

**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**

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

The Federal Trade Commission (“Commission”) initiated an investigation of the proposed acquisition by Respondent Bristol-Myers Squibb Company (“BMS”) of all of the voting securities of Respondent Celgene Corporation (“Celgene”) collectively “Respondents.” The Commission’s Bureau of Competition prepared and furnished to Respondents the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents 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.

Respondents and the Bureau of Competition executed an agreement (“Agreement Containing Consent Order” or “Consent Agreement”) containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint; (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true; (3) waivers and other provisions as required by the Commission’s Rules; and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the said Acts, and that a complaint should issue stating its charges in

that respect. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings, and issues the following Decision and Order (“Order”):

1. Respondent Bristol-Myers Squibb Company is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 430 East 29<sup>th</sup> Street, 14<sup>th</sup> Floor, New York, New York 10016.
2. Respondent Celgene Corporation is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 86 Morris Avenue, Summit, New Jersey 07901.
3. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

## **ORDER**

### **I. Definitions**

**IT IS ORDERED** that, as used in the Order, the following definitions shall apply:

- A. “BMS” means Bristol-Myers Squibb Company, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates, controlled by Bristol-Myers Squibb Company (including, but not limited to, Burgundy Merger Sub, Inc.), and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- B. “Celgene” means Celgene Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates, in each case controlled by Celgene Corporation, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Respondents” means BMS and Celgene.
- E. “Acquirer(s)” means the following:
  1. Amgen; or

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 originals 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 (*i.e.*, 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 a 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, 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 a Respondent’s employees shall not exceed then-current average hourly wage rate for such employee.
- Q. “Divestiture Date” means the date on which a Respondent (or a Divestiture Trustee) closes on the divestiture of the Otezla Assets to an Acquirer as required by Paragraph II of this Order.
- R. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph X of this Order.
- S. “Domain Name” means the domain name(s) and the related uniform resource locators(s) and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration.
- T. “Drug Master File” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- U. “Excluded Assets” means, the following:
1. any real estate and the buildings and other permanent structures located on such real estate;
  2. corporate names or corporate trade dress of a Respondent or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by a Respondent or the related corporate logos thereof; or general registered images or symbols by which a Respondent can be identified or defined;
  3. the portion of any Business Information that contains information about any of a Respondent’s business other than the Otezla Business;
  4. any original document that a Respondent has a legal, contractual, or fiduciary obligation to retain the original; *provided, however*, that the Respondents shall provide copies of the document to the Acquirer and shall provide the Acquirer access to the original document if copies are insufficient for regulatory or evidentiary purposes; and
  5. (i) any tax asset relating to (a) the Otezla Assets for pre-Divestiture Date tax periods or (b) any tax liability that Respondents are responsible for arising out of the divestiture of the Otezla Assets, (ii) all accounts receivable, notes receivable, rebates receivable and other miscellaneous receivables of Respondents that are related to the Otezla Business and arising out of the operation of the Otezla Business prior to the Divestiture Date, and (iii) all cash, cash equivalents, credit

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, or non-U.S. government; 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.
- AA. “Monitor” means any monitor appointed pursuant to Paragraph IX of this Order or Paragraph III of the related Order to Maintain Assets.
- BB. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- CC. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and

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 the 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 related exclusively to the Otezla Products, and the content related exclusively to the Otezla Products that is displayed on any website that is not dedicated exclusively to the Otezla Products;
12. all Product Development Reports;
13. at the option of the Acquirer, all Otezla Contracts;
14. all Business Information; *provided however*, that such Business Information may be redacted to exclude information that discusses with particularity the business of a Retained Product, where such redaction does not impair the usefulness of the information related to the Otezla Business;
15. a list of any finished Otezla Product batch or lot determined to be out-of-specification during the three (3) year period immediately preceding the Divestiture Date, and, for each such batch or lot: (i) a detailed description of the known deficiencies or defects (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure); (ii) the corrective actions taken to remediate the cGMP deficiencies in the Otezla Product; and (iii) to the extent known by Respondent Celgene, the employees (whether current or former) responsible for taking such corrective actions;

16. for each Otezla Product:
  - a. to the extent known or available to the Respondents, 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 as is available; and
  - b. to the extent known by the Respondents, 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 manufacture of an Otezla Product;
3. relating to any Clinical Trials involving an Otezla Product;
4. with universities or other research institutions for the use of an Otezla Product in scientific research;
5. for the marketing of an Otezla Product or educational matters relating solely to the Otezla Products;

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 arrangement 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 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, or financial 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 evidence that the manufacturing process is capable of consistently delivering quality Products, (vi) managing the operation of the manufacturing process, or (vii) managing the technological transfer of the manufacturing process to a different facility, of the Product Manufacturing Technology related to the Otezla Products within the three (3) year period immediately prior to the termination of any contract to provide Transition Manufacturing.
- NN. “Otezla Manufacturing Equipment” means equipment that is being used, or has been used at any time since Respondent BMS entered into the agreement to acquire Respondent Celgene, by Respondents to manufacture the Otezla Products.
- OO. “Otezla Marketing Employee(s)” means all management-level 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, or financial compliance) in any of the following related to the Otezla Business in the United States: sales management, brand management, sales training, market research, patient support programs, health insurer marketing and contracting, pharmacy benefit

management marketing and contracting, managed care marketing and contracting, hospital marketing and contracting, or specialty pharmacy marketing and contracting, *excluding* administrative assistants within the eighteen (18) month period immediately prior to the Divestiture Date.

PP. “Otezla Marketing Materials” means all marketing materials used specifically in the marketing or sale of the Otezla Products in the United States as of the Divestiture Date that are owned or controlled by a Respondent, 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 dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, advertising and display materials, speaker lists, promotional and marketing materials, website content, artwork for the production of packaging components, television masters, and other similar materials related to the Otezla Products.

QQ. “Otezla Patent(s)” means the following:

1. the Patents listed in Schedule 2.1(a)(i) to the APA defined in this Order under the Otezla Divestiture Agreements; and
2. any other Patent(s) related to the Otezla Business.

RR. “Otezla Product(s)” means:

1. the Products manufactured, in Development, marketed, or sold pursuant to the following FDA Authorizations: NDA No. 205437 and NDA No. 206088, and any supplements, amendments, or revisions to these NDAs; and,
2. any other Product manufactured by or for Respondent Celgene, or in Development, marketed, or sold by Respondent Celgene prior to the Divestiture Date that contains apremilast as the active pharmaceutical ingredient.

SS. “Otezla Releasee(s)” means any of the following Persons:

1. the Acquirer;
2. any Person controlled by or under common control with the Acquirer;
3. any Manufacturing Designee(s);
4. any Clinical Trial Research Organization Designee(s); and
5. any licensees, sublicensees, manufacturers, suppliers, distributors, and Customers of the Acquirer, or of such Acquirer-affiliated entities, in each such case, as related to the Otezla Product(s).

TT. “Otezla Research and Development 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, or financial

compliance) in any of the following related to the Otezla Business: research, Development, regulatory approval process, or Clinical Trials of the Otezla Products, within the eighteen (18) month period immediately prior to the Divestiture Date.

- UU. “Otezla Sales Employee(s)” 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, or financial compliance) in any of the following related to the Otezla Business in the United States: the detailing, marketing, or promotion of the Otezla Products directly to physicians, pharmacists, professional distributors, managed care or other insurance providers, hospitals, employers, or governmental entities within the eighteen (18) month period immediately prior to the Divestiture Date.
- VV. “Patent(s)” means all patents and 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 Divestiture 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.
- WW. “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.
- XX. “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 FDA Authorization.
- YY. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other regulatory 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, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any FDA Authorization related to that Product.
- ZZ. “Product Development Report(s)” means:
1. pharmacokinetic study reports related to any Otezla Product;
  2. bioavailability study reports (including Reference Listed Drug information) related to any Otezla Product;
  3. bioequivalence study reports (including Reference Listed Drug information) related to any Otezla Product;
  4. all correspondence, submissions, notifications, communications, registrations, or

- 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

(90) days of the execution date of any Otezla Divestiture Agreement); and

2. with respect to each such employee, the following information:
  - a. direct contact information for the employee, including telephone number;
  - b. the date of hire and effective service date;
  - c. job title or position held;
  - d. a specific description of the employee's responsibilities related to the Otezla Products; *provided, however*, in lieu of this description, a Respondent may provide the employee's most recent performance appraisal;
  - e. base salary or current wages;
  - f. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;
  - g. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
  - h. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
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 Otezla Core Employees.

BBB. "Product Manufacturing Technology" means all of the following related to a Product: all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of the Product, including the following: all product specifications, processes, analytical methods, product designs, plans, 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, FDA Authorization(s) conformance and cGMP compliance, labeling and all other information related to the manufacturing process, and supplier lists.

CCC. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information related to a Product.

DDD. "Proposed Acquirer" means a Person proposed by a 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.

EEE. "Regulatory Package" means, with respect to each Otezla 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 Otezla Product or required to Develop, manufacture, distribute, or otherwise commercialize such Otezla 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).

FFF. “Retained Product(s)” means any Product(s) other than an Otezla Product that is manufactured, in Development, marketed, sold, owned, controlled, or licensed by a Respondent.

GGG. “Shared Intellectual Property” means all intellectual property of any kind (other than trademarks and Domains Names) that (i) is used in connection with, the Otezla Business as of the Divestiture Date, and (ii) Respondents can demonstrate has been used, and continues to be used, in connection with the manufacture of any Retained Product that is the subject of an active (not discontinued or withdrawn) NDA or ANDA as of the Acquisition Date.

HHH. “Supply Cost” means the actual cost of materials, ingredients, packaging, direct labor, and direct overhead *excluding* any allocation or absorption of costs for excess or idle capacity, and *excluding* any intracompany transfer profits *plus* the actual cost of shipping and transportation where those costs are incurred by the Respondents.

III. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to the 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 or other Persons working on behalf of a Respondent knowledgeable about the Product Manufacturing Technology related to the Otezla Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the 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 the Otezla Products 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 related to the Otezla Products to the Acquirer or its Manufacturing Designee;
4. permitting employees of the Acquirer to visit the Respondents’ facility where the

Otezla Products are made for the purposes of evaluating and learning the manufacturing process of the Otezla Products and/or discussing the process with employees of Respondents involved in the manufacturing process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, methods to ensure batch or lot consistency), pharmaceutical development, and validation of the manufacturing of the Otezla Products at the Respondent's facility; and

5. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
  - a. manufacture the Otezla Products in the quality and quantities achieved by a Respondent, or the manufacturer and/or developer of the Otezla Products;
  - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee to manufacture, distribute, market, and sell the Otezla Products in commercial quantities and to meet all Agency-approved specifications for the Otezla Products; and
  - c. receive, integrate, and use all Product Manufacturing Technology related to the Otezla Products used in, and all Otezla Intellectual Property that is related to, the manufacture of the Otezla Products.

JJJ. "Transition Manufacture" and "Transition Manufacturing" mean the following:

1. to manufacture, or to cause to be manufactured, a Transition Manufacture Product on behalf of an Acquirer (including, without limitation, for the purposes of Clinical Trials and/or commercial sales); or
2. to provide, or to cause to be provided, any part of the manufacturing process including, the finish and/or packaging of a Transition Manufacture Product on behalf of an Acquirer.

KKK. "Transition Manufacture Product(s)" means the Otezla Products, in finished dosage form, and any ingredient, material, or component used in the manufacture of the Otezla Products including the active pharmaceutical ingredient(s), excipient(s), or packaging materials.

LLL. "United States" means the United States of America, and its territories, districts, commonwealths and possessions.

## **II. Divestiture**

**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Otezla Assets, absolutely and in good faith, to Amgen pursuant to, and in accordance with, the Otezla Divestiture Agreements.
- B. Respondent BMS may receive a non-exclusive license from the Acquirer to use the

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 final and effective, the Commission notifies Respondents that:
1. Amgen is not an acceptable purchaser of any of the Otezla Assets, then Respondents shall immediately rescind the transaction with Amgen as directed by the Commission, and shall divest the Otezla Assets within one hundred eighty (180) days after 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; or
  2. the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Otezla Assets to Amgen (including, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.
- E. Prior to the Divestiture Date, Respondents shall provide the Acquirer with the opportunity to review all Otezla Contracts for the purposes of the Acquirer's determination of whether to assume the Otezla Contracts.
- F. Prior to the Divestiture Date, Respondents shall secure all consents and waivers from all non-governmental third parties that are necessary to permit Respondents to divest the Otezla Assets to an Acquirer, and to permit the Acquirer to continue the Otezla Business in the United States without interruption or impairment;
- provided, however,* Respondents may satisfy this requirement by certifying that the Acquirer for the Otezla Assets has executed all such agreements directly with each of the relevant third parties.
- G. Respondents shall provide, or cause to be provided, to the Acquirer in a manner consistent with the Technology Transfer Standards:
1. all Product Manufacturing Technology related to the Otezla Products; and
  2. all rights to all Product Manufacturing Technology related to the Otezla Products that is owned by a third party and licensed to a Respondent.

Respondents shall obtain any consents from third parties required to comply with this provision. Respondents 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 the Acquirer to use or to acquire from the third party a 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 Divestiture Date, Respondents shall grant a release to each third party that is subject to such agreements that allows the third party to provide the Product Manufacturing Technology related to the Otezla Products to the Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to the Acquirer.

- H. Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale related to the Otezla Products to assist the Acquirer in the transfer and integration of the Otezla Business into the Acquirer's business.
- I. Respondents shall not, in the United States:
  - 1. use any of the Otezla™ trademarks or any mark confusingly similar to those trademarks as a trademark, tradename, or service mark, *except* as may be agreed upon with the Acquirer for the purposes of selling inventory, finished goods, packaging or similar materials bearing the Otezla™ trademarks for the benefit of the Acquirer during a transition period;
  - 2. attempt to register the Otezla™ trademarks;
  - 3. attempt to register any mark confusingly similar to the Otezla™ trademarks;
  - 4. challenge or interfere with an Acquirer's use and registration of the Otezla™ trademarks; or
  - 5. challenge or interfere with an Acquirer's efforts to enforce its trademark registrations for, and trademark rights in, the Otezla™ trademarks against third parties.
- J. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Otezla Releasees under any Patent that was pending or issued on or before the Acquisition Date if such suit would limit or impair the Acquirer's freedom to research, Develop, or manufacture an Otezla Product anywhere in the world, or to distribute, market, sell, or offer for sale within the United States any Otezla Product.
- K. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents (*i.e.*, employees of Respondents that were involved in the Development of Otezla Products) to assist the Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a third party related to the Otezla Intellectual Property.
- L. For any patent infringement suit that is filed or to be filed within the United States that is (i) filed by, or brought against, a Respondent prior to the Divestiture Date related to the

Otezla Products or the Otezla Patents issued by the United States or (ii) any potential patent infringement suit that a Respondent has prepared, or is preparing, to bring or defend 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 that 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 Agency-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 an agreement to Transition Manufacture.
- F. Respondents shall give priority to supplying a Transition Manufacture Product to the Acquirer over manufacturing and supplying of Products for Respondents' own use or sale.
- G. Respondents shall agree to hold harmless and indemnify the Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of the Respondents to deliver the Transition Manufacture Product(s) in a timely manner *unless* (i) Respondents

can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents, and (ii) Respondents are able to cure the supply failure not later than thirty (30) days after the receipt of notice from the Acquirer of a supply failure;

*provided, however,* the Otezla Divestiture Agreement attached to this Order may contain limits on Respondents' aggregate liability for any penalty incurred by an Acquirer from a Customer directly related to the Acquirer's inability to supply the Otezla Product to that Customer that was the result of Respondents' failure to supply the Otezla Product to the Acquirer.

- H. During the term of any agreement to Transition Manufacture, upon written request of the Acquirer or the Monitor, Respondents shall make available to the Acquirer and the Monitor all records that relate directly to the manufacture of the relevant Transition Manufacture Products that are generated or created after the Divestiture Date.
- I. For each Transition Manufacture Product for which a Respondent purchases the active pharmaceutical ingredient(s), component(s), or excipient(s) from a third party, Respondents shall provide the Acquirer with the actual price paid by that Respondent for each active pharmaceutical ingredient(s), component(s), and excipient(s), respectively, used to manufacture that Transition Manufacture Product.
- J. During the term of any agreement to Transition Manufacture, Respondents shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Transition Manufacture Product(s).
- K. Respondents shall not be entitled to terminate any agreement to Transition Manufacture due to (i) a breach by the Acquirer of a Divestiture Agreement, or (ii) an Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law.

*provided, however,* that this Paragraph shall not prohibit Respondents from seeking compensatory damages from the Acquirer for the Acquirer's breach of its payment obligations to the Respondents under the agreement.

- L. Respondents shall permit the Acquirer to terminate any agreement to Transition Manufacture at any time upon commercially reasonable notice and without cost or penalty (other than costs or penalties due by Respondents to third parties pursuant to the termination of such agreement, which shall be the responsibility of the Acquirer).
- M. During the term of any agreement to Transition Manufacture, Respondents shall provide consultation with knowledgeable employees of Respondents and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all Product Approvals to manufacture the Otezla Products in final dosage form in the same quality achieved by, or on behalf of, a Respondent and in commercial quantities, and in a

manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of the Acquirer that its personnel (or its Manufacturing Designee's personnel) are adequately trained in the manufacture of the Otezla Products.

## V. Employees

**IT IS FURTHER ORDERED** that:

A. Respondents shall:

1. for a period of:
  - a. six (6) months after the termination of any agreement to provide Transition Manufacturing, provide the Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Otezla Manufacturing Employees; and,
  - b. one (1) year after the Divestiture Date, provide the Acquirer with the opportunity to enter into employment contracts with the other Otezla Core Employees.

Each of these periods is hereinafter referred to as the "Otezla Core Employee Access Period(s);"

2. provide the Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Otezla Core Employees not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to the Respondents to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer. Failure by Respondents to provide the Product Employee Information for any Otezla Core Employee within the time provided herein shall extend the Otezla 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; (ii) use the information solely in connection with considering whether to provide, or providing, to Otezla Core Employees the opportunity to enter into employment contracts during an Otezla Core Employee Access Period; and (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use;
3. during the Otezla Core Employee Access Period, (i) not interfere with the hiring or employing by the Acquirer or its Manufacturing Designee of the Otezla Core Employees, and remove any impediments within the control of a Respondent that may deter or prevent these employees from accepting employment with the Acquirer or its Manufacturing Designee, including any noncompete or nondisclosure provisions of employment; and (ii) not make any counteroffer to any Otezla Core Employee who has received a written offer of employment from the

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(s) 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 continuation of all employee compensation and benefits offered by a Respondent until the Divestiture Date(s) for the divestiture of the Otezla Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by law).

- B. From the Divestiture Date until the date that is one (1) year after the Divestiture Date, Respondents shall not, directly or indirectly, solicit any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to an Otezla Product ("Otezla Product Employee") to leave the service or employment of the Acquirer or its Manufacturing Designee;

*provided, however,* that such prohibitions do not apply to: (i) general solicitations for employment through advertisements or similarly directed efforts; (ii) general solicitations by third parties (such as recruiters); (iii) any such employee that has been terminated by the Acquirer or its Manufacturing Designee; or (iv) any Otezla Product Employee who contacts a Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from that Respondent.

## **VI. Confidential Business Information**

**IT IS FURTHER ORDERED** that:

- A. Respondents shall:
1. transfer and deliver to the Acquirer, at Respondents' expense, all Otezla Confidential Business Information;
    - 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;

2. pending complete delivery of all such Otezla Confidential Business Information to the Acquirer, provide the Acquirer with access to all such Otezla Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the Business Information that contain such Otezla Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
3. not use, directly or indirectly, any such Otezla Confidential Business Information other than as necessary to comply with the following:
  - a. the requirements of the Orders;
  - b. Respondents' obligations to the Acquirer under the terms of the Otezla Divestiture Agreements; or
  - c. applicable law;
4. not disclose or convey any Otezla Confidential Business Information, directly or indirectly, to any Person *except* (i) the Acquirer, (ii) other Persons specifically authorized by the Acquirer or staff of the Commission to receive such information (*e.g.*, employees of a Respondent providing transition services or Transition Manufacturing for Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed) and *except* to the extent necessary to comply with applicable law;
5. not provide, disclose, or otherwise make available, directly or indirectly, any Otezla Confidential Business Information to the employees associated with the business that is being retained, owned, or controlled by the Respondents, other than those employees providing transition services or Transition Manufacturing to the Acquirer or who are engaged in the transfer and delivery of the Product Manufacturing Technology related to the Otezla Products or the ongoing Clinical Trials related to the Otezla Products to the Acquirer;
6. institute procedures and requirements to ensure that those employees of the Respondents that are authorized by the Acquirer to have access to Otezla Confidential Business information:
  - a. do not provide, disclose, or otherwise make available, directly or indirectly, any Otezla Confidential Business Information in contravention of the Orders; and
  - b. do not solicit, access, or use any Otezla Confidential Business Information that they are prohibited from receiving for any reason or purpose; and
7. take all actions necessary and appropriate to prevent access to, and the disclosure or use of, the Otezla Confidential Business Information by or to any Person(s) not authorized to access, receive, and/or use such information pursuant to the terms of the Orders or the Otezla Divestiture Agreements, including:

- a. establishing and maintaining appropriate firewalls, confidentiality protections, internal practices, training, communications, protocols, and system or network controls and restrictions;
  - b. to the extent practicable, maintaining Otezla Confidential Business Information separate from other data or information of the Respondents; and
  - c. ensuring by other reasonable and appropriate means that the Otezla Confidential Business Information is not shared with Respondents' personnel engaged in the Business related to the same or substantially the same type of Business as the Otezla Products (*e.g.*, Products Developed or in Development for the same or similar indications as the Otezla Products).
- B. Respondents shall require, as a condition of continued employment post-divestiture of the Otezla Assets, that each employee that has had responsibilities related to the marketing or sales of the Otezla Products within the one (1) year period prior to the Divestiture Date, and each employee that has responsibilities related to the Development, marketing, or sales of those Retained Products that are Developed or in Development for the same or similar indications as the Otezla Products, in each case who have or may have had access to Otezla Confidential Business Information, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Otezla Confidential Business Information as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of the Respondents (other than as necessary to comply with the requirements of this Order).
- C. Not later than thirty (30) days after the Divestiture Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Otezla Confidential Business Information by that Respondents' personnel to all of its employees who (i) may be in possession of such Otezla Confidential Business Information or (ii) may have access to such Otezla Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for two (2) years after the Divestiture Date. Respondents shall provide a copy of the notification to the Acquirer. Respondents shall maintain complete records of all such notifications at that Respondent's principal executive offices within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide the Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.
- D. Each 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 copies of documents are insufficient or otherwise unavailable, and for the following purposes:



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 withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

## **VII. Asset Maintenance**

**IT IS FURTHER ORDERED** that:

- A. Until Respondents fully transfer and deliver the Otezla Assets to the Acquirer and fully provide, or cause to be provided, the related Product Manufacturing Technology related to the Otezla Products and Clinical Trials related to the Otezla Products to the Acquirer, Respondents shall take actions as are necessary to:
  1. maintain the full economic viability and marketability of the Otezla Assets;
  2. prevent the destruction, removal, wasting, deterioration, or impairment of any of the Otezla Assets;
  3. ensure that the Otezla Assets are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Otezla Business; and
  4. ensure the completeness of the transfer and delivery of such Product Manufacturing Technology and Clinical Trials.
- B. Respondents shall not sell, transfer, encumber, or otherwise impair the Otezla Assets (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Otezla Assets.

## **VIII. Clinical Trials**

**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 (*i.e.*, the phase as of the Divestiture Date) until such time or specified event as agreed upon with the Acquirer in an 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 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 Respondent's compliance with the Orders.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the 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 Monitor.
- H. Respondents shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by the Acquirer with respect to the performance of a Respondent's obligations under the Orders. Within thirty (30) days after the Order Date and every ninety (90) days thereafter, and at such other times as may be requested by staff of the Commission, the Monitor shall report in writing to the Commission concerning performance by the Respondents of the Respondents' obligations under the Orders. Among other things, the Monitor shall report in writing to the Commission concerning

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.

The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

#### **X. Divestiture Trustee**

**IT IS FURTHER ORDERED** that:

- A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Otezla 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 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, Respondents 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 a Respondent to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have 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 Respondents of the identity of any proposed Divestiture Trustee, Respondents 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, Respondents 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. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents 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(s) 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. 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 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 Respondents, 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 Respondents, 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 Respondents, 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. Respondents 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 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) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

9. Respondents 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(s) required by this Order.

## **XI. Compliance Reports**

**IT IS FURTHER ORDERED** that:

- A. Not later than five (5) days after the Acquisition Date, Respondents shall notify Commission staff of the Acquisition Date, including electronic copies of the notification to the Secretary of the Commission at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov) and to the Compliance Division at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov).
- B. Not later than five (5) days after the Divestiture Date, Respondents shall notify Commission staff of the Divestiture Date, including electronic copies of the notification to the Secretary of the Commission at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov) and to the Compliance Division at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov).

- 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](mailto:ElectronicFilings@ftc.gov) and to the Compliance Division at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov).
- D. Within thirty (30) days after the Order Date, and every ninety (90) days thereafter until Respondents have completed all of the following: (i) the transfer and delivery of all of the Otezla Assets to the Acquirer, (ii) the transfer and delivery of all of the Product Manufacturing Technology related to the Otezla Products to the Acquirer, (iii) the transfer and delivery of all Otezla Confidential Business Information to the Acquirer, and (iv) the provision of Transition Manufacturing to the Acquirer, Respondents shall submit to the Commission and, at the same time, to the Monitor, a verified written report setting forth in detail the manner and form in which the Respondents intend to comply, are complying, and have complied with the requirements of the Orders (“Compliance Reports”).
- E. Each Compliance Report shall contain sufficient information and documentation to enable the Commission independently to determine whether Respondents are in compliance with the Orders. Conclusory statements that Respondents have complied with their obligations under the Orders are insufficient. Respondents shall include in their Compliance Reports, among other things that are required from time to time, a full description of the efforts being made to comply with the Orders, including:
1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the transfer and delivery of all of the Otezla Assets to the Acquirer, (ii) the transfer and delivery of all of the Product Manufacturing Technology related to the Otezla Products and the Clinical Trial(s) related to the Otezla Products to the Acquirer, (iii) the transfer and delivery of all Otezla Confidential Business Information to the Acquirer, and (iv) the provision of Transition Manufacturing to the Acquirer; and
  2. a detailed description of the timing for the completion of such obligations.
- F. One (1) year after the Order Date, annually for the next nine (9) years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents 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.
- G. Respondents shall verify each Compliance Report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or other officer or employee specifically authorized to perform this function. Respondents shall submit an original and 2 copies of each Compliance Report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov) and to the Compliance Division at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov). In addition, Respondents shall provide a copy of each Compliance Report to the Monitor.

## **XII. Change in Respondents**



**IT IS FURTHER ORDERED** that Respondents 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 Respondents 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 Respondents 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 the date ten (10) years after the Order Date.

By the Commission.

April J. Tabor  
Acting Secretary

SEAL