Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however,* that this obligation shall not require Respondent to be liable for any negligent act or omission of that Acquirer or for any representations and warranties, express or implied, made by that Acquirer that exceed the representations and warranties made by the Respondent to that Acquirer in an agreement to Contract Manufacture;

*provided further, however,* that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for an Oncology Product, each such agreement may contain limits on Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to that Acquirer pursuant to such Remedial Agreement to meet cGMP;

3. give at least the same level of priority to manufacturing and supplying a Contract Manufacture Product to the Acquirer as Respondent gives to the manufacture and supply of Products for the Respondent's own use or sale;



4. promptly advise the Acquirer, the Interim Monitor and the Commission in the event material supply issues arise or appear likely to arise;
5. make representations and warranties to the Acquirer being supplied by the Respondent that the Respondent shall hold harmless and indemnify that Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless the Respondent can demonstrate that the failure was in no part the result of negligence or willful misconduct by the Respondent;  
*provided, however,* that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (ii) such agreement becomes a Remedial Agreement for an Oncology Product, each such agreement may contain limits on the Respondent's aggregate liability for such a failure;
6. during the term of any agreement to Contract Manufacture, upon written request of the Acquirer or the Interim Monitor (if any has been appointed), make available to that Acquirer and the Interim Monitor (if any has been appointed) all records that are available to the Respondent that relate directly to the manufacture of the applicable Contract Manufacture Products that are generated or created after the Closing Date;
7. during the term of any agreement to Contract Manufacture, Respondent shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
8. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Interim Monitor to monitor compliance with the obligations to Contract Manufacture;
9. upon reasonable written notice and request from an Acquirer to the Respondent, provide consultation with knowledgeable employees of the Respondent and training, at a facility chosen by the requesting Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee(s) of the Acquirer) to obtain all Product Approvals to manufacture the Oncology Products acquired by that Acquirer in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to satisfy management of that Acquirer that its personnel (or personnel of the Manufacturing Designee(s)) are adequately trained in the manufacture of such Oncology Products;

The foregoing provisions, II.G.1. – 9., shall remain in effect with respect to each Oncology Product until the earliest of: (i) the date the Acquirer of that Oncology Product (or the Manufacturing Designee(s) of the Acquirer), respectively, is approved by the FDA to manufacture and sell such Oncology Product in the United States and able to manufacture such Oncology Product in commercial quantities, in a manner consistent

with cGMP, independently of Respondent; (ii) the date the Acquirer of a particular Oncology Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture such 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 of a particular Oncology Product has abandoned its efforts to manufacture such Oncology Product, or (iv) the date thirty (30) months from the Closing Date.

H. Respondent shall require, as a condition of continued employment post-divestiture of the Divestiture Product Assets, that:

1. each employee who has or may have had access to Confidential Business Information sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information as strictly confidential, including the nondisclosure of that information to all other employees, subcontractors, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order); and,
2. each employee who has responsibilities, within the one (1) year period before or during the two (2) year period after the Closing Date, 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 type of mechanism of action to treat such disease, sign an agreement pursuant to which that employee shall not seek to obtain Confidential Business Information from employees who have or have had access to such Confidential Business Information;

Respondent shall advise the direct supervisors of any such employee of the responsibilities and restrictions related to the treatment of the Confidential Business Information under this Order.

I. Not later than thirty (30) days after the Closing Date, 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 described in Paragraph II.H. 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 three (3) years 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 related to the Oncology Product(s) acquired by that Acquirer.

J. 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 requesting 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 the Oncology Product Core Employee Access Period and not for any other purpose whatsoever, (iii) restrict access to the information to such of the applicable 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;
3. during the Oncology Product Core Employee Access Period(s), not interfere with the hiring or employing by the Acquirer, its Manufacturing Designee, or its Clinical Research Organization Designee(s) of the Oncology Product Core Employees, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with the Acquirer, its Manufacturing Designee(s), 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 an Acquirer, its Manufacturing Designee or its Clinical Research 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 an 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 applicable Oncology Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the applicable Oncology Product(s), and to ensure successful execution of the pre-Acquisition Development plans for the applicable Oncology Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Closing Date(s) for the divestiture of the assets related to the Oncology Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

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

*provided further, however,* that the 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 the Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondent.

- K. Until Respondent completes the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to a particular Oncology Product(s) to the Acquirer and transfers the Clinical Trials related to a particular Oncology Product(s) to the Acquirer,
1. Respondent shall take actions as are necessary to:
    - a. maintain the full economic viability and marketability of the Businesses related to that Oncology Product;
    - b. minimize any risk of loss of competitive potential for that Business;
    - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Oncology Product;
    - d. ensure the assets related to each Oncology Product are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business related to each Oncology Product;
    - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
  2. Respondent shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to that Oncology Product.
- L. For each Acquirer, and with respect to any ongoing Clinical Trial(s) as of the Closing Date related to the Oncology Products being acquired by that Acquirer, Respondent shall:
1. designate employees of the Respondent that have worked on such Clinical Trial(s) who will be responsible for communicating directly with the Acquirer and/or its Clinical Research Organization Designee(s), and the Interim Monitor (if one has been appointed), for the purpose of effecting any transition agreed upon between the Respondent and the Acquirer for the purposes of ensuring the continued prosecution of such Clinical Trials in a timely manner;
  2. coordinate with the Acquirer to prepare any protocols necessary to transfer the Clinical Trials to the Acquirer or the Acquirer's Clinical Research Organization Designee(s);
  3. assist the Acquirer to prepare and implement any Clinical Plan(s) and Regulatory Package(s) for the current phase of the Clinical Trial (*i.e.*, the phase as of the Closing Date) until such time or specified event as agreed upon with the Acquirer in a Remedial Agreement occurs;
  4. prepare and implement a detailed transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such information related to such Clinical Trial(s) to the Acquirer and/or its Clinical Research Organization Designee(s); and

5. provide, in a timely manner, assistance and advice to enable the Acquirer and/or its Clinical Research Organization Designee(s) to continue such Clinical Trial in its phase as of the Closing Date in the same quality, scope, and pace as was being achieved by the Respondent and in a manner consistent with Good Clinical Practices.

M. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Oncology Product Releasee(s) of the Acquirer under the following:

1. any Patent owned by or licensed to the Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;
2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Oncology Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Oncology Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of Oncology Product(s) acquired by that Acquirer. Respondent shall also covenant to the Acquirer that, as a condition of any assignment or license from the Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer or the related Oncology Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Oncology Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Oncology Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Oncology Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by or licensed to or from the Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

N. Upon reasonable written notice and request from an Acquirer to the Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist the requesting Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (i) the research,

Development, or manufacture anywhere in the world of the Oncology Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Oncology Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Oncology Product(s) acquired by that Acquirer.

- O. For any patent infringement suit filed prior to the Closing Date in which the Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that the Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Oncology Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Oncology Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Oncology Product(s) acquired by that Acquirer, the Respondent shall:
1. cooperate with the applicable Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from the Respondent in connection with obtaining resolution of any pending patent litigation related to the applicable Oncology Product;
  2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent the Acquirer in any ongoing patent litigation related to the applicable Oncology Product; and/or
  3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work-product in the possession of the Respondent's outside counsel related to the applicable Oncology Product.
- P. The purpose of the divestiture of the B-Raf Inhibitor Assets and the MEK Inhibitor Assets, the provision of the related Product Manufacturing Technology, and the transfer of the related Clinical Trials and the related obligations imposed on the Respondent by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business related to each Oncology Product within the Geographic Territory;
  2. to create a viable and effective competitor that is independent of Respondent in the Business related to each Oncology Product within the Geographic Territory; and
  3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

### III.

#### **IT IS FURTHER ORDERED** that:

- A. At any time after the Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor (“Interim Monitor”) to assure that the Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets 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 Order in a manner consistent with the purposes of the Order.
- 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 Order, 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 Order 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 to each respective Acquirer in a manner that fully satisfies the requirements of this Order and, with respect to each Oncology Product, until the earliest of: (i) the date the Acquirer of that Oncology Product (or that Acquirer’s Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Oncology Product and able to manufacture that Oncology Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture that Oncology Product; or (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, 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 this Order 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 Order 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 Order; *provided, however,* beginning one hundred twenty (120) days after Respondent has filed its final report pursuant to Paragraph VII.B., 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 Order.
- M. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

#### IV.

##### **IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey either the B-Raf Inhibitor Assets or the MEK Inhibitor Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey these assets, as applicable, in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
  2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
  3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
  4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in

the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation 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 Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee'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 Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

**V.**

**IT IS FURTHER ORDERED** that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, the Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where redacted documents or copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. To assure the Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the applicable Oncology Product(s) or the assets and Businesses associated with those Oncology Product(s);

*provided, however,* that the Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement or arrangement;

*provided further, however,* that, pursuant to this Paragraph V, the Respondent shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but the Respondent shall not be deemed to have violated this requirement if the Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

## VI.

### **IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement related to each of the Oncology Product(s) a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. Respondent shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Oncology Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- E. Unless otherwise determined by the Commission, each of the Oncology Product Divestiture Agreements shall become a Remedial Agreement on the Order Date.
- F. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

## VII.

### **IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II.A., II.B., II.C., II.D., II.E.1, II.E.2, II.E.3, II.E.7., II.F., II.G. II.H., II.I. and II.J., 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 this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order 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 full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

1. 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
  2. a detailed description of the timing for the completion of such obligations.
- C. Respondent shall notify the Commission prior to consenting to and/or entering into any agreement with, and/or proposing any remedial or other action from, any non-U.S. Government Entity that might have the effect of causing the Respondent and/or the Acquirer to sell or otherwise dispose of, any assets or intellectual property related to the Oncology Products that relate to countries outside of the United States of America. Respondent shall include in such notification, among other things that might be required by staff of the Commission, a full description of all substantive contacts or negotiations related to the sale or disposal of such assets and/or intellectual property rights and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning the sale and/or disposal of such assets and/or intellectual property rights.
- D. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

#### **VIII.**

**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 this Order.

#### **IX.**

**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 the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the 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
- to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

**X.**

**IT IS FURTHER ORDERED** that this Order shall terminate on April 7, 2025.

By the Commission.

Donald S. Clark  
Secretary

SEAL  
ISSUED: April 7, 2015



**NON-PUBLIC APPENDIX I  
ONCOLOGY PRODUCT DIVESTITURE AGREEMENTS**

**[Redacted From the Public Record Version, But Incorporated By Reference]**

**NON-PUBLIC APPENDIX II  
OTHER AGREEMENTS RELATED TO  
THE ONCOLOGY PRODUCTS**

**[Redacted From the Public Record Version, But Incorporated By Reference]**