UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Joseph J. Simons, Chairman
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter
Christine S. Wilson

In the Matter of	)	
BRISTOL-MYERS SQUIBB COMPANY, a corporation;	)	
and	)	DECISION AND ORDER Docket No. C-
CELGENE CORPORATION , a corporation.	)	

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of the

2. any other Person the Commission approves to acquire the Otezla Assets pursuant to this Decision and Order.

F. "Acquisition Date" means the date on which BMS acquires 50 percent or more of the voting securities of Celgene.

G. "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, but is not limited to, the FDA.

H. "Amgen" means Amgen Inc., a corporation organized, existing and doing business under and by virtue of the laws of Delaware with its principal executive offices located at One Amgen Center Drive, Thousand Oaks, California 91320-1799.

I. "Business Information" means all original and all copies of any operating, financial, or other information, books, records, documents, data computer files (including files stored on a computer hard drive or other storage media), electronic files, ledgers, papers, instruments, and other materials, wherever located and however stored, whether stored or maintained in traditional paper format or by means of electronic, optical, or magnetic media or devices, photographic or video images, or any other format or media).

J. "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.

K. "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.

L. "Clinical Research Organization Designee" means any Person other than the Respondents that has been designated by an Acquirer to conduct a Clinical Trial related to an Otezla Product for the Acquirer.

M. "Clinical Trial" means a controlled study in humans of the safety, efficacy, or bioequivalence of a Product, and includes 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.

N. "Customer" means any Person that is a direct purchaser of any Otezla Product from Respondent or the Acquirer.

O. "Development" means all preclinical and clinical drug development activities, 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 and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

P. "Direct Cost" means a cost not to exceed the cost of labor, material, 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 Respondent's employees shall not exceed then-

cards and bank accounts of the Respondents;

6. any records or documents reflecting attorney-client, work product or similar privilege of Respondents or otherwise relating to the Otezla Assets as a result of legal counsel representing the Respondents in connection with the divestiture of the Otezla Assets pursuant to this Order or the Otezla Divestiture Agreements; and

7. any assets owned by Respondent BMS as of the Acquisition Date that have not been incorporated into the Otezla Assets on or before the Divestiture Date.

provided, however, that if Amgen is the Acquirer, notwithstanding anything to the contrary, no asset, property or right that is a "Transferred Asset" as defined in Section 2.1 of the APA or to which Amgen or any of its affiliates is otherwise entitled pursuant to any Otezla Divestiture Agreement, shall be deemed to be an Excluded Asset.

V. "FDA" means the United States Food and Drug Administration.

W. "FDA Authorization(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 holder and the FDA related thereto. "FDA Authorization" 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 holder and the FDA related thereto.

X. "Good Clinical Practice" means the current standards and practices 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 a Clinical Trial is being conducted.

Y. "Government Entity" means any Federal, state, local, non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.

Z. "Manufacturing Designee" means any Person other than a Respondent that has been designated by an Acquirer to manufacture an Otezla Product for that Acquirer.

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made a part of the Consent Agreement

DD. "Orders" means this Decision and Order and the related Order to Maintain Assets.

EE. "Otezla Assets" means all legal or equitable rights, title, and interest in and to all tangible and intangible assets, wherever located, relating to the Otezla Business, to the extent transfer is permitted by law and as such assets and rights are in existence as of the date the Respondents sign the Consent Agreement, including the following

1. all rights to all FDA Authorizations;
2. all rights to the Drug Master File filed with the FDA for the active pharmaceutical ingredient apremilast;
3. all rights to all Clinical Trials;
4. all Otezla Intellectual Property, including Shared Intellectual Property;
5. the Otezla™ trademarks and any other trademark used exclusively in the marketing, advertising, or sale of the Otezla Products;
6. all Product Approvals;
7. all Product Manufacturing Technology that is primarily related to the Otezla Products;
8. at the Acquirer's option, all Otezla Manufacturing Equipment;
9. all Otezla Marketing Materials;
10. all Product Scientific and Regulatory Material;
11. all website(s) and Domain Names related exclusively to the Otezla Products and the content thereon,

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16. for each Otezla Product:

    a. to the extent known or available to the Respondent, a list of the inventory levels (weeks of supply) in the possession of each Customer as of the date prior to and closest to the Divestiture Date that is available; and

    b. to the extent known by the Respondent, any pending reorder dates for a Customer as of the Divestiture Date;

17. at the option of the Acquirer, all inventory and all ingredients, materials, or components used in the manufacture of the Otezla Products in existence as of the Divestiture Date, including, the active pharmaceutical ingredient(s), excipient(s), raw materials, packaging materials, work-in-process, and finished goods related to the Otezla Products;

18. the quantity and delivery terms in all unfilled Customer purchase orders for the Otezla Products as of the Divestiture Date, to be provided to the Acquirer of the Otezla Products not later than five (5) days after the Divestiture Date; and

19. at the option of the Acquirer, the right to fill any or all unfilled Customer purchase orders for the Otezla Products as of the Divestiture Date;

provided, however, that "Otezla Assets" does not include the Excluded Assets.

FF. "Otezla Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of the Otezla Products.

GG. "Otezla Confidential Business Information" means all Business Information relating to the Otezla Business that is not in the public domain.

HH. "Otezla Contracts" means all contracts, agreements, mutual understandings, arrangements, or commitments related to the Otezla Business, including any contracts or agreements:

1. pursuant to which any third party purchases, or has the option to purchase, an Otezla Product from a Respondent;

2. pursuant to which a Respondent had, or has as of the Divestiture Date, the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any third party for use in connection with the Otezla Business;

6. pursuant to which a third party manufactures or plans to manufacture an Otezla Product as a finished dosage form on behalf of a Respondent;

7. pursuant to which a third party provides or plans to provide any part of the manufacturing process, including, without limitation, the finish and/or packaging of an Otezla Product on behalf of a Respondent;

8. pursuant to which a third party licenses the Product Manufacturing Technology related to an Otezla Product to a Respondent;

9. pursuant to which a third party is licensed by a Respondent to use the Product Manufacturing Technology related to an Otezla Product;

10. constituting confidentiality agreements involving an Otezla Product;

11. involving any royalty, licensing, covenant not to sue, or similar agreement related to an Otezla Product;

12. pursuant to which a third party provides any specialized services necessary to the research, Development, manufacture, or distribution of an Otezla Product to a Respondent, including, consultation arrangements; and/or

13. pursuant to which any third party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of an Otezla Product or the Otezla Business;

provided, however, that where any such contract or agreement also relates to a Retained Product, a Respondent shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the Otezla Product, but concurrently may retain similar rights for the purposes of the Retained Product.

II. "Otezla Copyrights" means rights to all original works of authorship of any kind directly related to an Otezla Product and any registrations and applications for registrations thereof throughout the world.

JJ. "Otezla Core Employees" means the Otezla Marketing Employees, Otezla Manufacturing Employees, Otezla Research and Development Employees, and Otezla Sales Employees.

KK. "Otezla Divestiture Agreement(s)" means the following:

1. the Asset Purchase Agreement between Celgene Corporation and Amgen, Inc., dated as of August 25, 2019 (the "APA");

2. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the APA for the approval of the Commission; and

3. any other agreement between a Respondent(s) 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.

The Otezla Divestiture Agreements that have been submitted to the Commission by the Respondents on or before the Order Date and are attached to this Order and contained in Non-Public Appendix I.

LL. "Otezla Intellectual Property" means intellectual property of any kind, related to or an Otezla Product that is owned, licensed, held, or controlled by a Respondent as of the Divestiture Date, including

1. Otezla Patents;
2. Otezla Copyrights;
3. Otezla™ trademarks;
4. Otezla™ 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 thereof, and to bring suit against a third party for the past, present, or future infringement, misappropriation, dilution, misuse, or other violation of any of the foregoing

MM. "Otezla Manufacturing Employees" means all employees of a Respondent who have participated (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, financial, or compliance) in any of the following related to the Otezla Business: (i) Developing and validating the commercial manufacturing process, (ii) formulating the manufacturing process performance qualification protocol, (iii) controlling the manufacturing process to assure performance Product quality, (iv) assuring that during routine manufacturing the process remains in a state of control, (v) collecting and evaluating data for the purposes of providing scientific ev (pe)-68r2 <20 (ys0 (t)-2 (ha)4 (t)-2 (9 0i71(i)-2 (c)4 d2 (9 0i71(2 (a(-1.

compliance) in any of the following related to the Otezla Business: research, Development, regulatory approval

other filings made to, received from, or otherwise conducted with the FDA relating to the FDA Authorization(s) related to any Otezla Product;

5. annual and periodic reports related to the above-described FDA Authorization(s), including any safety update reports;

6. FDA approved Product labeling related to any Otezla Product;

7. currently used or planned product package inserts (including historical change of controls summaries) related to any Otezla Product;

8. FDA approved patient circulars and information related to any Otezla Product;

9. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy related to any Otezla Product;

10. summaries of complaints from physicians or clinicians related to any Otezla Product;

11. summaries of complaints from Customers related to any Otezla Product;

12. Product recall reports filed with the FDA related to any Otezla 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 or defects found in any Otezla Product;

14. reports related to any Otezla Product from any Person (e.g., any consultant or outside contractor) engaged to investigate or perform testing for the purposes of resolving any Otezla Product or process issues, including, without limitation, identification and sources of impurities or defects;

15. reports from vendors of the component(s), active pharmaceutical ingredient(s), excipient(s), packaging component(s), and detergent(s) used to produce any Otezla Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of any Otezla Product;

16. analytical methods development records related to any Otezla Product;

17. manufacturing batch or lot records related to any Otezla Product;

18. stability testing records related to any Otezla Product;

19. change in control history related to any Otezla Product; and

20. executed validation and qualification protocols and reports related to any Otezla Product.

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

1. a complete and accurate list containing the name of each Otezla Core Employee (including former employees who were employed by a Respondent within ninety

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 United States equivalent thereof)), and any other reports, records, regulatory correspondence, and other materials relating to Product Approvals of such Otezla Product or required to Develop, manufacture, distribute, or otherwise commercialize such Otezla Product, including information that relates to pharmacology, toxicology, ch fi[(i) toxtriy ca (or.,3 ( )-10 (F)6 (i)-2 (l2 (hda i(s)1 (nD)2 (e62 (c)6 te)6 (s)1 (s)1 ary(o)-8 (r)5 (r)5 (e)-4 (e)6 (s)1 (o)-8 ndalyuoseuohdlin(

Shared Intellectual Property in the research, development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of any Retained Product that is not indicated for either the treatment of psoriasis or psoriatic arthritis.

C. Respondents shall grant to the Acquirer a perpetual, non-exclusive, fully paid-up, irrevocable, and royalty-free license to all Product Manufacturing Technology related to the Otezla Products that is not otherwise assigned to the Acquirer pursuant to this Order for use to manufacture any Otezla Products.

D. If Respondents have divested the Otezla Assets to Amgen prior to the Order Date, and if, at the time the Commission determines to make this Order [illegible]

Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Acquirer to use or to acquire from the third party any license or other right to the Product Manufacturing Technology related to the Otezla Products. Such agreements include agreements with respect to the disclosure of Otezla Confidential Business Information related to such Product Manufacturing Technology related to the Otezla Products. Not later than ten (10) days after the

Otezla Products or the Otezla Patents issued by the United States; (ii) any potential patent infringement suit that a Respondent has prepared, or is preparing or defending against as of the Divestiture Date that is related to the Otezla Products or the Otezla Patents issued by the United States; Respondents shall:

1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from all Respondent in connection with obtaining resolution of such patent infringement suit;
2. waive conflicts of interest, if any, to allow Respondents' outside legal counsel to represent the Acquirer in any such patent infringement suit; and
3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of the Respondents' outside counsel related to such patent infringement suit

III. Divestiture Agreements

IT IS FURTHER ORDERED that:

A. The Otezla Divestiture Agreements shall be incorporated by reference into this Order and made a part hereof, and any failure by a Respondent to comply with any term of the Otezla Divestiture Agreements shall constitute a violation of this Order;

provided however, that the Otezla Divestiture Agreements shall not limit, or be construed to limit, the terms of this Order. To the extent any provision in the Otezla Divestiture Agreements varies from or conflicts with any provision in this Order such that the Respondents cannot fully comply with both, Respondents shall comply with this Order.

B. Respondents shall include in the Otezla Divestiture Agreements a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondents' obligation to the Acquirer pursuant to this Order.

C. Respondents shall not modify or amend any of the terms of any Otezla Divestiture 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).

IV. Transition Manufacturing and Services by Respondents

IT IS FURTHER ORDERED that:

A. At the request of an Acquirer and in a manner that receives the prior approval of the Commission, Respondents shall provide transition services sufficient to enable the Acquirer to operate the Otezla Business in substantially the same manner that Respondents have operated the Otezla Business prior to the Acquisition Date.

provided, however, Respondents shall not require any Acquirer to pay

compensation for transition services that exceeds the Direct Cost of providing such assistance and services.

B. Upon reasonable written notice and request from the Acquirer to Respondents, Respondents shall Transition Manufacture and deliver, or cause to be manufactured and delivered, to the Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Transition Manufacture Products at Supply Cost.

C. At the option of the Acquirer:

1. the term for any such contract to Transition Manufacture the Otezla Products in final dosage form shall be twenty-four (24) months with the option to extend such term for two additional 6-month terms; and

2. the term for any such contract to Transition Manufacture the active pharmaceutical ingredient (apremilast) shall be eighteen (18) months with the option to extend such term for two additional 6-month terms.

D. Respondents shall make representations and warranties to the Acquirer that the Transition Manufacture Product(s) supplied by Respondents meet the relevant cGMP-approved specifications.

E. For the Transition Manufacture Product(s) to be marketed or sold in the United States, Respondents shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Transition Manufacture Product(s) supplied to the Acquirer pursuant to an Otezla Divestiture Agreement by that Respondent to meet cGMP, but the Respondents may make this obligation contingent upon the Acquirer giving Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the supplying 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 supplying Respondent's responsibilities to supply the Transition Manufacture Products in the manner required by this Order;

provided further, however, that this obligation shall not require such Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the supplying Respondent to the Acquirer in agreement to Transition Manufacture.

F. Respondents shall give

Acquirer or its Manufacturing Designee;

provided, however, that this Paragraph shall not prohibit a Respondent from continuing to employ any Otezla Core Employee under the terms of that employee's employment with a Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee; and

4. until the Divestiture Date, provide all Otezla Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Otezla Product (a) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Otezla Business and to ensure successful execution of the pre-Acquisition plans for that Otezla Product (s). Such incentives shall include a continuati

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1. to assure such Respondent's compliance with any Otezla Divestiture 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

2. 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 an Otezla Product, the Otezla Assets, or the Otezla Business;

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

provided further, *however*, that pursuant to this Paragraph, a Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if the Acquirer

IT IS FURTHER ORDERED that, with respect to any ongoing Clinical Trial(s) as of the Divestiture Date related to the Otezla Products, Respondents shall:

A. designate employees of the Respondents 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 Monitor, for the purpose of effecting any transition agreed upon between the Respondents and the Acquirer for the purposes of ensuring the continued prosecution of such Clinical Trials in a timely manner;

B. 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);

C. assist the Acquirer to prepare and implement any Clinical Plan(s) and Regulatory Package(s) for the current phase of the Clinical Trial(s) (i.e., the phase as of the Divestiture Date) until such time or specified event as agreed upon with the Acquirer in the Otezla Divestiture Agreement occurs;

D. 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

E. 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 Divestiture Date in the same quality, scope, and pace as was being achieved by the Respondents and in a manner consistent with Good Clinical Practice.

IX. Monitor

IT IS FURTHER ORDERED that:

A. Quantic Regulatory Services, LLC shall serve as the Monitor to observe and report on Respondents' compliance with all of Respondents' obligations as required by the Orders and the Otezla Divestiture Agreements pursuant to the agreement between the Monitor and Respondents in Appendices A and B to this Order.

B. Not later than one (1) day after the Acquisition Date, Respondents shall confer on the Monitor all rights, powers, and authorities necessary to monitor each Respondent's compliance with the terms of the Orders.

C. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:

1. The Monitor shall have the power and authority to monitor each 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 Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission;

2. Respondents shall provide access to all information and facilities, and make such

arrangements with third parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Transition Manufacture;

3. The Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or of the Commission;

4. The Monitor shall serve until Respondents complete the Transition Manufacturing for the Acquirer;

provided, however, that the Monitor's service shall not extend more than four (4) years after 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.

D. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders

E. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that

progress by the Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Otezla Product and obtaining the ability to manufacture each Otezla Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

I. Each Respondent may require the Monitor and each of the 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 Monitor from providing any information to the Commission.

J. The Commission may, among other things, require the Monitor and each of the 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 Monitor's duties.

K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor

1. the Commission shall select the substitute Monitor, subject to the consent of Respondent BMS, which consent shall not be unreasonably withheld. If Respondent BMS has not opposed, in writing, including the reasons for opposing the selection of a substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondent BMS of the identity of any substitute Monitor, Respondents shall be deemed to have consented to the selection of the substitute Monitor; and

2. not later than ten (10) days after the Commission's appointment of the substitute Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on that Monitor all the rights, powers, and authorities necessary to permit that Monitor to monitor each Respondent's compliance with the Orders in a manner consistent with the purposes of the Orders.

L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

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brings an action pursuant to § 5(

divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by a 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 Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to an Acquirer that receives the prior approval of the Commission 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 Respondents from among those approved by the Commission;

provided further, however, that Respondents shall select such Person , and within five (5) days after receiving notification [illegible]

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 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 Respondents and to the Commission every thirty (30)

C. Not later than thirty (30) day after the Divestiture Date, Respondents shall submit complete copies of all of the Divestiture Agreements to the Secretary of the Commission at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov

D.

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

A. any proposed dissolution of Bristol-Myers Squibb Company or Celgene Corporation;

B. any proposed acquisition, merger or consolidation of Bristol-Myers Squibb Company or Celgene Corporation; or

C. any other change in Respondent including assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

XIII. Access

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

A. access, during business office hours of that 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 that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and

B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

XIV. Purpose

IT IS FURTHER ORDERED that the purposes of the divestiture of the Otezla Assets and the provision of the related Product Manufacturing Technology and the related obligations imposed on the Respondents by this Order are:

A. to ensure the continued use of such assets for the purposes of the Otezla Business within the United States;

B. to create a viable and effective competitor that is independent of Respondent Celgene in the Otezla Business within the United States; and

C. to remedy the lessening of competition resulting from the proposed acquisition of Respondent Celgene by Respondent BMS as alleged in the Commission's Complaint in a timely and sufficient manner.

XV. Term

IT IS FURTHER ORDERED that this Order shall terminate on - D Q X D U \ .

By the Commission & R P P L V V L R Q H U V & K R S U D D Q G 6 O D X J K W H U G

April J. Tabor
Acting Secretary

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