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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill

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 be in effect [illegible]

E. “Acquisition” means Novartis’ acquisition of certain assets of Glaxo as described in the Acquisition Agreement.

F. “Acquisition Agreement” means the

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,

T. “Closing Date” means, as to the particular Divestiture Product Assets being divested, the date on which the

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

DD. “Geographic Territory” shall mean the United States of America, including all of its territories

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 betmgrtctive Dat and bar3t

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)" [redacted] llowing Persons:

1. the Acquirer for the asset [redacted] particular Oncology Product;
2. any Person controlled b[redacted] mmon control with that Acquirer; and
3. any Manufacturing De[redacted] nical Trial Research Organization De licensees, sublicense[redacted] rers, suppliers, distributors, and custo Acquirer, or of such [redacted] liated entities, in each such case, as r Oncology Product([redacted] red by that Acquirer.

PP. "Oncology Product(s)" r[redacted] Raf Inhibitor Products, and the MEK I Products, individually a[redacted] y.

QQ. "Orders" means this De[redacted] rder and the related Order to Maintain

RR. "Order Date" means th[redacted] ch the final Decision and Order in thi issued by the Commiss[redacted]

SS. "Order to Maintain Ass[redacted] e Order to Maintain Assets incorpora made a part of the Agr[redacted] ining Consent Orders.

TT. "Patent(s)" means all p[redacted] applications, including provisional p applications, invention[redacted] certificates of invention and applicatio certificates of invention[redacted] y invention registrations, in each case existence, on or before [redacted] Date (*except* where this Order specifie time), and includes all r[redacted] ions, divisions, continuations, continu[redacted], supplementary protectio[redacted] extensions and reexaminations there inventions disclosed ther[redacted] ghts therein provided by international conventions.

UU. "Person" means any indivi[redacted] ship, joint venture, firm, corporation, trust, unincorporated organ[redacted] er business or Government Entity, a subsidiaries, divisions, grou[redacted] s thereof.

VV. "Product(s)" Product(s)"n t([redacted] J4)Tj]Td1()i(ŕ)3Tw 2.ect(r)3l0(y6)y)[redacted]

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 y -4(tit 9r (t)p)-4(h (r)-17(t)-320.26)Tj /TT1-1(s)-1(a)4(l)-2(

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 report

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) monthtwpe ustcount.oion -d/[gn4e6Tol-16()-1(h)-4e f

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 Itor Produc1t

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

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 Ph[lprdugct

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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 r;26(M)-5(an)2(g)5.75 j 0.002 Tc -0 rel

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.

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 a0 Tw 0.93CDspplrehat-1(pono g3p64(t)-12(e)0 Tc 0)-10(not)-2(i)-2(c5 a)
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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;

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.

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

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.

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 F

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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]