

Complaint

IN THE MATTER OF

**BRISTOL-MYERS SQUIBB COMPANY
AND
CELGENE CORPORATION****CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT***Docket No. C-4690; File No. 191 0061**Complaint, November 15, 2019 – Decision, January 9, 2020*

This consent order addresses the \$74 billion acquisition by Respondent Bristol-Myers Squibb (“BMS”) Company of certain assets of Respondent Celgene that constitutes a violation of Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act. The complaint alleges that the effects of the Acquisition, if consummated, may be to substantially lessen competition and tend to create a monopoly by eliminating future competition between BMS and Celgene in the development and sale of oral products to treat moderate-to-severe psoriasis. Under the order respondent must divest the Otezla Assets to Amgen pursuant to the Otezla Divestiture Agreements, which will be incorporated by reference into the order, and provide transition services sufficient to enable the Acquirer to operate the Otezla business.

Participants

For the *Commission*: Kari A. Wallace.

For the *Respondents*: Debbie Feinstein, Arnold & Porter Kay Scholer LLP; Jacob (Chuck) Boyers and Matthew Reilly, Kirkland & Ellis LLP; Stephen Weissman, Baker Botts L.L.P.; Franco Castelli and Nelson Fitts, Wachtell, Lipton, Rosen & Katz.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Bristol-Myers Squibb Company (“BMS”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire the equity interests of Respondent Celgene Corporation (“Celgene”), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

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 29th Street, 14th Floor, New York, New York 10016.

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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. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and engages in business that is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

4. Pursuant to an agreement and plan of merger dated January 2, 2019, Respondent BMS proposes to acquire the equity interests of Respondent Celgene in a series of transactions valued at approximately \$74 billion (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

5. The relevant line of commerce in which to analyze the effects of the Acquisition is the research, development, manufacture, and sale of oral products to treat moderate-to-severe psoriasis.

6. The United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant line of commerce.

IV. THE STRUCTURE OF THE MARKET

7. Celgene’s Otezla is the most significant oral product to approved to treat moderate-to-severe psoriasis in the United States. Several older oral generic products, including methotrexate and acitretin, are approved by the U.S. Food and Drug Administration (“FDA”) to treat psoriasis that does not respond to topical medication and light therapy. While these drugs are still used occasionally to treat psoriasis, most doctors now prescribe agents that have better efficacy, better safety, or a more favorable side effect profile for patients with moderate-to-severe psoriasis who desire an oral treatment. BMS is developing BMS 986165, a selective tyrosine kinase 2 inhibitor, which is the most advanced oral treatment for moderate-to-severe psoriasis in development.

V. ENTRY CONDITIONS

8. Entry into the relevant markets described in Paragraphs 5 and 6 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not be timely because the combination of drug development times and FDA approval requirements is lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

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VI. EFFECTS OF THE ACQUISITION

9. The effects of the Acquisition, if consummated, may be to substantially lessen competition and tend to create a monopoly in the relevant lines of commerce, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others by eliminating future competition between BMS and Celgene in the development and sale of oral products to treat moderate-to-severe psoriasis.

VII. VIOLATIONS CHARGED

10. The Acquisition described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

11. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fifteenth day of November, 2019 issues its Complaint against said Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

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 Orders” 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

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provisions as required by the Commission's Rules; and (4) a proposed Decision and Order and this Order to Maintain Assets.

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

1. Respondent 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 29th Street, 14th 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 HEREBY ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), which are incorporated herein by reference and made a part hereof, 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.

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- C. “Respondents” means BMS and Celgene.
- D. “Monitor” means any monitor appointed pursuant to Paragraph IV of this Order to Maintain Assets or Paragraph IX of the Decision and Order.
- E. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.
Asset Maintenance

IT IS FURTHER ORDERED that:

- A. Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of the Otezla Business, to minimize any risk of loss of competitive potential for such Otezla Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Otezla Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber, or otherwise impair the Otezla Assets (other than in the manner prescribed in the Decision and Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Otezla Business.
- B. Respondents shall maintain the operations of the Otezla Business in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business and as consistent with standard operating procedures to ensure professionalism, safety, and quality of any product or service offered by the business, to maintain all related information technology infrastructure and data contained therein, to maintain compliance with all applicable healthcare laws, and to maintain any licenses or approvals with any Government Entity) and/or as may be necessary to preserve the full economic viability, marketability, and competitiveness of such Otezla Business and shall use their best efforts to preserve the existing relationships with the following: clients; patients; suppliers; licensors; licensees; advertisers; vendors and distributors; Customers; physicians and other health care providers; insurers; Government Entities; employees; and others having business relations with the Otezla Business. Respondents’ responsibilities shall include, but are not limited to, the following:
 - 1. providing the Otezla Business with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans, and promotional activities for the Otezla Business;
 - 2. continuing, at least at their scheduled pace, any expenditures for the Otezla Business authorized prior to the date the Consent Agreement was signed by the Respondents;

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3. providing such resources as may be necessary to respond to competition prior to the complete transfer and delivery of the Otezla Assets to an Acquirer;
 4. providing such resources as may be necessary to maintain the competitive strength and positioning of the Otezla Business;
 5. making available for use by the Otezla Business funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the Otezla Assets; and
 6. providing such support services to the Otezla Business as were being provided to such Otezla Business by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Respondents shall maintain a work force that is (i) materially equivalent in size (as measured in full time equivalents) and (ii) comparable in training, professionalism, and expertise to what has been associated with the Otezla Business for the Otezla Business's last fiscal year.

III.**Confidential Business Information****IT IS FURTHER ORDERED** that:

- A. Respondents shall not use, directly or indirectly, any Otezla Confidential Business Information other than as necessary to comply with the following:
1. the requirements of the Orders;
 2. Respondents' obligations to the Acquirer under the terms of the Otezla Divestiture Agreements; or
 3. applicable law.
- B. Respondents shall 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;
- C. Respondents shall 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

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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;

- D. Respondents shall institute procedures and requirements to ensure that those employees of the Respondents that are authorized by the Acquirer to have access to the Otezla Confidential Business Information:
1. do not provide, disclose, or otherwise make available, directly or indirectly, any Otezla Confidential Business Information in contravention of the Orders; and
 2. do not solicit, access, or use any Otezla Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- E. Respondents shall 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:
1. Establishing and maintaining appropriate firewalls, confidentiality protections, internal practices, training, communications, protocols, and system and network controls and restrictions;
 2. To the extent practicable, maintaining Otezla Confidential Business Information separate from other data or information of the Respondents; and
 3. Ensuring by other reasonable and appropriate means that 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 Business (*e.g.*, commercialization of Products Developed or in Development for the same or similar indications as the Otezla Products).

**IV.
Monitor**

IT IS FURTHER ORDERED that:

- A. Quantic Regulatory Services, LLC shall serve as the Monitor pursuant to the agreement executed by the Monitor and Respondents, and attached as Appendix A ("Monitor Agreement") and Non-Public Appendix B ("Monitor Compensation"). The Monitor is appointed to monitor Respondents' compliance with the terms of

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this Order to Maintain Assets, the Decision and Order, and the Otezla Divestiture Agreements.

- 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 Orders, 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; and
 - 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.

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- 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 (including information technology experts), 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 date this Order to Maintain Assets is issued 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. After the Decision and Order becomes final, the Monitor shall report to the Commission as described in the Decision and Order.
- 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.

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- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the following manner:
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 Respondents 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.
- M. The Monitor appointed pursuant to this Order to Maintain Assets may be the same Person appointed as the Monitor pursuant to the Decision and Order.
- N. The Monitor appointed pursuant to this Order to Maintain Assets may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

V.
Compliance Reports

IT IS FURTHER ORDERED that:

- A. Within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every ninety (90) days thereafter until Respondents have fully complied with this Order to Maintain Assets, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with the Orders ("Compliance Reports").
- B. 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

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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 services to the Acquirer; and
 2. a detailed description of the timing for the completion of such obligations.
- C. 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 two (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 and to the Compliance Division at bccompliance@ftc.gov. In addition, Respondents shall provide a copy of each Compliance Report to the Monitor.
- D. After the Decision and Order in this matter becomes final, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission on the same timing as, the Compliance Reports required to be submitted by Respondents pursuant to the Decision and Order.

VI.**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 a Respondent including assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

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**VII.
Access**

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to a Respondent made to its principal place of business as identified in the Orders, registered office of its United States subsidiary, or its headquarters address, the notified 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 business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), 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.

**VIII.
Purpose**

IT IS FURTHER ORDERED that the purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Otezla Business through its full transfer and delivery to an Acquirer; to minimize any risk of loss of competitive potential for the Otezla Business; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Otezla Assets except for ordinary wear and tear.

**IX.
Term**

IT IS FURTHER ORDERED that, unless the Commission directs otherwise, this Order to Maintain Assets shall terminate on the earlier of:

- A. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. the day after all of the Otezla Assets, the Product Manufacturing Technology related to the Otezla Products, and the Clinical Trials related to the Otezla Products have been transferred to and are in the physical possession of the Acquirer, as required by and described in the Decision and Order.

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By the Commission, Commissioners Chopra and Slaughter dissenting.

Appendix A**MONITOR AGREEMENT**

This Monitor Agreement (this “Agreement”) entered into this 12th day of October, 2019 by and among Quantic Regulatory Services, LLC (the “Monitor”), Bristol-Myers Squibb Company (“BMS”) and Celgene Corporation (“Celgene”) (BMS and Celgene are referred to in this Agreement collectively as the “Respondents”, and individually as a “Respondent”) (the Monitor and the Respondents, each a “Party” and collectively the “Parties”) provides as follows:

WHEREAS, the United States Federal Trade Commission (the “Commission”) is expected to accept for public comment an Agreement Containing Consent Order, including a proposed Decision and Order and Order to Maintain Assets (the “Orders”), which, among other things, contemplates the appointment of a Monitor to monitor the Respondents’ compliance with its obligations under the Orders;

WHEREAS, the staff will recommend that the Commission appoint William Hitchings of Quantic Regulatory Services, LLC as Monitor pursuant to the Orders, and William Hitchings of Quantic Regulatory Services, LLC has consented to such appointment;

WHEREAS, the Orders will further provide that the Respondents shall execute an agreement, subject to the prior approval of the Commission, that confers all the rights and powers necessary to permit the Monitor to monitor the Respondents’ compliance with the terms of the Orders; and

WHEREAS, the Parties to this Agreement intend to be legally bound, subject only to the Commission’s approval of this Agreement.

NOW, THEREFORE, the Parties agree as follows:

All capitalized terms used in this Agreement and not specifically defined herein shall have the respective definitions given to them in the Orders.

ARTICLE I

1.1 Monitor’s Responsibilities. The Monitor shall be responsible for monitoring the Respondents’ compliance with its obligations as set forth in the Orders and the Otezla Divestiture Agreement, as defined in the Orders (“Monitor Responsibilities”).

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1.2 Access to Relevant Information and Facilities. Subject to any legally recognized privilege and applicable law of which the Respondents shall notify the Monitor as the reason for not providing the access requested by the Monitor, the Monitor shall have full and complete access to the personnel, facilities, books, and records of Respondents related to the Respondents' obligations under the Orders and the Otezla Divestiture Agreement (as defined in the Orders), as the Monitor may reasonably request. Respondents shall cooperate with any reasonable request of the Monitor. The Monitor shall give the Respondents reasonable notice of any request for such access or such information and shall attempt to schedule any access or requests for information in such a manner as will not unreasonably interfere with any of either Respondent's business or operations. At the reasonable request and reasonable advanced notice of the Monitor to any Respondent, such Respondent shall promptly arrange meetings and discussions, including tours of relevant facilities, at reasonable times and locations between the Monitor and employees of such Respondent who have knowledge relevant to the proper discharge of the Monitor's responsibilities under the Orders.

1.3 Compliance Reports. The Respondents shall report to the Monitor in accordance with the requirements of the Orders.

1.4 Monitor's Obligations. The Monitor shall:

- a. carry out the Monitor's Responsibilities, including submission of periodic reports to the Commission staff, and such additional written reports as may be requested by the Commission staff, in each case regarding the Respondents' compliance with the Orders;
- b. maintain the confidentiality of all confidential information, including Otezla Confidential Business Information, and any other non-public confidential information provided to the Monitor by or on behalf of any Respondent, any supplier or customer of any Respondent, or the Commission, and shall use such confidential information only for the purpose of discharging the Monitor's obligations pursuant to this Agreement and not for any other purpose, including, without limitation, any other business, scientific, technological, or personal purpose. The Monitor may disclose confidential information only to:
 - i. persons working with the Monitor under this Agreement (and only to the extent such persons have executed a confidentiality agreement consistent with the provisions of this Agreement); and/or
 - ii. persons employed at the Commission with involvement in this matter.
- c. except to the extent professional obligations require confidentiality, require any consultants, accountants, attorneys, and any other representatives or assistants retained by the Monitor to assist in carrying out the Monitor's Responsibilities to execute a confidentiality agreement that requires such

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third parties to treat confidential information with the same standards of care and obligations of confidentiality to which the Monitor must adhere under this Agreement;

- d. maintain the confidentiality of all other aspects of the performance of the Monitor's Responsibilities and not disclose any confidential information, including Otezla Confidential Business Information, related thereto;
- e. ensure that Dr. Hitchings or any individual monitor of the Monitor performing the services under this Agreement shall not be personally involved in any way in counseling related to, or the management, production, supply and trading, sales, marketing, and financial operations of, any products that contain apremilast as the active pharmaceutical ingredient that compete with the products sold by any of the Respondents except to the extent permitted by the Orders for a period of three (3) years after the termination of this Agreement or the cessation of such persons services under this Agreement. and
- f. upon termination of the Monitor's duties under this Agreement, consult with the Commission's staff regarding disposition of any written and electronic materials (including materials that the Respondents provided to the Monitor) in the possession or control of the Monitor that relate to the Monitor's duties, and the Monitor shall dispose of such materials, which may include sending such materials to the Commission's staff, as directed by the staff. In response to a written request by any Respondent to return or destroy materials that such Respondent provided to the Monitor, the Monitor shall inform the Commission's staff of such request and, if the Commission's staff do not object, shall comply with such Respondent's request. Notwithstanding the foregoing, the Monitor shall not be required to return or destroy confidential information contained in any archived computer, and the Monitor may retain a copy of confidential information, subject to the terms of this Agreement, in accordance with the Monitor's internal record retention procedures for legal or regulatory purposes. Nothing herein shall abrogate the Monitor's duty of confidentiality (which includes an obligation not to disclose or use any non-public information obtained while acting as a Monitor) for a period of ten (10) years after the termination of this Agreement except for trades secrets, for which the obligations of confidentiality shall not terminate or expire.
- g. For the purpose of this Agreement, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the Monitor can demonstrate that such information was already known to the Monitor at the time of receipt or thereafter becomes known to the

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Monitor from a source other than the Respondents, or any director, officer, employee, agent, consultant or affiliate of the Respondents, when such source was not known to recipient after due inquiry to be restricted from making such disclosure to such recipient.

- h. In the event that confidential information must be disclosed by the Monitor under applicable law or pursuant to legal process, the Monitor shall, to the extent not otherwise prohibited, give prompt written notice to the Respondents that such disclosure is required so that any of the Respondents may, at its sole expense, seek an appropriate protective order or waive compliance with the terms hereof or both. absent the entry of a protective order or the receipt of a waiver of this Monitor Agreement, the Monitor is compelled by law or legal process to disclose any confidential information, the Monitor, as and to the extent advised by its legal counsel to do so, (x) may disclose such information solely to the extent required by law; (y) shall not disclose such information until such time as it is required by law; and (z) shall exercise commercially reasonable efforts, at the Respondents sole cost and expense, including without limitation, fees for time expended, to obtain reliable assurances that confidential treatment will be accorded to any confidential information so disclosed. Notwithstanding the foregoing, the Monitor or any person referenced in Section 1.4(b)(ii) herein may disclose confidential information to any regulatory or self-regulatory agency having jurisdiction over such party in the course of routine reviews or audits when such disclosure is required by law, which confidential information may be disclosed with written notice to Respondents and after compliance by the Monitor with the procedures set forth in this Section 1.4(h).

1.5 Monitor Payment. The Respondents will pay the Monitor the hourly fee specified in the attached confidential fee schedule ("Hourly Fee") for all reasonable time spent in performance of the Monitor's duties under this Agreement. In addition, the Respondents will pay: (a) out-of-pocket expenses reasonably incurred by the Monitor in the performance of the Monitor's duties; and (b) fees and disbursements reasonably incurred by such independent third party consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities hereunder; however, all such fees and disbursements contemplated by clauses (a) and (b) of this Section 1.5 (other than consulting fees paid to Dr. Hitchings or any individual monitor whose employment arrangement with the Monitor is in the form of a consultancy similar to that of Dr. Hitchings and who performs services under this Agreement) in excess of the aggregate amount of \$25,000.00 per annum must be pre-approved in writing by the Respondents. The Monitor shall provide the Respondents with an invoice on a bi-weekly basis that includes details and an explanation of all matters for which Monitor submits an invoice and the Respondents shall pay such invoices within sixty (60) days of receipt. Any consultants, accountants, attorneys, and other representatives and assistants retained by the Monitor in accordance with this Section 1.5 shall invoice their services to the Monitor who will review and approve such invoices and submit to Respondents for payment. At their own

Order to Maintain Assets

expense, the Respondents may retain an independent auditor to verify such invoices. The Monitor and the Respondents shall submit any disputes about invoices to the Commission for assistance in resolving such disputes.

1.6 Monitor's Indemnification. The Respondents agree to indemnify the Monitor and the Respondents shall hold the Monitor harmless (regardless of any action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities, or expenses arising out of or in connection with, the performance of the Monitor's duties and obligations hereunder, 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 liabilities, losses, damages, claims, or expenses result from gross negligence, willful misconduct, or bad faith by the Monitor, in each case, as proven by final non-appealable judgment in a court of law.

The Monitor's maximum liability to the Respondents relating to services rendered pursuant to this Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the lesser of \$50,000.00 and the total sum of the fees paid by the Respondents to the Interim Monitor, except in the case of gross negligence, willful misconduct, or bad faith by the Monitor, in each case, as proven by final non-appealable judgment in a court of law. IN NO CIRCUMSTANCES WHATSOEVER SHALL INTERIM MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES.

The Respondents agree that the Respondents' obligations to indemnify the Monitor extend to any agreement that is entered between the Interim Monitor and any Commission-approved Acquirer and relates to the Interim Monitor's responsibilities under the Monitor Agreement and/or the Orders.

1.7 Disputes. In the event of a disagreement or dispute between any Respondent and the Monitor concerning such Respondent's obligations under the Orders, and in the event that such disagreement or dispute cannot be resolved by the Parties, any Party may seek the assistance of the individual in charge of the Commission's Compliance Division.

1.8 Conflicts of Interest. If the Monitor becomes aware during the term of this Agreement that he has or may have a conflict of interest that would reasonably likely have an effect on the performance by the Monitor of any of the Monitor's Responsibilities, the Monitor shall immediately inform the Respondents and the Commission of any such conflict.

ARTICLE II

2.1 Termination. This Agreement shall terminate upon *the earlier of* (a) the expiration or termination of the Orders; (b) the termination of the Monitor's term of service under the Orders; (c) the Respondents' receipt of written notice from the Commission that the Commission has determined that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve as Monitor; or (d) with at least thirty (30) days advance written notice to be provided by the Monitor to the Respondents and to the Commission, upon resignation of the

Order to Maintain Assets

Monitor. If this Agreement is terminated for any reason, the confidentiality obligations set forth in Section 1.4 above will remain in force.

2.2 Governing Law; Jurisdiction. This Agreement and the rights and obligations of the Parties hereunder shall in all respects be governed by the substantive laws of the state of New York, including all matters of construction, validity and performance. The Orders shall govern this Agreement and any provisions herein which conflict or are inconsistent with them may be declared null and void by the Commission and any provision not in conflict shall survive and remain a part of this Agreement. Each of the Parties also hereby irrevocably and unconditionally consent to submit to the jurisdiction of the courts of the State of New York and of the United States of America located in the City of New York for any actions, suits or proceedings arising out of or relating to this agreement and the transactions contemplated hereby (and you agree not to commence any action, suit or proceeding relating thereto except in such courts), and further agree that service of any process, summons, notice or document by U.S. registered mail to your address set forth above shall be effective service of process for any action, suit or proceeding brought against you in any such court. **Each of the Parties irrevocably waives any and all right to trial by jury in any legal proceeding arising out of or relating to this Non-Disclosure Agreement.** You hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding arising out of this agreement or the transactions contemplated hereby in the courts of the State of New York or of the United States of America located in the City of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

2.3 Disclosure of Information. Nothing in this Agreement shall require any Respondent to disclose any material information that is subject to a legally recognized privilege or that any Respondent is prohibited from disclosing by reason of law or an agreement with a third party.

2.4 Assignment. This Agreement may not be assigned or otherwise transferred by any Respondent or the Monitor without the consent of such Respondent and the Monitor and the approval of the Commission. Any such assignment or transfer shall be consistent with the terms of the Orders.

2.5 Modification. No amendment, modification, termination, or waiver of any provision of this Agreement shall be effective unless made in writing, signed by all Parties, and approved by the Commission. Any such amendment, modification, termination, or waiver shall be consistent with the terms of the Orders.

2.6 Entire Agreement. This Agreement, and those portions of the Orders incorporated herein by reference, constitute the entire agreement of the Parties and supersede any and all prior agreements and understandings between the Monitor and the Respondents, written or oral, with respect to the subject matter hereof.

Order to Maintain Assets

2.7 Duplicate Originals. This Agreement may be executed in several counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same document.

2.8 Section Headings. Any heading of a section is for convenience only and is to be assigned no significance whatsoever as to its interpretation and intent.

ARTICLE III

3.1 In the performance of his functions and duties under this Agreement, the Monitor shall exercise the standard of care and diligence that would be expected of a reasonable person in the conduct of its own business affairs.

3.2 It is understood that the Monitor will be serving under this Agreement as an independent contractor and that the relationship of employer and employee shall not exist between the Monitor and any Respondent. The Monitor shall not have a fiduciary responsibility to any Respondent, but shall have fiduciary duties to the Commission.

3.3 This Agreement is for the sole benefit of the Parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give, or be construed to give, any other person any legal or equitable rights hereunder.

3.4 In the event that the Monitor wishes to terminate this Agreement, subject to Section 2.1, the Monitor shall provide prior written notice to the Respondents and the Commission. The Respondents and the Monitor shall work in good faith with the Commission to identify and propose to the Commission a successor Monitor, in accordance with the procedures in the Orders. The Monitor shall continue to serve as Monitor under the terms of this Agreement until such time as the Commission approves a successor Monitor, and the Monitor's termination of this Agreement shall be effective only upon the approval by the Commission of a successor Monitor.

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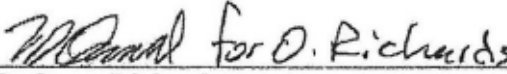
FEDERAL TRADE COMMISSION DECISIONS
VOLUME 169

Order to Maintain Assets

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first above written.

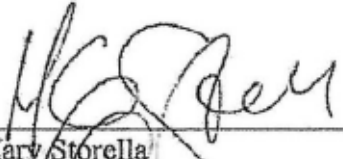
MONITOR

RESPONDENTS



R. Owen Richards
President
Quantic Regulatory Services, LLC

P. Joseph Campisi, Jr.
Senior Vice President and Deputy General
Counsel
Bristol-Myers Squibb Company



Mary Storella
Vice President, Senior Counsel
Celgene Corporation

Decision and Order

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first above written.

MONITOR

RESPONDENTS

R. Owen Richards
President
Quantic Regulatory Services, LLC

Sandra Leung
~~Joseph Campbell, Jr.~~
~~Senior Vice President and Deputy General~~
~~Counsel~~ *Executive Vice President + General Counsel*
Bristol-Myers Squibb Company

Mary Storella
Vice President, Senior Counsel
Celgene Corporation

**Non-Public Appendix B
(Monitor Compensation)**

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

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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 29th Street, 14th 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.

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- 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.

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- 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.

Decision and Order

- 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.

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- 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;

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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:

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- 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;

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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.

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- 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.

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- 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 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.

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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

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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;

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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.

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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,

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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 Domain 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.

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- 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

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- 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:

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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

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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

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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 Agreement

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).

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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;

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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), components(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

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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);"

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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

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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;

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- 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;

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- 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

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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

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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.

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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.

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- 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.

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- 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.

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- 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

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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.

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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 and to the Compliance Division at 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

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notification to the Secretary of the Commission at ElectronicFilings@ftc.gov and to the Compliance Division at 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 and to the Compliance Division at 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

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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 and to the Compliance Division at 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.

Concurring Statement

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 January 9, 2030.

By the Commission, Commissioners Chopra and Slaughter dissenting.

STATEMENT OF COMMISSIONER NOAH JOSHUA PHILLIPS

I write to address the dissenting statements issued by my colleagues, Commissioners Chopra and Slaughter.

From these statements, a reader unfamiliar with the U.S. antitrust laws could be forgiven for gleaning several inaccurate conclusions. First, companies in the U.S. may not merge unless the antitrust enforcement agencies permit them to do so. Second, to stop a merger, the government need not provide any theory as to why a merger violates the law, nor any evidence to support that theory. Third, antitrust enforcement agencies can and should condemn mergers they cannot prove violate the law because the agencies deem the business justifications for the merger insufficient.

The unfamiliar reader would be wrong on each count. That is not the law. (Nor, for that matter, is it sound policy.)

The structural remedy agreed to by the merging parties in this case addresses every competition concern uncovered after an extensive investigation. Every one. But Commissioners Chopra and Slaughter still dissent. Why?

Concurring Statement

Commissioner Chopra cites a study purporting to show that mergers “can choke off innovation”. Okay. But how does this merger do that? Without an answer to that question, the logic is rather like saying an individual defendant is guilty of a crime because there is too much of that crime in society. Thank goodness that is not how our criminal justice system works.

He next writes that we must approach our investigations of pharmaceutical mergers with careful scrutiny and with great humility. I agree completely. What I fail to see is how careful scrutiny and great humility lead to the conclusion, without any clearly articulated theory of liability or facts to support it, that this merger violates the law – or, again without any facts in support, that the remedy is inadequate.

The next basis Commissioner Chopra offers for his dissent is his view that the merger is animated by financial and tax considerations, which he deems insufficient to justify the merger. Leaving aside the question of why he thinks the job of antitrust enforcers is to value-judge a merger beyond its impact upon competition, that gets the law precisely backwards. The parties get to merge unless we can show a harm to competition, not the other way round.

This dissent also alludes to “distorted” incentives of the buyer due to the overlapping ownership of the parties. I must admit that the precise meaning of that escapes me. Perhaps it is a reference to the theory of “common ownership”, which has stoked great academic debate and about which I have spoken repeatedly.¹ Whatever the meaning, Commissioner Chopra fails to articulate how the merger will distort the buyer’s incentives, much less in a way that violates the law. To sue, or to seek an additional remedy, we need more.

The dissenting commissioners both criticize the Commission’s investigations of pharmaceutical mergers generally, expressing concern that they fail to capture all the harms to competition posed by such mergers.² But, again, the most they offer is speculation about vaguely articulated harms, without reference to any evidence that *this* merger is likely to exacerbate them. Nor do the dissenters cite a previous case that resulted in anticompetitive effects that they insinuate the Commission missed. The dissenting statements mention various violations of the antitrust laws committed by firms in the pharmaceutical industry, but neither explains how this merger makes such conduct more likely. For decades, the Federal Trade Commission has pursued enforcement against many different kinds of anticompetitive conduct in the pharmaceutical industry. That work, critical to controlling healthcare costs for Americans, will continue.

1 Noah Joshua Phillips, Commissioner, U.S. Fed. Trade Comm’n, Taking Stock: Assessing Common Ownership, Address at the Global Antitrust Economics Conference (June 1, 2018), https://www.ftc.gov/system/files/documents/public_statements/1382461/phillips_-_taking_stock_6-1-18_0.pdf; Noah Joshua Phillips, Commissioner, U.S. Fed. Trade Comm’n, Competing for Companies: How M&A Drives Competition and Consumer Welfare, Address at the Global Antitrust Economics Conference (May 31, 2019), https://www.ftc.gov/system/files/documents/public_statements/1524321/phillips_-_competing_for_companies_5-31-19_0.pdf.

2 Like Commissioner Wilson, I believe staff conducted a careful investigation of this merger. See Statement of Commissioner Christine S. Wilson, In the Matter of Bristol-Myers Squibb Company / Celgene Corporation.

Concurring Statement

Neither dissenting commissioner argues that the consent order and associated divestiture are bad for competition or consumers, or identifies any additional remedy they believe is warranted. And neither proposes any basis to sue to stop the merger.³ So, again, why dissent? At the end of the day, we are left only with the sense that Commissioners Chopra and Slaughter feel the merger will threaten competition and wish to dissociate themselves with it. To me, that is not enough. (Even if it were, a vote to join Commissioners Chopra and Slaughter would result, at the end of the day, in the merger without the remedy. Are they calling on their colleagues to vote with them?)

Returning to our unfamiliar reader, here is how the law actually works. First, to block a merger outright, U.S. antitrust enforcement agencies must convince a judge that it violates the law. In this country, where people and companies are free to do what they wish with their property subject to the constraints imposed by the law, our judges are somewhat hostile to the notion that we should block a merger when the parties have agreed to address *every* problem that we can identify. Second, we need to articulate a viable theory of harm to competition posed by the merger and produce evidence to support that theory. Third, our job is to enforce the antitrust laws, which guard against particular (competitive) harms that mergers may present. Other parts of the government guard against other harms posed by mergers, for example the Committee on Foreign Investment in the United States, which looks at certain investments for their potential impact on national security,⁴ or the Securities and Exchange Commission, which reviews transactions to protect investors.⁵ Our job is not to opine on whether a merger is “good” or “bad” for society as a whole, or to use our authority to make sure firms merge for reasons that someone might like (innovation) as opposed to reasons that they may not (tax).⁶

In reviewing the dissenting statements, readers – unfamiliar and otherwise – would do well to keep all of that in mind.

3 In fairness, Commissioner Chopra does state his view that the agency should litigate to block more pharmaceutical mergers outright. But he fails to answer whether the Commission should litigate this case, and – more importantly – on what legal and factual basis. That is the question we face today.

4 See 50 U.S.C. § 4565.

5 See, e.g., 15 U.S.C. §§ 78m(d), 78n(d).

6 This is not to say that we should view financial or tax considerations as improper motivations for a merger.

Dissenting Statement

DISSENTING STATEMENT OF COMMISSIONER ROHIT CHOPRA**Summary**

- Today's troubles in the pharmaceutical industry are well known. Drug pricing is out-of-control and innovation is too slow. Given the consequences for human life, the FTC must ensure fierce competition in this market through close scrutiny of mergers and conduct.
- The agency has scored big victories in court to combat anticompetitive conduct in the industry. But, when it comes to mergers, Commissioners have typically voted to steer clear of the courtroom, instead focusing on settlements that address product overlaps.
- Given the size and potential impact of this massive merger, I am skeptical that the status quo approach will uncover the range of potential harms to American patients.

When it comes to life-saving pharmaceuticals, the Federal Trade Commission should never ignore serious warning signs that most Americans see clearly. Many of us depend on prescription drugs to survive, but too many cannot afford the high costs. The argument that sky-high prices are necessary for innovation has been falling apart, as more evidence reveals that many new drugs seem to be designed to extend exclusivity, rather than providing meaningful therapeutic benefits.¹

Predicting the anticompetitive effects of massive mergers in any industry is difficult. This is especially true in pharmaceuticals, where research and discovery are core to competition. Some evidence shows that these mergers have choked off innovation,² creating harms that are immeasurable for those waiting for a cure.

Routine vs. Rigor

Over the years, the agency has worked to combat abuse of intellectual property and other anticompetitive conduct by pharmaceutical companies, achieving major victories in courts across the country. Our approach to pharmaceutical mergers, however, has focused primarily on reaching settlements, rather than litigation or in-depth merger studies. The agency has focused on seeking divestitures of individual products, usually to another major pharmaceutical player.

There have been longstanding, bipartisan concerns about whether this strategy is truly working. For example, in 2005, as he reflected on his six years of service as Commissioner,

1 Donald W. Light & Joel R. Lexchin, *Pharmaceutical R&D: What do we get for all that money?*, 345 *British Med. J.* 22, 24 (2012), <https://www.bmj.com/bmj/section-pdf/187604?path=/bmj/345/7869/Analysis.full.pdf>.

2 See generally, Justus Haucap & Joel Stiebale, *How Mergers Affect Innovation: Theory and Evidence from the Pharmaceutical Industry* (Düsseldorf Inst. for Competition Economics, Discussion Paper No. 218, 2016), http://www.dice.hhu.de/fileadmin/redaktion/Fakultaeten/Wirtschaftswissenschaftliche_Fakultaet/DICE/Discussion_Paper/218_Hauca_p_Stiebale.pdf.

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Thomas Leary lamented that the agency's approach to these investigations mostly stayed the same, despite overarching concerns about other anticompetitive harms.³

During my time as a Commissioner, I have pushed for the agency to be more rigorous across all of our work by opening our eyes to new types of analysis and sources of evidence,⁴ while avoiding assumptions that may be outdated. Given some of the clear warning signs in the industry, we must approach our investigations of pharmaceutical mergers with careful scrutiny and great humility about our longstanding practices.

This massive \$74 billion merger between Bristol-Myers Squibb (NYSE: BMY) and Celgene (NASDAQ: CELG) may have significant implications for patients and inventors, so we must be especially vigilant. In my view, this transaction appears to be heavily motivated by financial engineering⁵ and tax considerations⁶ (as opposed to a genuine drive for greater discovery of life-saving medications), without clear benefits to patients or the public. The buyer's incentives might also be distorted, given overlaps in ownership.⁷ In addition, there are also concerns about a

3 Interview with Commissioner Thomas B. Leary, 19 (3) A.B.A. ANTITRUST HEALTH CARE CHRONICLE 1, 5 (2005), <https://www.ftc.gov/public-statements/2005/09/health-care-interview-commissioner-thomas-b-leary>.

4 I have previously noted that the agency can enhance its assessments of the likelihood of entry by new innovators, as well as its approach to vetting the financial condition of divestiture buyers. Statement of Commissioner Rohit Chopra, In the Matter of Fresenius Medical Care AG & Co. KGaA and NxStage Medical, Inc. (Feb. 19, 2019), <https://www.ftc.gov/public-statements/2019/02/statement-commissioner-chopra-matter-fresenius-medical-care-ag-co-kgaa>; Statement of Commissioner Rohit Chopra, In the Matter of Linde AG, Praxair, Inc., and Linde PLC (Oct. 22, 2018), <https://www.ftc.gov/public-statements/2018/10/statement-commissioner-chopra-matter-linde-ag-praxair-inc-linde-plc>.

5 This transaction will lead to changes in the merged firm's capital structure, as well as an acceleration of share buybacks. I fear that these changes will alter the firm's incentives in ways that might increase the likelihood of anticompetitive conduct. See Bristol-Myers Squibb, Press Release, Bristol-Myers Squibb Announces Agreement Between Celgene and Amgen to Divest OTEZLA® for \$13.4 Billion (Aug. 26, 2019, 6:30 AM), <https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-announces-agreement-between-celgene-and-a>.

6 Tax avoidance appears to be one of the primary motivations of the deal, rather than a meaningful increase in the firms' ability to innovate or operate effectively. See, e.g., Siri Bulusu, *Celgene Holders May See Tax Benefit From Bristol-Myers Deal (1)*, BLOOMBERG TAX (Jan. 4, 2019, 4:43 PM), <https://news.bloombergtax.com/daily-tax-report/celgene-holders-may-see-tax-benefit-from-bristol-myers-deal-1> (noting that the buyer went out of its way to make sure the stock component of the merger will be taxable and describing how that tax would be deductible by Celgene shareholders). Tax considerations were also relevant to Amgen, the Commission's approved buyer of a divested asset. Amgen publicly disclosed that it would recognize \$2.2 billion in tax benefits, on a present value basis. See Michael Erman & Manas Mishra, *Amgen to buy Celgene psoriasis drug Otezla for \$13.4 billion*, REUTERS (Aug. 26, 2019), <https://www.reuters.com/article/us-bristol-myers-divestiture-amgen/amgen-to-buy-celgene-psoriasis-drug-otezla-for-13-4-billion-idUSKCN1VG102>.

7 For example, I noted with great interest that two-thirds of Bristol-Myers Squibb's 100 largest shareholders also have stakes in Celgene, according to data assembled by Refinitiv. See, e.g., Svea Herbst-Bayliss & Michael Erman, *Starboard joins opposition to Bristol-Myers' \$74 billion Celgene deal*, REUTERS (Feb. 28, 2019, 6:59 AM), <https://www.reuters.com/article/us-celgene-m-a-bristol-myers-wellington/starboard-joins-opposition-to-bristol-myers-74-billion-celgene-deal-idUSKCN1QH1K7>.

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history of anticompetitive conduct.⁸ Expansive investigation for mergers like these is time well spent.

Again, with a few exceptions,⁹ many FTC Commissioners have primarily scrutinized pharmaceutical mergers based on an examination of whether there are any product overlaps between the merging corporations, or where there may be clear-cut incentives to foreclose rivals with the ability to compete.¹⁰ When there are no obvious overlaps or foreclosure possibilities, the Commission typically does not challenge any aspect of the transaction.¹¹

I am deeply skeptical that this approach can unearth the complete set of harms to patients and innovation, based on the history of anticompetitive conduct of the firms seeking to merge and the characteristics of today's pharmaceutical industry when it comes to innovation. Will the merger facilitate a capital structure that magnifies incentives to engage in anticompetitive conduct or abuse of intellectual property? Will the merger deter formation of biotechnology firms that fuel much of the industry's innovation? How can we know the effects on competition if we do not rigorously study or investigate these and other critical questions? Given our approach, I am not confident that the Commission has sufficient information to determine the full scope of potential harms to competition of this massive merger.

8 For example, last year, the Food & Drug Administration published a list of drug makers that were the subject of complaints that they had restricted generic drug companies from accessing drug samples, which enable generic firms to develop viable alternatives. Celgene was a top recipient of these complaints. Alison Kodjak, *How a Drugmaker Gamed The System To Keep Generic Competition Away*, NPR (May 17, 2018; 5:00 AM), <https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away>.

9 See, e.g., Statement of the Federal Trade Commission, In the Matter of Teva Pharmaceuticals Industries Ltd. and Allergan plc (July 27, 2016), <https://www.ftc.gov/public-statements/2016/07/statement-federal-trade-commission-matter-teva-pharmaceuticals-industries>; cf. Concurring Statement of Commissioner J. Thomas Rosch, Federal Trade Commission v. Ovation Pharmaceuticals, Inc. (Dec. 16, 2008), <https://www.ftc.gov/public-statements/2008/12/concurring-statement-commissioner-j-thomas-rosch-federal-trade-commission>.

10 In this matter, the Analysis of Agreement Containing Consent Orders to Aid Public Comment focuses primarily on a specific product market overlap. This is similar to many past analyses contained in public notices seeking comment on proposed consent orders in the FTC's pharmaceutical merger actions. See, e.g., Analysis Of Agreement Containing Consent Orders To Aid Public Comment, *In the Matter of Boston Scientific Corporation*, File No. 191-0039, https://www.ftc.gov/system/files/documents/cases/191_0039_boston_scientific_aapc.pdf; Analysis Of Agreement Containing Consent Orders To Aid Public Comment, *In the Matter of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Impax Laboratories, Inc., and Impax Laboratories, LLC*, File No. 181-0017, https://www.ftc.gov/system/files/documents/cases/1810017_amneal_impax_analysis_4-27-18.pdf. See also Markus Meier et al., FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCT AND DISTRIBUTION (2019), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf

11 For example, in January 2015 the Commission granted early termination of the Hart-Scott-Rodino waiting period and took no enforcement action against the proposed \$66 billion merger between Actavis plc and Allergan, Inc. See Fed. Trade Comm'n, Early Termination Notices, 20150313: *Actavis plc; Allergan, Inc.* (Jan. 9, 2015), <https://www.ftc.gov/enforcement/premerger-notification-program/early-termination-notices/20150313>.

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Conclusion

The financial crisis and the Great Recession taught our country a tough lesson: when watchdogs wear blindfolds or fail to evolve with the marketplace, millions of American families can suffer the consequences. The regulators and enforcers of the mortgage industry failed to stop the widespread abuses that plagued the marketplace. And there are many more examples every year, from the opioid crisis to the failures of the Boeing 737 Max, where blindfolded regulators and the absence of rigorous investigation proved to be catastrophic to human life, despite so many warning signs.

When enforcers conduct wide-ranging, intensive inquiries that do not uncover unlawful conduct, then, of course, they cannot take action. However, when they wear blindfolds or cling to the status quo, they cannot assume that the public is protected.

For these reasons, I respectfully dissent.

DISSENTING STATEMENT OF COMMISSIONER REBECCA KELLY SLAUGHTER

The Federal Trade Commission has a long history of reviewing mergers between pharmaceutical manufacturers using an analytical framework that identifies specific product overlaps between the merging parties, including of drugs in development, and requiring divestitures of one of those products. This approach addresses significant competitive concerns in these mergers,¹ but I am concerned that it does not fully capture all of the competitive consequences of these transactions.²

The consent decree in this case follows the Commission's standard approach. It remedies a serious concern about a drug-level overlap between BMS's development-stage BMS 986165 (or "TYK2") and Celgene's on-market Otezla for the treatment of moderate-to-severe psoriasis. This is important, and I support the Commission's effort to remedy this drug-level overlap.

1 Within the standard analytical framework for pharmaceutical mergers, the Commission has done a good job of studying the effects of previous divestitures, and has taken seriously the lesson that divestitures of on-market, rather than pipeline products, are often more likely to succeed in preserving competition among the overlapping products. See Bruce Hoffman, *It Only Takes Two to Tango: Reflections on Six Months at the FTC*, at 6 (Feb. 2, 2018).

2 The Commission has been very successful in negotiating settlements with merging parties to address drug overlaps. The Commission has not recently litigated pharmaceutical merger cases, and, although merger litigation in other industries and merger guidelines provide useful guidance, we simply do not have a contemporary body of pharmaceutical merger caselaw to clarify the boundaries for our analytical approach.

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However, I remain concerned that this analytical approach is too narrow. In particular, I believe the Commission should more broadly consider whether any pharmaceutical merger is likely to exacerbate anticompetitive conduct by the merged firm or to hinder innovation.

Several recent developments enhance my concerns. Branded drug prices have increased substantially in recent years,³ and pharmaceutical merger activity persists at a high pace.⁴ The high rate of drug company consolidation has coincided with a sea change in the structure of pharmaceutical research and development; recent studies suggest mergers may inhibit research, development, or approval in this changing environment.⁵ In addition, the pharmaceutical industry has long been the focus of anticompetitive conduct enforcement by both the Commission and private litigants, including for practices such as pay-for-delay settlements,⁶ sham litigation,⁷ and anticompetitive product hopping.⁸ We must carefully consider the facts in each specific merger to understand whether or how it may facilitate anticompetitive conduct, and therefore be more likely to result in a substantial lessening of competition.

Going forward, I hope the Commission will take a more expansive approach to analyzing the full range of competitive consequences of pharmaceutical mergers. I urge not only the Commission, but also researchers and industry experts to think carefully and creatively about these

3 See IQVIA Institute for Human Data Science, *The Global Use of Medicine in 2019 and Outlook to 2023*, at 11 (Jan. 29, 2019); IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.*, at 8 (Apr. 19, 2018); Laura Entis, *Why Does Medicine Cost So Much? Here's How Drug Prices Are Set*, TIME (Apr. 9, 2019), <https://time.com/5564547/drug-prices-medicine/>; see also Joanna Shepherd, *The Prescription for Rising Drug Prices: Competition or Price Controls?*, 27 HEALTH MATRIX 315, 315-16 (2017); Aimee Picchi, *Drug Prices in 2019 are Surging, With Hikes at 5 Times Inflation*, CBS NEWS (July 1, 2019), <https://www.cbsnews.com/news/drug-prices-in-2019-are-surging-with-hikes-at-5-times-inflation/>.

4 See Barak Richman, et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 LOY. U. CHI. L. J. 787, 790-91 (2017); Meagan Parrish, *What's Behind all the M&A Deals in Pharma*, PHARMA MANUFACTURING (July 31, 2019).

5 See Justus Haucap & Joel Stiebale, *Research: Innovation Suffers When Drug Companies Merge*, HARVARD BUSINESS REVIEW (Aug. 3, 2016); Justus Haucap & Joel Stiebale, *How Mergers Affect Innovation: Theory and Evidence From the Pharmaceutical Industry* (2016) (finding a negative effect on research and development activity of the merged firm and rival firms); but see Richman, et al., *supra* note 4 at 799-801, 817-18 (finding a positive correlation between increased pharmaceutical merger and drug development activity, but noting competitive concerns about a “bottleneck” in FDA approval).

6 See Press Release, Fed. Trade Comm’n, *Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company “Reverse Payments”* (Feb. 28, 2019), <https://www.ftc.gov/news-events/press-releases/2019/02/last-remaining-defendant-settles-ftc-suit-led-landmark-supreme>.

7 See Press Release, Fed. Trade Comm’n, *Statement of FTC Chairman Joe Simons Regarding Federal Court Ruling in FTC v. AbbVie* (June 29, 2018), <https://www.ftc.gov/news-events/press-releases/2018/06/statement-ftc-chairman-joe-simons-regarding-federal-court-ruling>.

8 See Press Release, Fed. Trade Comm’n, *Reckitt Benckiser Group plc to Pay \$50 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone* (July 11, 2019), <https://www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc>.

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cases, and in particular to study the effects of recent consummated mergers on drug research, development, and approval. Outside of merger enforcement, we should also continue to police aggressively business practices that suppress competition. Indeed, as Commissioner Chopra and I have explained elsewhere, we should unleash the full scope of our authority under Section 5 to combat high drug prices.⁹

The problem of high drug prices is too important to leave any potential solutions unexhausted. As a society, we should also consider all other policy interventions that would help combat high drug prices.¹⁰

9 See Statement of Commissioners Rohit Chopra and Rebecca Kelly Slaughter Regarding the Federal Trade Commission Report on the Use of Section 5 to Address Off-Patent Pharmaceutical Price Spikes, (June 27, 2019).

10 The problem of high drug prices has prompted a number of proposed policy solutions in addition to antitrust enforcement, including (1) reference pricing, (2) reforming import restrictions, (3) innovation prizes, and (4) Medicare Part D price negotiation. See So-Yeon Kang, et al., *Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials With Other Countries*, 5 HEALTH AFF. 38 (2019); Tim Wu, *How to Stop Drug Price Gouging*, N.Y. TIMES (Apr. 20, 2017), <https://www.nytimes.com/2017/04/20/opinion/how-to-stop-drug-price-gouging.html>; Charles Silver & David A. Hyman, *Here's a Plan to Fight High Drug Prices That Could Unite Libertarians and Socialists*, VOX (Jun. 21, 2018), <https://www.vox.com/the-big-idea/2018/6/21/17486128/prescription-drug-prices-monopolies-epipen-shkreli-sanders-patents-prizes>; Juliette Cubanski & Tricia Neuman, *Searching for Savings in Medicare Drug Price Negotiations*, Henry J. Kaiser Family Foundation (Apr. 26, 2018).

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STATEMENT OF COMMISSIONER CHRISTINE S. WILSON

The Commission has accepted, subject to final approval after receiving public comments, an Agreement Containing Consent Order from Bristol-Myers Squibb Company and Celgene Corporation that remedies the anticompetitive effect that otherwise would arise from BMS's proposed acquisition of Celgene. All members of the Commission (including Commissioners Chopra and Slaughter)¹ agree that the *only* evidence of harm to competition that staff found was in the market for oral products that treat moderate-to-severe psoriasis.² All members of the Commission also agree that the remedy in that market – a complete divestiture of all of Celgene's products and associated assets in that area – will preserve competition in that market. Moreover, this \$13 billion divestiture is the largest in the history of U.S. merger enforcement.

I agree with Commissioner Slaughter that pharmaceutical price levels in the United States today are cause for concern. And there is ample evidence that prices of branded pharmaceuticals have increased much faster – perhaps six to eight times as fast – as prices in the rest of the economy.³

1 See Dissenting Statement of Commissioner Rebecca Kelly Slaughter, In the Matter of Bristol-Myers Squibb and Celgene; Dissenting Statement of Commissioner Rohit Chopra on Bristol-Myers Squibb/Celgene.

2 While Commissioner Chopra agrees that there is no evidence of harm to innovation, he concludes that the lack of evidence implies there is a problem with the investigative process. I disagree with Commissioner Chopra's hypothesis.

Staff conducted the investigation of this proposed transaction in the same careful manner that all pharmaceutical transactions are investigated. The investigation examined the likely competition between and among all of BMS and Celgene's current products and those now in development. The investigation identified a likely harm to innovation involving oral products to treat moderate-to-severe psoriasis; the identified overlap includes a product that is still in development by BMS. In addition, staff investigated whether the proposed transaction would decrease innovation competition; instead, the investigation found that reduced innovation competition was unlikely.

Moreover, there is no reason to believe there will be reduced innovation in the pharmaceutical industry as a result of this transaction. No fewer than 711 companies are conducting late-stage research and development in oncology, the therapeutic category in which BMS and Celgene conduct research. See IQVIA Institute Global Oncology Trends 2019, at 19, May 2019, available at <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-oncology-trends-2019.pdf>.

To support his hypothesis that there must be additional unidentified harm to innovation, Commissioner Chopra seeks to introduce factors outside the analytical framework demanded by the statutes enforced by the Commission, including Section 7 of the Clayton Act, without offering any evidence to show that these non-competition factors may reduce innovation.

3 See, e.g., SUZANNE M. KIRCHHOFF ET AL., CONGRESSIONAL RESEARCH SERVICE, FREQUENTLY ASKED QUESTIONS ABOUT PRESCRIPTION DRUG PRICING AND POLICY, at 8-9 (Apr. 24, 2018), available at <https://fas.org/sgp/crs/misc/R44832.pdf> (plotting CPI-U data from the U.S. Bureau of Labor Statistics); STEPHEN W. SCHONDELMAYER & LEIGH PURVIS, AARP PUBLIC POLICY INSTITUTE, RX PRICE WATCH REPORT: TRENDS IN RETAIL PRICES OF BRAND NAME PRESCRIPTION DRUGS WIDELY USED BY OLDER AMERICANS: 2017 YEAR-END UPDATE, at (Sept. 2018), available at <https://www.aarp.org/content/dam/aarp/ppi/2018/09/trends-in-retail-prices-of-brand-name-prescription-drugs-year-end-update.pdf> (using data from Truven MarketScan to estimate that “brand name drug prices went up more than 8.5 times the rate of general inflation during [the] 12-year period [from December 31, 2005 to December 31, 2017]”); Robert Pearl, *How Big Pharma Might Be Cut Down to Size*, FORBES.COM, May 11, 2017, available at <https://www.forbes.com/sites/robertpearl/2017/05/11/how-big-pharma-might-be-cut-down-to-size/>

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Unfortunately, many of the causes of higher drug prices, including systemic distortions created by massive regulatory regimes and a pervasive principal/agent problem, fall outside the jurisdiction and legal authority of the Federal Trade Commission. But within its limited authority as a competition agency, the Commission can – and does – pursue a comprehensive agenda to address anticompetitive mergers and unlawful conduct in the pharmaceutical industry. Specifically, the Commission:

- **Carefully Screens Pharmaceutical Mergers:** Similar to the current enforcement action, the Commission routinely has challenged anticompetitive mergers and acquisitions. During the past five years, the Commission has issued complaints challenging 13 mergers and required the divestiture of 130 branded and generic products to address competitive overlaps for the sale or development of particular drugs.⁴
- **Combats Anticompetitive Patent Litigation Settlements:** In 2013, the FTC won a landmark victory at the Supreme Court in the *Actavis* case,⁵ and has prevailed in subsequent challenges of similar agreements. For instance, earlier this year, the Commission issued a unanimous opinion condemning a patent litigation settlement after finding that the brand manufacturer possessed market power in the market for branded and generic oxymorphone ER, the potential generic entrant received a large and unjustified payment, and the respondent failed to show a cognizable justification for the restraint.⁶ The Commission’s successful challenges of prior settlements have substantially reduced the number of anticompetitive patent litigation settlements into which companies are entering today.
- **Challenges Abuse of FDA Regulatory Processes:** The Commission has brought several cases alleging that pharmaceutical companies misuse FDA regulatory processes to impede competition. For example, in 2014 the FTC challenged a pharmaceutical company for abusing the litigation process by filing meritless patent lawsuits against competitors to keep them off the market. The Commission won a

(“[A]ccording to the U.S. Bureau of Labor Statistics, prices for U.S.-made pharmaceuticals have climbed over the past decade six times as fast as the cost of goods and services overall.”); CHARLES SILVER & DAVID A. HYMAN, *OVERCHARGED: WHY AMERICANS PAY TOO MUCH FOR HEALTH CARE* 25-27 (2018) (discussing analyses from Schondelmeyer & Purvis, Pearl, and others).

⁴ See *Baxter Int’l Inc.*, Dkt. No. C-4620 (F.T.C. July 20, 2017); *Amneal Holdings, LLC*, Dkt. No. C-4650 (F.T.C. Apr. 27, 2018); *FTC v. Mallinckrodt ARD Inc.*, No. 1:17-cv-00120 (D.D.C. Jan. 18, 2017); *Mylan, N.V.*, Dkt. No. C-4590 (F.T.C. July 26, 2016); *Teva Pharmaceutical Indus. Ltd.*, Dkt. No. C-4589 (F.T.C. July 26, 2016); *Hikma Pharmaceuticals PLC*, Dkt. No. C-4572 (F.T.C. Mar. 28, 2016); *Hikma Pharmaceuticals PLC*, Dkt. No. C-4568 (F.T.C. Feb. 26, 2016); *Lupin Ltd.*, Dkt. No. C-4566 (F.T.C. Feb. 18, 2016); *Endo Int’l PLC*, Dkt. No. C-4539 (F.T.C. Sept. 24, 2015); *Pfizer Inc.*, Dkt. No. C-4537 (F.T.C. Aug. 21, 2015); *Impax Labs, Inc.*, Dkt. No. C-4511 (F.T.C. Mar. 5, 2015); *Novartis AG*, Dkt. No. C-4510 (F.T.C. Feb. 20, 2015); *Sun Pharmaceutical Indus. Ltd.*, Dkt. No. C-4506 (F.T.C. Jan. 30, 2015).

⁵ *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

⁶ See, e.g., *Impax Laboratories, Inc.*, Dkt. No. 9373 (F.T.C. April 3, 2019) (Commission Decision).

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judgment for \$448 million.⁷ The FTC also sued Shire ViroPharma in 2017, alleging anticompetitive abuse of the FDA citizen-petition process to keep the FDA from approving the competitive products, thereby keeping those lower-cost drugs off the market. (Unfortunately, the Commission lost the case on a statutory construction issue that kept the Court of Appeals from ruling on the merits of the allegations.⁸) And under Chairman Tim Muris, the FTC challenged wrongful listings in the FDA Orange Book⁹ by BMS, one of the very parties before us today, that allegedly were used to obtain unwarranted automatic 30-month stays of FDA approval of generic pharmaceuticals that would have competed with BMS branded products.¹⁰

- **Advocates for the Reform of Misused Regulations:** The FTC advised the FDA and Congress of possible abuses of the Risk Evaluation and Mitigation Strategy (REMS) framework to forestall competitors' entry by denying access to branded drugs required to conduct bioequivalence testing, a gating factor for FDA approval to launch.¹¹ In remarks before a Subcommittee of the Senate Committee on Commerce, Science, and Transportation, I encouraged Congress to take action on this front.¹² And under the bipartisan leadership of first Chairman Bob Pitofsky and then Chairman Tim Muris, the FTC conducted a 6(b) study of generic drugs and issued a report recommending refinements to the Hatch Waxman Act and changes to the FDA regulatory framework, many of which were implemented, so as to fulfill the original balance of innovation and competition struck by the Hatch Waxman Act.

7 FTC v. AbbVie, Inc. 329 F. Supp. 3d 98 (E.D. Pa. 2018).

8 FTC v. Shire ViroPharma, Inc., 917 F.3d 147, 156 (3d Cir. 2019).

9 Pursuant to the FDC Act, a brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA"). At the time the NDA is filed, the NDA filer must also provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA. 21 U.S.C. § 355(b)(1). Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book." *Id.* § 355(j)(7)(A).

10 See Complaint, *Bristol-Myers Squibb Co.*, Dkt. No. C-4076 (F.T.C. filed Apr. 14, 2003).

11 See, e.g., Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (July 16, 2018); Prepared Statement of Markus H. Meier, Acting Director, Bureau of Competition, Federal Trade Commission before the U.S. House of Representatives, Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Laws, on "Antitrust Concerns and the FDA Approval Process" (July 27, 2017).

12 See Commissioner Christine S. Wilson, Oral Statement before Senate Committee on Commerce, Science & Transportation, Subcommittee on Consumer Protection, Product Safety, Insurance, & Data Protection (Nov. 27, 2018).

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- **Challenges Novel Anticompetitive Strategies As They Arise:** Earlier this year the Commission challenged and settled a case against Reckitt Benckiser Group plc alleging that Reckitt introduced a film version of Suboxone, which treats opioid addiction, and pushed the market to use the film version rather than the existing tablet version that was about to face generic competition.¹³ The complaint alleged that Reckitt pushed the market toward the film and away from the tablets by claiming the film was safer than tablets while having no data to back up the claim and significantly raising the price of the tablet when the film was costlier to make. Under the terms of the settlement, Reckitt was required to contribute \$50 million to a fund to be distributed to those who were overcharged.¹⁴
- **Informs Courts of Relevant Competition Principles and Policies:** The Commission has filed briefs as *amicus curiae* in cases involving patent litigation settlements,¹⁵ REMS and restricted distribution systems,¹⁶ and product hopping.¹⁷

This list of actions by the FTC is by no means exhaustive.¹⁸ But the message is clear — the FTC uses the full force and weight of its authority to protect consumers from unlawful conduct that increases prices and reduces innovation in this important sector of our economy.

Notwithstanding the Commission's valiant efforts, there are many factors that contribute to increasing drug prices but that are not cognizable under the antitrust laws, and therefore that the FTC does not have the legal authority to fix. Even if the FTC and other government enforcers did

13 See Joint Motion for Entry of Stipulated Order for Permanent Injunction and Equitable Monetary Relief, FTC v. Reckitt Benckiser Group, PLC, No. 1:19-cv-00028 (W.D. Va. filed July 11, 2019).

14 I was recused from this enforcement action because, before joining the Commission, I represented a generic drug company before the FTC and FDA challenging this anticompetitive conduct.

15 See, e.g., Br. of *amicus curiae* Federal Trade Commission in Support of Plaintiffs-Appellants, *In re Lamictal Direct Purchaser Antitrust Litigation*, No. 2:12-cv-995, (3d Cir. filed Apr. 28, 2014) (explaining that a commitment not to introduce an authorized generic product is the type of settlement subject to antitrust scrutiny); Supp. Br. of *amicus curiae* Federal Trade Commission in Support of Plaintiffs-Appellants, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479 (3d Cir. filed Mar. 17, 2016) (explaining that litigation settlements among private parties are private commercial agreements and are not exempt from antitrust scrutiny under the *Noerr* doctrine).

16 See, e.g., Br. of *amicus curiae* Federal Trade Commission, Mylan Pharmaceuticals, Inc. v. Celgene, No. 2:14-cv-2094 (D.N.J. filed June 17, 2014) (explaining that a monopolist's refusal to sell to potential competitors may, under certain limited circumstances, violate Section 2 of the Sherman Act and that a brand name drug manufacturer's patents do not reach activities undertaken in connection with bioequivalence testing).

17 See Br. of *amicus curiae* Federal Trade Commission, Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Ltd. Co., No. 12-cv-3824 (E.D. Pa. filed Nov. 21, 2012) (explaining that minor, non-therapeutic changes to a branded pharmaceutical product that harm generic competition can constitute exclusionary conduct that violates U.S. antitrust laws).

18 For a complete review of the Commission's ongoing and extensive efforts to combat anticompetitive mergers and unlawful conduct in the pharmaceutical industry, see Markus H. Meier, Bradley S. Albert, & Kara Monahan, Overview of FTC Actions in Pharmaceutical Products and Distribution (Sept. 2019), available at https://www.ftc.gov/system/files/attachments/competition-policy-guidance/20190930_overview_pharma_final.pdf.

Concurring Statement

their job flawlessly (and our “retrospective” reviews of our past work suggests we do quite well), pharmaceutical prices would still rise for many other reasons. For example, last year the Trump Administration released two reports identifying various market imperfections in health care markets, including prescription drug markets, and various regulatory and legislative reforms that would increase consumer choice and provider competition.¹⁹ Similarly, former FDA Administrator Scott Gottlieb has identified several flaws in the market for biosimilars – generic biologic medicines – that he believes require Congressional action.²⁰ And Professors David Hyman (also a former FTC Special Counsel) and Charles Silver have identified a host of other legal and regulatory factors that increase drug prices,²¹ including FDA delays in processing generic applications and a Medicare system pursuant to which the government purchases one- third of all retail drugs but is barred from negotiating the prices that it pays.²²

There is broad concern about prescription drug price levels, and I share those concerns. But here, Commission staff conducted a thorough investigation and found evidence that the acquisition of Celgene by BMS would, if not addressed, diminish competition in one relevant market. Commission staff then negotiated a record-breaking consent agreement that replaces the competition otherwise lost because of the merger by divesting all of Celgene’s relevant products and assets to a new and robust competitor. Rather than asserting that staff should have found something – anything – more to justify asking a court to block the transaction, we should recognize the limited authority we have been granted by Congress and encourage other responsible governmental actors to fix the many problems in this sector that lie beyond our jurisdiction.

19 U.S. DEP’T OF HEALTH AND HUMAN SERVS., AMERICAN PATIENTS FIRST: A TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS (May 2018), *available at* <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>; U.S. DEP’T OF HEALTH AND HUMAN SERVS., U.S. DEP’T OF THE TREASURY, & U.S. DEP’T OF LABOR, REFORMING AMERICA’S HEALTHCARE SYSTEM THROUGH CHOICE AND COMPETITION 63-67 (2018), *available at* <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf> (discussing, *e.g.*, the use of “any-willing-provider” laws in the context of drug prescription plans and Medicare Part D). FTC staff consulted with HHS on the latter report. *See id.* at 3 (“Executive Order 13813, ... requires the Secretary of Health and Human Services (HHS), in consultation with the secretaries of the Treasury and Labor and the Federal Trade Commission, to provide a report to the President.”).

20 Scott Gottlieb, Op-Ed, *Don’t Give Up on Biosimilars—Congress Can Give Them a Boost*, WALL ST. J., Aug. 25, 2019, <https://www.wsj.com/articles/dont-give-up-on-biosimilarscongress-can-give-them-a-boost-11566755042>

21 *See, e.g.*, Charles Silver & David A. Hyman, *Here’s a Plan to Fight High Drug Prices that Could Unite Libertarians and Socialists*, VOX.COM, June 21, 2018, <https://www.vox.com/the-big-idea/2018/6/21/17486128/prescription-drug-prices-monopolies-epipen-shkreli-sanders-patents-prizes>; *see also* Statement of Commissioner Rebecca Kelly Slaughter, *supra* note 1, at 2 n.10 (citing Silver & Hyman approvingly).

22 *See* SILVER & HYMAN, *supra* note 3, at 53-60.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDERS TO AID PUBLIC COMMENT**INTRODUCTION**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Bristol-Myers Squibb Company (“BMS”) and Celgene Corporation (“Celgene”) designed to remedy the anticompetitive effects resulting from BMS’s proposed acquisition of Celgene. The proposed Decision and Order (“Order”) contained in the Consent Agreement requires Celgene to divest all rights and assets related to its Otezla business to Amgen, Inc. (“Amgen”).

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

Pursuant to an Agreement and Plan of Merger dated as of January 2, 2019, BMS plans to acquire all of the voting securities of Celgene in a cash and stock transaction with an equity value of approximately \$74 billion (the “Acquisition”). The Commission’s Complaint alleges that the proposed Acquisition, if consummated, would violate 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, by substantially lessening competition in the U.S. market for oral products to treat moderate-to-severe psoriasis. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in this market as a result of the proposed Acquisition.

THE PARTIES

Headquartered in New York City, BMS researches, develops, manufactures, and sells prescription pharmaceutical products and biologic products in several therapeutic areas, including oncology, cardiology, virology, and inflammatory diseases. Among other products, BMS is developing an oral product to treat moderate-to-severe psoriasis. Like BMS, Celgene researches, develops, manufactures and sells prescription pharmaceutical products in the United States. Celgene markets eight products, including an oral treatment for moderate-to-severe psoriasis.

THE RELEVANT PRODUCT AND STRUCTURE OF THE MARKET

Psoriasis is a chronic skin disease caused by an overactive immune system. The disease causes skin cells to multiply faster than normal and leads to a build-up of cells on the skin surface, forming bumpy red patches that are covered with white scales, known as plaques. The plaques can appear anywhere on the body, although they are most commonly found on the scalp, elbows, knees, and lower back. The severity of psoriasis (mild, moderate, or severe) is determined based upon the percentage of body surface area affected and the parts of the body that are affected. Typically, mild psoriasis covers less than 3 percent of the body, moderate psoriasis covers 3 to 10 percent of the body and severe psoriasis covers more than 10 percent of the body.

Analysis to Aid Public Comment

When deciding how to treat psoriasis, dermatologists typically evaluate the severity of the disease, any risk factors or contraindications for the patient, and the patient's preferences. Dermatologists consider efficacy data, safety data, and side effect profile of each product, as well as mode of administration to select the appropriate treatment course for their patients. While many injectable and infused products are approved to treat moderate-to-severe psoriasis, a number of patients object to such injections or find them inconvenient. For those patients, dermatologists often select an oral product.

Celgene's apremilast, marketed under the brand name Otezla, is a phosphodiesterase 4 inhibitor. Otezla is the most popular oral product approved to treat moderate-to-severe psoriasis in the United States. Several older oral generic products, including methotrexate and acitretin, are approved by the U.S. Food and Drug Administration ("FDA") to treat psoriasis that does not respond to light, topical agents, and other forms of therapy. These drugs are still occasionally used in the treatment of psoriasis, but most doctors have moved to prescribing newer agents with better efficacy, better safety, or a more favorable side effect profile for patients with moderate- to-severe psoriasis who desire an oral treatment. BMS is developing BMS 986165, an oral, selective tyrosine kinase 2 inhibitor that is the most advanced oral treatment in development for moderate-to-severe psoriasis.

THE RELEVANT GEOGRAPHIC MARKET

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. Oral products to treat moderate-to-severe psoriasis are prescription pharmaceutical products and regulated by FDA. As such, products sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

COMPETITIVE EFFECTS OF THE ACQUISITION

The proposed Acquisition would likely result in substantial competitive harm to consumers in the market for oral products to treat moderate-to-severe psoriasis. Celgene is currently the market leader and BMS would likely be the next entrant into the market. Upon entry, BMS 986165 likely will compete directly with, and take sales from, Otezla.

ENTRY CONDITIONS

Entry in the relevant market would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry would require significant investment of time and money for product research and development, regulatory approval by the FDA, developing clinical history supporting the long-term efficacy of the product, and establishing a U.S. sales and service infrastructure. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

Analysis to Aid Public Comment

THE CONSENT AGREEMENT

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring BMS and Celgene to divest Celgene's worldwide Otezla business, including its regulatory approvals, intellectual property, contracts, and inventory to Amgen.¹ BMS and Celgene also must transfer all confidential business information, research and development information, regulatory, formulation, and manufacturing reports related to the divested products, as well as provide access to employees who possess or are able to identify such information. Additionally, to ensure that the divestiture is successful and to maintain continuity of supply, the proposed Order requires BMS and Celgene to supply Amgen with Otezla for a limited time while Amgen establishes its own manufacturing capability. The provisions of the Consent Agreement ensure that Amgen becomes an independent, viable, and effective competitor in the U.S. market.

Founded in 1980 and headquartered in Thousand Oaks, California, Amgen discovers, develops, manufactures and sells innovative human pharmaceutical and biologic products.

Amgen's existing business includes products that are highly complementary to the divestiture assets. Amgen has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition.

BMS and Celgene must accomplish the divestitures no later than ten days after consummating the proposed Acquisition. If the Commission determines that Amgen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires BMS and Celgene to unwind the sale of rights and assets to Amgen and then divest the affected product to a Commission-approved acquirer within six months of the date the Order becomes final. To ensure compliance with the Order, the Commission has agreed to appoint a Monitor to ensure that BMS and Celgene comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the Otezla rights and assets to Amgen. The proposed Order further allows the Commission to appoint a trustee in the event that BMS and Celgene fail to divest the products as required.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

¹ News reports have suggested that the combined BMS/Celgene will be allowed to retain BMS's marketed cancer drug, Opdivo, and divest Celgene's development-stage cancer drug, tislelizumab. *See* Alaric Dearment, *BeiGene regains global rights to checkpoint inhibitor from Celgene*, MEDCITYNEWS (June 18, 2019), <https://medcitynews.com/2019/06/beigene-regains-global-rights-to-checkpoint-inhibitor-from-celgene/>. However, Celgene returned the rights to tislelizumab to BeiGene in June, eliminating the potential future overlap between Opdivo and tislelizumab.

Complaint

IN THE MATTER OF

DCR WORKFORCE, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT*Docket No. C-4698; File No. 182 3188**Complaint, January 13, 2020 – Decision, January 13, 2020*

This consent order addresses DCR Workforce, Inc.’s violation of Section 5 of the Federal Trade Commission Act by stating it complied with the EU-U.S. Privacy Shield Framework when it was not a current participant. The complaint alleges that Respondent obtained the Privacy Shield certification through the Department of Commerce in January 2017, that certification lapsed by February 2018, but continued to claim that it participates in the EU-U.S. Privacy Shield framework after its certification lapsed. Under the order Respondent must not misrepresent in any manner the extent to which Respondent is a participant in any privacy or security program sponsored by a government or any self-regulatory or standard-setting organization.

Participants

For the *Commission*: *Monique F. Einhorn and Robin Wetherill.*

For the *Respondents*: *Andrew N. Cove, Cove Law, P.A..*

COMPLAINT

The Federal Trade Commission (“FTC”), having reason to believe that DCR Workforce, Inc., a corporation, has violated the Federal Trade Commission Act (“FTC Act”), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent DCR Workforce, Inc. is a Florida corporation with its principal office or place of business at 7795 NW Beacon Square Boulevard, Suite 201, Boca Raton, FL 33487.
2. Respondent provides workforce management software.
3. The acts and practices of Respondent as alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act.
4. Respondent has set forth on its website, <https://www.dcrworkforce.com/privacy-policy.html>, privacy policies and statements about its practices, including statements related to its participation in the EU-U.S. Privacy Shield framework agreed upon by the U.S. government and the European Commission.

Privacy Shield

5. The EU-U.S. Privacy Shield framework (“Privacy Shield”) was designed by the U.S. Department of Commerce (“Commerce”) and the European Commission to provide a