

Complaint

IN THE MATTER OF

**ABBVIE INC.,
AND
ALLERGAN PLC**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-4713; File No. 191 0169
Complaint, May 5, 2020 – Decision, September 3, 2020*

This consent order addresses the \$63 billion acquisition by AbbVie Inc. of certain assets of Allergan plc. The complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition in the U.S. markets for (1) prescription drugs for the treatment of exocrine pancreatic insufficiency (“EPI”); (2) Interleukin-23 (“IL-23”) inhibitors for the treatment of moderate-to-severe Crohn’s disease; and (3) IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. The consent order requires Allergan to divest all rights and assets related to its Zenpep and Viokase products to Nestlé S.A. The Order also requires that Allergan return its rights and assets related to brazikumab to AstraZeneca plc.

Participants

For the *Commission*: Catherine M. Sanchez and Kari A. Wallace.

For the *Respondents*: Emily Blackburn and Debbie Feinstein, Arnold & Porter Kaye Scholer LLP; Michael DeRita, Samantha Morelli, and Matthew Reilly, Kirkland & Ellis LLP; Natalie Hayes, Brianne Kucerik, and Ann Malester; Weil, Gotshal & Manges LLP.

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 AbbVie Inc. (“AbbVie”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire the equity interests of Respondent Allergan plc (“Allergan”), a public limited company 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 AbbVie Inc. is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware with its executive offices and principal place of business located at 1 North Waukegan Road, North Chicago, Illinois 60064.

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2. Respondent Allergan plc is a public limited company organized, existing, and doing business under, and by virtue of, the laws of the Republic of Ireland with its principal executive offices located at Clonsaugh Business and Technology Park, Coolock Dublin, D17 E400, Ireland. Allergan's United States address for service of process is, as follows: Chief Legal Officer, Allergan plc, 5 Giralda Farms, Madison, New Jersey 07940.

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 a Scheme of Arrangement under Irish law, AbbVie proposes to acquire all of the voting securities of Allergan for approximately \$63 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 lines of commerce in which to analyze the effects of the Acquisition are:

- a. the sale of prescription drugs to treat exocrine pancreatic insufficiency ("EPI");
- b. the development and sale of Interleukin-23 ("IL-23") inhibitor drugs for the treatment of moderate-to-severe Crohn's disease; and
- c. the development and sale of IL-23 inhibitor drugs for the treatment of moderate-to-severe ulcerative colitis.

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 MARKETS

7. EPI is a condition that results from a deficiency of pancreatic enzymes. Patients who have EPI cannot properly digest fats, proteins, and carbohydrates in the foods they eat and, as a result, may suffer from malnutrition and have uncomfortable gastrointestinal symptoms when they eat. Only four companies sell prescription drugs to treat EPI in the United States: AbbVie, Allergan, Vivus Inc. and Chiesi USA, Inc. AbbVie is the clear market leader with its product, Creon, and Allergan is the second-largest supplier, with its product, Zenpep. Together, AbbVie and Allergan account for more than 95 percent of the market for drugs to treat EPI.

8. Ulcerative colitis and Crohn's disease are the most common causes of chronic inflammation of the digestive tract. Though they are different diseases—the primary difference between them is the location of the inflammation in the digestive tract—the treatments are

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similar. A variety of drugs are approved to treat ulcerative colitis and Crohn's disease, but the effectiveness of most drugs is limited. The IL-23 inhibitors are a new class of drugs to treat both diseases. Johnson & Johnson's Stelara is the only IL-23 inhibitor currently approved to treat moderate-to-severe Crohn's disease and ulcerative colitis in the United States. Stelara is both an IL-23 inhibitor and an Interleukin-12 inhibitor. Only three other companies—AbbVie, Allergan, and Eli Lilly and Company—have IL-23 inhibitors in late-stage development. Johnson & Johnson also has a second IL-23 inhibitor in clinical development for ulcerative colitis and Crohn's disease that is only an IL-23 inhibitor.

V. ENTRY CONDITIONS

9. 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.

VI. EFFECTS OF THE ACQUISITION

10. 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:

- a. by eliminating actual, direct, and substantial competition between AbbVie and Allergan and reducing the number of independent significant competitors in the markets for prescription drugs to treat EPI, thereby increasing the likelihood that: (1) AbbVie would be able to unilaterally exercise market power in these markets; (2) the remaining competitors would engage in coordinated interaction between or among each other; and (3) customers would be forced to pay higher prices; and
- b. by eliminating future competition between AbbVie and Allergan in the development and sale of (1) IL-23 inhibitors to treat Crohn's disease and (2) IL-23 inhibitors to treat ulcerative colitis.

VII. VIOLATIONS CHARGED

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

12. 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.

Order to Maintain Assets

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fifth day of May, 2020 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 AbbVie Inc. of all of the voting securities of Respondent Allergan plc. The Commission’s Bureau of Competition prepared and furnished to each Respondent 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 Containing Consent Orders (“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 this Order to Maintain Assets.

The Commission considered the matter and determined to accept the executed Consent Agreement and to place it 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 AbbVie Inc. is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware with its executive offices and principal place of business located at 1 North Waukegan Road, North Chicago, Illinois 60064.
2. Respondent Allergan plc is a public limited company, existing, and doing business under, and by virtue of, the laws of the Republic of Ireland with its principal executive offices located at Clonsaugh Business and Technology Park, Coolock Dublin, D17 E400, Ireland. Allergan’s United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain

Order to Maintain Assets

Assets is as follows: Chief Legal Officer, Allergan plc, 5 Giralda Farms, Madison, New Jersey 07940.

3. The Federal Trade 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 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. “AbbVie” means AbbVie Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by AbbVie Inc. (including, Venice Subsidiary LLC), and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- B. “Allergan” means Allergan plc, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Allergan plc, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” means AbbVie and Allergan.
- 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 each of the Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Divestiture Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Assets (other than in the manner prescribed in the Decision and

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Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of each of the Divestiture Product Businesses.

- B. Respondents shall maintain the operations of each of the Divestiture Product Businesses 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 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 Divestiture Product Businesses 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 each of the Divestiture Product Businesses, respectively. Respondents' responsibilities shall include, but are not limited to, the following:
1. providing each Divestiture Product 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 that Divestiture Product Business;
 2. continuing, at least at their scheduled pace, any expenditures for each of the Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by the Respondents;
 3. providing such resources as may be necessary to respond to competition prior to the complete transfer and delivery of each of the Divestiture Assets to an Acquirer;
 4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Product Businesses;
 5. making available for use by each of the Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the Divestiture Assets; and
 6. providing such support services to each of the Divestiture Product Businesses as were being provided to such Divestiture Product Businesses by Respondents as of the date the Consent Agreement was signed by Respondents.

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- 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 each Divestiture Product Business for the respective Divestiture Product Business's last fiscal year.

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

- A. Respondents shall not use, directly or indirectly, any Confidential Business Information related to the Divestiture Product Businesses other than as necessary to comply with the following:
1. the requirements of the Orders;
 2. Respondents' obligations to the Acquirer of such Divestiture Product Business(es) under the terms of the related Divestiture Agreements; or
 3. applicable law.
- B. Except to the extent necessary to comply with applicable law, Respondents shall not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person *except* (i) the Acquirer of the relevant Divestiture Product Business, (ii) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (e.g., employees of a Respondent providing transition services, Transition Packaging, or who are engaged in the transfer and delivery of the Product Manufacturing Technology to that Acquirer), (iii) the Commission, or (iv) the Monitor.
- C. Respondents shall not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information to the employees associated with the business that is being retained, owned, or controlled by the Respondents, other than those employees specifically authorized as described above.
- D. Respondents shall institute procedures and requirements to ensure that those employees of the Respondents that are authorized to have access to such Confidential Business Information:
1. do not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information in contravention of the Orders; and
 2. do not solicit, access, or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose.

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- E. Respondents shall take all actions necessary and appropriate to prevent access to, and the disclosure or use of, such 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 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 such Confidential Business Information separate from other data or information of the Respondents; and
 3. ensuring by other reasonable and appropriate means that such 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 Divestiture Product Businesses (*e.g.*, commercialization of Products Developed, in Development, marketed or sold for the same or similar indications as the Divestiture Products).

IV. 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 Divestiture Agreements pursuant to the agreement between Monitor and Respondents in Appendix A and Non-Public Appendix B to the Decision and Order.
- B. Not later than 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

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Monitor to monitor compliance with the obligations to Transition Package and to transfer and deliver the Product Manufacturing Technology;

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 Packaging, transition services, and the transfer of the Clinical Trials, as applicable, for each Acquirer *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.
- D. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders.
- E. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Respondents shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by the Acquirer with respect to the performance of a Respondent's obligations under the Orders. Within 30 days after the date this Order to Maintain Assets is issued and every 90 days thereafter, and at such other times as may be requested by staff of the Commission, the Monitor

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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 toward obtaining FDA approval (i) for indications on a Divestiture Product related to any Clinical Trials that were planned or ongoing on or before the Divestiture Date, and (ii) to manufacture in commercial quantities, in a manner consistent with cGMP, independently of Respondents, each Divestiture Product that was manufactured by a Respondent on or before the Divestiture Date.

- I. Each Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor:
 - 1. the Commission shall select the substitute Monitor, subject to the consent of Respondent AbbVie, which consent shall not be unreasonably withheld. If Respondent AbbVie has not opposed, in writing, including the reasons for opposing, the selection of a substitute Monitor within 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 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.

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- 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 30 days after the date this Order to Maintain Assets is issued by the Commission, and every 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 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:
 - a. the transfer and delivery to the relevant Acquirer of all of the following: (i) the Divestiture Assets; (ii) the Product Manufacturing Technology related to the Divestiture Products; (iii) the Clinical Trial(s) related to the Divestiture Products; (iv) the Confidential Business Information related to the Divestiture Product Business; and
 - b. the provision of Transition Packaging and/or 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
- D. to perform this function. Respondents shall submit an original and 2 copies of each Compliance Report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the

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Compliance Division at bccompliance@ftc.gov. In addition, Respondents shall provide a copy of each Compliance Report to the Monitor.

- E. 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 30 days prior to:

- A. any proposed dissolution of AbbVie Inc. or Allergan plc;
- B. any proposed acquisition, merger, or consolidation of AbbVie Inc. or Allergan plc; 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.

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-days' notice to a Respondent made to its principal United States offices, 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 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.

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 each of the Divestiture Product Businesses through its full transfer and delivery to an Acquirer; to minimize any risk of

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loss of competitive potential for each of the Divestiture Product Businesses; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture 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. 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 Divestiture Assets, the Product Manufacturing Technology, and the Clinical Trials related to each of the Divestiture Products, have been transferred to and are in the physical possession of the relevant Acquirer, as required by and described in the Decision and Order.

By the Commission.

DECISION

The Federal Trade Commission (“Commission”) initiated an investigation of the proposed acquisition by Respondent AbbVie Inc. of all of the voting securities of Respondent Allergan plc. The Commission’s Bureau of Competition prepared and furnished to each Respondent 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 Containing Consent Orders (“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

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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 AbbVie Inc. is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware with its executive offices and principal place of business located at 1 North Waukegan Road, North Chicago, Illinois 60064.
2. Respondent Allergan plc is a public limited company organized, existing, and doing business under, and by virtue of, the laws of the Republic of Ireland with its principal executive offices located at Clonsaugh Business and Technology Park, Coolock Dublin, D17 E400, Ireland. Allergan’s United States address for service of process is as follows: Chief Legal Officer, Allergan plc, 5 Giralda Farms, Madison, New Jersey 07940.
3. The Federal Trade 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 this Order, the following definitions apply:

- A. “AbbVie” means AbbVie, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by AbbVie, Inc. (including Venice Subsidiary, LLC), and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- B. “Allergan” means Allergan plc, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Allergan plc, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Acquirer(s)” means:
 1. a Person specified by name in this Order to acquire particular Divestiture Assets pursuant to this Decision and Order; or

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2. any other Person that the Commission approves to acquire particular Divestiture Assets pursuant to this Decision and Order.
- E. “Acquisition Date” means the date on which AbbVie acquires 50 percent or more of the voting securities of Allergan.
- F. “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 the FDA.
- G. “AstraZeneca” means AstraZeneca PLC, a public limited company, organized, existing, and doing business under and by virtue of the laws the United Kingdom with its executive offices and principal place of business located at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom, and any Person controlled by or under common control of AstraZeneca PLC.
- H. “Brazikumab Divestiture Agreement” means the Termination Agreement by and among AstraZeneca Collaboration Ventures, LLC, Allergan Pharmaceuticals International Limited, Allergan Therapeutics LLC, and Allergan Finance, LLC, dated as of January 25, 2020; and all amendments, exhibits, attachments, agreements, attached to this Order and contained in Non-Public Appendix I.
- I. “Brazikumab Divestiture Assets” means all rights, title and interest in the Divestiture Product Business related to the Brazikumab Products, including all of the Transferred Assets related to the Brazikumab Products.
- J. “Brazikumab Products” mean:
1. brazikumab (an investigational product), with International Nonproprietary Name ID #10425, and a development code MEDI2070; and
 2. any other Product manufactured by or for Respondent Allergan, or in Development, marketed, or sold by Respondent Allergan prior to the Divestiture Date that is a human monoclonal antibody that targets Interleukin-23.
- K. “Business” means (i) the research, Development, or manufacture of a Product wherever located throughout the world, and (ii) the commercialization, distribution, marketing, advertisement, and sale of a Product within the United States, including, the importation of a Product into the United States.

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- L. “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).
- M. “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.
- N. “Clinical Plan” means a written clinical plan setting forth the protocol for the conduct of a Clinical Trial, preparation and filing of each Clinical 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.
- O. “Clinical Regulatory Package” means, with respect to each Divestiture 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 Divestiture Product or required to Develop, manufacture, distribute, or otherwise commercialize such Divestiture 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).
- P. “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.
- Q. “Clinical Trial Research Organization Designee” means any Person other than the Respondents that has been designated by an Acquirer to conduct a Clinical Trial related to a Divestiture Product for an Acquirer.
- R. “Confidential Business Information” means all Business Information relating to the Divestiture Product Business that is not in the public domain.
- S. “Customer” means any Person that is a direct purchaser of any Divestiture Product from a Respondent or the Acquirer.

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- T. “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.
- U. “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.
- V. “Divestiture Agreements” mean:
1. the Brazikumab Divestiture Agreement;
 2. the Pancrelipase Divestiture Agreement; 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.
- W. “Divestiture Assets” mean:
1. the Brazikumab Divestiture Assets; and
 2. the Pancrelipase Divestiture Assets.
- X. “Divestiture Date” means, for each of the respective Divestiture Assets, the date on which a Respondent (or a Divestiture Trustee) close on the sale of those Divestiture Assets to an Acquirer.
- Y. “Divestiture Products” mean:
1. the Brazikumab Products;
 2. the Viokace Products; and
 3. the Zenpep Products.
- Z. “Divestiture Product Business” means the Business related to a Divestiture Product.

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- AA. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph X of this Order.
- BB. “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.
- CC. “Drug Master File” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- DD. “Excluded Assets” mean:
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 a Divestiture Product Business, in those cases in which the redaction does not impair the usefulness of the information related to the Divestiture Product Business;
 4. any original document for which 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;
 5. (i) any tax asset relating to (a) the Divestiture Assets for pre-Divestiture Date tax periods or (b) any tax liability that any Respondent is responsible for arising out of the divestiture of the Divestiture Assets, (ii) all accounts receivable, notes receivable, rebates receivable and other miscellaneous receivables of any Respondent that are related to the Divestiture Product Business and arising out of the operation of the Divestiture Product Business prior to the Divestiture Date, and (iii) all cash, cash equivalents, credit cards and bank accounts of any Respondent; and
 6. any records or documents reflecting attorney-client, work product or similar privilege of any Respondent or otherwise relating to the Divestiture Assets as a result of legal counsel representing any Respondent in connection with the divestiture of the Divestiture Assets pursuant to this Order or the Divestiture Agreements.

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- EE. “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. “FDA Authorization” also includes any Biologic License Application (“BLA”) filed or to be filed with the FDA pursuant to 21 C.F.R. 601.2, et seq., and Section 351 of the Public Health Service Act, and any NDA deemed to be a Biologic License Application by the FDA, and all supplements, amendments, revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondents and the FDA or other Agency relative thereto.
- FF. “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.
- GG. “Manufacturing Designee” means any Person other than a Respondent that has been designated by an Acquirer to perform any part of the manufacturing process, including the finish and/or packaging, of a Divestiture Product on behalf of an Acquirer.
- HH. “Monitor” means any monitor appointed pursuant to Paragraph IX of this Order or Paragraph IV of the related Order to Maintain Assets.
- II. “Nestlé” means Nestlé S.A., a Société Anonyme, organized, existing, and doing business under and by virtue of the laws of the Swiss Confederation with its executive offices and principal place of business located at Avenue Nestlé 55, CH-1800 Vevey, Switzerland, and any Person controlled by or under common control of Nestlé S.A.
- JJ. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.
- KK. “Orders” means this Decision and Order and the related Order to Maintain Assets.

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- LL. “Pancrelipase Divestiture Agreement” means the Asset Purchase Agreement between Allergan Therapeutics LLC, Allergan Sales, LLC, Aptalis Pharma Canada ULS, as the Sellers, and Société des Produits Nestlé S.A., as Purchaser, dated as of January 25, 2020, and all amendments, exhibits, attachments, agreements, attached to this Order and contained in Non-Public Appendix II.
- MM. “Pancrelipase Divestiture Assets” mean:
1. the Zenpep Divestiture Assets; and
 2. the Viokace Divestiture Assets.
- NN. “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.
- OO. “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.
- PP. “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.
- QQ. “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.
- RR. “Product Contracts” means all contracts, agreements, mutual understandings, arrangements, or commitments related to the Divestiture Product Business, including those:
1. pursuant to which any third party purchases, or has the option to purchase, a Divestiture 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 a Divestiture Product;
 3. relating to any Clinical Trial involving a Divestiture Product;
 4. with universities or other research institutions for the use of a Divestiture Product in scientific research;
 5. for the marketing of a Divestiture Product;
 6. for educational matters relating solely to the Divestiture Products;
 7. pursuant to which a third party manufactures or plans to manufacture a Divestiture Product as a finished dosage form on behalf of a Respondent;
 8. 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 a Divestiture Product on behalf of a Respondent;
 9. pursuant to which a third party licenses any of the Product Manufacturing Technology related to a Divestiture Product to a Respondent;
 10. pursuant to which a third party is licensed by a Respondent to use any of the Product Manufacturing Technology related to a Divestiture Product;
 11. constituting confidentiality agreements involving a Divestiture Product;
 12. involving any royalty, licensing, covenant not to sue, or similar arrangement related to a Divestiture Product;
 13. pursuant to which a third party provides any specialized services necessary to the research, Development, manufacture, or distribution of a Divestiture Product to a Respondent including, consultation arrangements; and
 14. pursuant to which any third party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of a Divestiture Product or the Divestiture Product Business.
- SS. “Product Core Employees” mean the Product Marketing Employees, Product Manufacturing Employees, Product Research and Development Employees and Product Sales Employees.

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- TT. “Product Development Reports” mean Business Information, as related to the Development of a Product, including:
1. pharmacokinetic study reports;
 2. bioavailability study reports (including Reference Listed Drug information);
 3. bioequivalence study reports (including Reference Listed Drug information);
 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);
 5. annual and periodic reports related to the above-described FDA Authorization(s), including any safety update reports;
 6. FDA approved labeling;
 7. currently used or planned product package inserts (including historical change of controls summaries);
 8. FDA approved patient circulars and information;
 9. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy;
 10. summaries of complaints from physicians or clinicians;
 11. summaries of complaints from Customers;
 12. Product recall reports filed with the FDA, 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 Product;
 14. reports from any Person (e.g., any consultant or outside contractor) engaged to investigate or perform testing for the purposes of resolving any Product or process issues, including, without limitation, identification and sources of impurities 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 Product that relate to the specifications, degradation,

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chemical interactions, testing, and historical trends of the production of any Product;

16. analytical methods development records;
17. manufacturing batch or lot records;
18. stability testing records;
19. change in control history; and
20. executed validation and qualification protocols and reports.

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

1. 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 Divestiture Product Business; *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);
 - 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
2. 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 Product Core Employees.

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- VV. “Product Intellectual Property” means intellectual property of any kind, that is owned, licensed, held, or controlled by a Respondent related to the specified Divestiture Product as of the Divestiture Date, including:
1. Patents;
 2. Product Manufacturing Technology;
 3. copyrights;
 4. trademarks;
 5. trade dress;
 6. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and
 7. 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.
- WW. “Product 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 specified Divestiture Product: (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, (vii) managing the technological transfer of any part of the manufacturing process to a different facility or (viii) providing any assistance to a third party that provides any part of the manufacturing process to a Respondent, within the 3 year period immediately prior to the Divestiture Date.
- XX. “Product Manufacturing Equipment” means equipment that is being used, or has been used at any time since Respondents entered into the Acquisition Agreement to manufacture the specified Divestiture Products.
- YY. “Product Manufacturing Technology” means 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

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product specifications, processes, analytical methods, product designs, plans, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA, FDA Authorization(s) conformance and cGMP compliance, labeling, packaging, and all other information related to the manufacturing process, and supplier lists.

ZZ. “Product 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 specified Divestiture Product 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-month period immediately prior to the Divestiture Date.

AAA. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of any Divestiture Product 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 Divestiture Products

BBB. “Product Releasee(s)” means any of the following Persons:

1. the Acquirer;
2. any Person controlled by or under common control with an Acquirer;
3. any Manufacturing Designee(s);
4. any Clinical Trial Research Organization Designee(s); and

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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 Divestiture Products acquired by that Acquirer.
- CCC. “Product 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 a specified Divestiture Product: research, Development, regulatory approval process, or Clinical Trials of the Divestiture Products, within the eighteen-month period immediately prior to the Divestiture Date.
- DDD. “Product 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 specified Divestiture Products in the United States: the detailing, marketing, or promotion of the Products directly to physicians, pharmacists, professional distributors, managed care or other insurance providers, hospitals, employers, or governmental entities within the eighteen-month period immediately prior to the Divestiture Date.
- EEE. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information related to a Product.
- FFF. “Proposed Acquirer” means a Person proposed by a Respondent (or a Divestiture Trustee) to 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.
- GGG. “Retained Product(s)” means any Product(s) other than a Divestiture Product that is manufactured, in Development, marketed, sold, owned, controlled, or licensed by a Respondent anywhere in the world on or before the Acquisition Date and that has not been discontinued or permanently withdrawn from the market.
- HHH. “Shared Intellectual Property” means all Product Intellectual Property of any kind (other than trademarks, Domain Names, and FDA Authorizations related to a Divestiture Product) (i) that is used in connection with a Divestiture Product Business as of the Divestiture Date, and (ii) that has been used, and continues to be used in connection with any Retained Product.
- III. “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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- JJJ. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to that 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 who will be responsible for communicating directly with that Acquirer and/or its Manufacturing Designee, and the Monitor, 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 Product that are acceptable to that 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 that Acquirer;
 4. for any part of the manufacturing process (including packaging) that is performed by a Respondent, permitting employees of the Acquirer and/or its Manufacturing Designee to visit the Respondent’s facility where that process occurs for the purposes of evaluating and learning that process or discussing the process with employees of Respondents involved in that process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, methods to ensure batch or lot consistency); and
 5. providing, in a timely manner, assistance and advice to enable the Acquirer to:
 - a. manufacture the Product in the quality and quantities achieved by a Respondent, or the manufacturer and/or developer of the Product;
 - b. obtain any Product Approvals necessary for the Acquirer to manufacture, distribute, market, and sell the Product in commercial quantities and to meet all Agency-approved specifications for the Product; and
 - c. receive, integrate, and use all Product Manufacturing Technology used in, and all Product Intellectual Property that is related to, the manufacture of the Product.

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KKK. “Transferred Assets” means all right, title, and interest in and to the assets, properties, and rights, wherever located in the world, relating to the Business of the specified Divestiture Product, as such assets, properties, and rights shall exist at the date the Respondents sign the Consent Agreement, including the following:

1. all FDA Authorizations;
2. all Clinical Trials;
3. all Product Intellectual Property;
4. all Product Approvals;
5. at the Acquirer’s option, all Product Manufacturing Equipment;
6. all Product Marketing Materials;
7. all Product Scientific and Regulatory Material;
8. all website(s) and Domain Names related exclusively to the Divestiture Product and the content thereon related exclusively to the Divestiture Product, and the content related exclusively to the Divestiture Product that is displayed on any website that is not dedicated exclusively to the Divestiture Product;
9. at the option of the Acquirer, all Product Contracts;
10. all Business Information, which includes the Product Development Reports;
11. a list of any finished Divestiture Product batch or lot determined to be out-of-specification during the three-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 Divestiture Product; and (iii) to the extent known by any Respondent, the employees (whether current or former) responsible for taking such corrective actions;
12. for each Divestiture Product:
 - a. to the extent known or available to the Respondents, a list of the inventory levels (weeks of supply) in the possession of each Customer as of the date prior to and closest to the Divestiture Date as is available; and

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

13. at the option of the Acquirer, all inventory and all ingredients, materials, or components used in the manufacture of the Divestiture 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 Divestiture Products;

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

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

provided, however, that “Transferred Assets” does not include the Excluded Assets.

LLL. “Transition Package” and “Transition Packaging” mean to provide, or to cause to be provided, any part of the packaging of a finished dosage form of a Divestiture Product that is being packaged by Respondents at the time of the Consent Agreement on behalf of an Acquirer (including for the purposes of Clinical Trials and/or commercial sales).

MMM. “United States” means the United States of America, and its territories, districts, commonwealths and possessions.

NNN. “Viokace Divestiture Assets” mean all rights, title and interest in the Divestiture Product Business related to the Viokace Products, including all of the Transferred Assets related to the Viokace Products, including the Viokace trademarks.

OOO. “Viokace Products” mean the Products manufactured, in Development, marketed, or sold pursuant to the following FDA Authorization: NDA No. 022542 (now deemed by the FDA a BLA), and any supplements, amendments, or revisions to this NDA or BLA.

PPP. “Zenpep Divestiture Assets” means all rights, title and interest in the Divestiture Product Business related to the Zenpep Products, including all of the Transferred Assets related to the Zenpep Products, including the Zenpep trademarks.

QQQ. “Zenpep Products” mean:

1. the Products manufactured, in Development, marketed, or sold pursuant to the following FDA Authorization: NDA No. 022210 (now deemed by the

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FDA a BLA), and any supplements, amendments, or revisions to this NDA or BLA; and

2. any Product, other than the Viokace Products, manufactured by or for Respondent Allergan, or in Development by Respondent Allergan for commercialization, distribution, marketing, advertisement or sale within the United States, and any other Product marketed or sold by Respondent Allergan within the United States prior to the Divestiture Date that contains lipase as an active pharmaceutical ingredient.

II. Divestiture

IT IS FURTHER ORDERED that:

- A. No later than 10 days after the Acquisition Date, Respondents shall divest the Brazikumab Divestiture Assets, absolutely and in good faith, to AstraZeneca pursuant to, and in accordance with the Brazikumab Divestiture Agreement;

provided, however, the Respondents may need to divest Excluded Assets if the Commission, in its sole discretion and within 12 months of the date this Order is issued, determines in consultation with the Acquirer and the Monitor, that any such assets are necessary for the Acquirer to operate the Brazikumab Divestiture Assets or the relevant Divestiture Product Business in a manner that achieves the purposes of this Order.

- B. No later than 10 days after the Acquisition Date, Respondents shall divest the Pancrelipase Divestiture Assets, absolutely and in good faith, to Nestlé pursuant to, and in accordance with the Pancrelipase Divestiture Agreement;

provided, however, the Respondents may need to divest Excluded Assets if the Commission, in its sole discretion and within 12 months of the date this Order is issued, determines in consultation with the Acquirer and the Monitor, that any such assets are necessary for the Acquirer to operate the Pancrelipase Divestiture Assets or the relevant Divestiture Product Business in a manner that achieves the purposes of this Order.

- C. Respondents may receive a non-exclusive license from each 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 either (i) not indicated for the same treatment of disease as the Divestiture Products being acquired by that Acquirer, or (ii) not for commercialization, distribution, marketing, advertisement, or sale within the United States.

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- D. If Respondents have divested any of the Divestiture Assets to an Acquirer prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that:
1. the named Acquirer is not an acceptable purchaser of any of the Divestiture Assets, then Respondents shall immediately rescind the transaction with that Acquirer as directed by the Commission, and shall divest the Divestiture Assets within 180 after the Order Date, absolutely and in good faith, at no minimum price, to a different 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 Divestiture Assets to Acquirer named in this Order (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 relevant Acquirer with the opportunity to review all Product Contracts related to the Divestiture Products being acquired by that Acquirer for the purposes of that Acquirer's determination of whether to assume such Product Contracts;
- provided, however,* that in cases in which any Product Contract 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 Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product.
- F. Prior to the Divestiture Date, Respondents:
1. shall secure all approvals, consents, ratifications, waivers, or other authorizations from all non-governmental third parties that are necessary to permit Respondents to divest the Divestiture Assets to an Acquirer, and to permit each Acquirer to continue the Divestiture Product Business in the United States without interruption or impairment; and
 2. as related to licensed Product Manufacturing Technology, 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 such Divestiture Products. Such agreements include agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than 10 days after the Divestiture

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Date, Respondents shall grant a release to each third party that is subject to such agreements that allows the third party to provide the Product Manufacturing Technology related to the Acquirer. Within 5 days of the execution of each such release, Respondents shall provide a copy of the release to the relevant Acquirer;

provided, however, Respondents may satisfy this requirement by certifying that the relevant Acquirer has executed all such agreements directly with each of the relevant third parties.

- G. Respondents shall deliver to the Acquirer the Product Manufacturing Technology – either divested or licensed by a third party – related to the Divestiture Products being acquired by or licensed to that Acquirer in a manner consistent with the Technology Transfer Standards.
- H. Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale related to the Divestiture Products to assist each Acquirer to transfer and integrate the Divestiture Product Business(es) acquired by that Acquirer.
- I. Respondents shall not:
 - 1. use any of the trademarks divested pursuant to this Order or any mark confusingly similar to those trademarks as a trademark, tradename, or service mark, *except* as may be agreed upon with the relevant Acquirer for the purposes of selling inventory, finished goods, packaging or similar materials bearing the relevant trademarks for the benefit of the relevant Acquirer during a transition period;
 - 2. attempt to register the divested trademarks;
 - 3. attempt to register any mark confusingly similar to the divested trademarks;
 - 4. challenge or interfere with an Acquirer's use and registration of the divested trademarks; or
 - 5. challenge or interfere with an Acquirer's efforts to enforce its trademark registrations for, and trademark rights in, the divested trademarks against third parties.
- J. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Product 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 the Divestiture Product(s) acquired

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by that Acquirer anywhere in the world, or to distribute, market, sell, or offer for sale within the United States any such Divestiture 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 or at such cost as provided in a Divestiture Agreement, assistance of knowledgeable employees of Respondents (*i.e.*, employees of Respondents that were involved in the Development of the Divestiture Products) to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a third party related to the Product Intellectual Property related to the Divestiture Products acquired by that Acquirer.
- 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 any Divestiture Products or (ii) any potential patent infringement suit that a Respondent has prepared, or is preparing, to bring or defend against as of the Divestiture Date that is related to any Divestiture Products, Respondents shall:
1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of such patent infringement suit;
 2. waive conflicts of interest, if any, to allow Respondents' outside legal counsel to represent the Acquirer in any such patent infringement suit; and
 3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of the Respondents' outside counsel related to such patent infringement suit.

III. Divestiture Agreements

IT IS FURTHER ORDERED that:

- A. The Divestiture Agreements shall be incorporated by reference into this Order and made a part hereof, and any failure by Respondents to comply with the terms of either of the Divestiture Agreements shall constitute a violation of this Order; *provided, however*, that the Divestiture Agreements shall not limit, or be construed to limit, the terms of this Order. To the extent any provision in the Divestiture Agreements varies from or conflicts with any provision in the Order such that Respondents cannot fully comply with both, Respondents shall comply with the Order.
- B. Respondents shall not modify or amend the terms of the Divestiture Agreements after the Commission issues the Order without the prior approval of the Commission, except as otherwise provided in Commission Rule 2.41(f)(5), 16 C.F.R. § 2.41(f)(5).

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IV. Transition Packaging and Services by Respondents**IT IS FURTHER ORDERED** that:

- A. At the request of an Acquirer, in a timely manner, at no greater than Direct Cost or at such cost as provided in a Divestiture Agreement, Respondents shall provide transition services sufficient to enable the Acquirer to operate each Divestiture Product Business acquired by that Acquirer in substantially the same manner that Respondents have operated that Business prior to the Acquisition Date.
- B. Upon reasonable written notice and request from an Acquirer of a Divestiture Product to Respondents, Respondents shall Transition Package and deliver, or cause to be packaged and delivered, to a facility(ies) designated by that Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Divestiture Products at no greater than Supply Cost or at such cost as provided in a Divestiture Agreement, for a period of time sufficient to allow that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all of the relevant Product Approvals necessary to package in commercial quantities, and in a manner consistent with cGMP, the finished dosage form drug product independently of Respondents, and to secure sources of supply of the necessary packaging components from Persons other than the Respondents.
- C. Respondents shall make representations and warranties to the relevant Acquirer that any Transition Packaging provided by Respondents for the packaged finished dosage form of any Divestiture Product meet the relevant Agency-approved specifications.
- D. For the Divestiture Products 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 packaging the of the Divestiture Product(s) supplied to the Acquirer pursuant to Divestiture Agreements by Respondents 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 Divestiture Products in the manner required by this Order;

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

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- E. Respondents shall give at least the same level of priority to packaging and supplying a Divestiture Product to the relevant Acquirer as Respondents give to the packaging and supplying of Products for Respondents' own use or sale.
- F. Respondents shall agree to hold harmless and indemnify that Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of the Respondents to package and supply the Divestiture 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 30 days after the receipt of notice from that Acquirer of a supply failure;

provided however, the Divestiture Agreements 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 a Divestiture Product to that Customer that was the result of Respondent's failure to supply the Divestiture Product to the Acquirer.

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

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

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- K. Respondents shall permit the Acquirer to terminate any agreement to Transition Package 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).
- L. During the term of any agreement to Transition Package, 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 package the Divestiture 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 packaging of the Divestiture Products.

V. Employees**IT IS FURTHER ORDERED** that:

- A. Respondents shall for a period of 2 years after the Divestiture Date, or until Respondents have completed their obligations to Transition Package pursuant to Paragraph IV. of the Order, whichever occurs later:
 - 1. cooperate with and assist any Proposed Acquirer or Acquirer of the Divestiture Assets to evaluate independently and offer employment to the Product Core Employees relating to each of the Divestitures;
 - 2. provide the Proposed Acquirer or Acquirer with a complete and accurate list containing the name of each Product Core Employee (including former employees who were employed by a Respondent in the 90 days preceding the execution date of the related Divestiture Agreement);
 - 3. not later than 10 days after written request by a Proposed Acquirer or Acquirer, provide the Product Employee Information related to the Product Core Employees;
 - 4. Provide a reasonable opportunity for the Proposed Acquirer or Acquirer:
 - a. to interview any Product Core Employee;
 - b. to meet personally, and outside the presence or hearing of any employee or agent of Respondents, with any of the Product Core Employees; and

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- c. to make offers of employment to any of the Product Core Employees.

provided, however, that the provision of such information may be conditioned upon the Proposed Acquirer's or 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 Product Core Employees the opportunity to enter into employment contracts; 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;

- 5. not interfere with the hiring or employing by the Acquirer or its Manufacturing Designee of the Product 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;
- 6. not make any counteroffer to any Product 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 Product 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.

- B. Until the Divestiture Date, provide all Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divestiture Product Businesses and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by a Respondent until the Divestiture Date(s) for the divestiture of the Divestiture Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by law).
- C. If, at any point within 6 months of the Divestiture Date, the Commission, in consultation with the Acquirer and the Monitor, determines in its sole discretion that the Acquirer should have the ability to interview, make offers of employment to, or hire any of Respondents' employees who were not included as Product Core Employees, but who either (i) were involved with any of the Divestiture Products at Allergan, or (ii) provided Transition Packaging or transition services to an

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Acquirer, then the Commission may notify Respondents that such employees are to be designated as Product Core Employees, and the provisions of this Paragraph V shall apply to such employees as of that notification date.

- D. From the Divestiture Date until the date that is 1 year after the Divestiture Date, Respondents shall not, directly or indirectly, solicit any employee of an Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture 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 Divestiture 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, for the Confidential Business Information that is related to the Divestiture Product Business(es) acquired by a particular Acquirer:
1. transfer and deliver to that Acquirer, at Respondents’ expense, all 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 Confidential Business Information to that Acquirer, provide the Acquirer with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the Business Information that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
 3. not use, directly or indirectly, any such Confidential Business Information other than as necessary to comply with the following:

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- a. the requirements of the Orders;
 - b. Respondents' obligations to that Acquirer under the terms of the related Divestiture Agreement; or
 - c. applicable law;
4. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person *except* (i) that Acquirer, (ii) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (*e.g.*, employees of a Respondent providing transition services or Transition Packaging for Acquirer), (iii) the Commission, or (iv) the Monitor and *except* to the extent necessary to comply with applicable law;
5. not provide, disclose, or otherwise make available, directly or indirectly, any 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 Packaging to the Acquirer or who are engaged in the transfer and delivery of the Product Manufacturing Technology related to the Divestiture Products or the ongoing Clinical Trials related to the Divestiture 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 Confidential Business information:
 - a. do not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of the Orders; and
 - b. do not solicit, access, or use any 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 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 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 Confidential Business Information separate from other data or information of the Respondents; and
 - c. ensuring by other reasonable and appropriate means that the 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 Divestiture Products (*e.g.*, Products Developed or in Development for the same or similar indications as the Divestiture Products).
- B. Respondents shall require, as a condition of continued employment post-divestiture of the Divestiture Assets, that each employee that has had responsibilities related to the marketing or sales of the Divestiture 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 Divestiture Products, in each case who have or may have had access to 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 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 30 days after the Divestiture Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information by that Respondents' personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such 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 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

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where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

1. to assure such Respondent's compliance with any 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 a Divestiture Product, the Divestiture Assets, or the Divestiture Product 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 Divestiture Assets to the Acquirer and fully provide, or cause to be provided, the related Product Manufacturing Technology related to the Divestiture Products and Clinical Trials related to the Divestiture Products to the Acquirer, Respondents shall take actions as are necessary to:
 1. maintain the full economic viability and marketability of the Divestiture Assets;
 2. prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets;
 3. ensure that the Divestiture Assets are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Divestiture Product 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 Divestiture 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 Divestiture 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 Divestiture 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 Clinical 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 the relevant 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 Divestiture Agreements pursuant to the agreement between Monitor and Respondents in Appendices A and B to this Order.
- B. Not later than 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 Package and to transfer and deliver the Product Manufacturing Technology;
 - 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 Packaging, transition services, and the transfer of Clinical Trials, as applicable, for each Acquirer;

provided, however, that the Monitor's service shall not extend more than 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

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request, related to that Respondent's compliance with its obligations under the Orders.

- E. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Respondents shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by the Acquirer with respect to the performance of a Respondent's obligations under the Orders. Within thirty 30 days after the Order Date and every 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 toward obtaining FDA approval (i) for indications on a Divestiture Product related to any Clinical Trials that were planned or ongoing on or before the Divestiture Date, and (ii) to manufacture in commercial quantities, in a manner consistent with cGMP, independently of Respondents, each Divestiture Product that was manufactured by a Respondent on or before the Divestiture Date.
- 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

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materials and information received in connection with the performance of the Monitor's duties.

- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor:
1. the Commission shall select the substitute Monitor, subject to the consent of Respondent AbbVie, which consent shall not be unreasonably withheld. If Respondent AbbVie has not opposed, in writing, including the reasons for opposing, the selection of a substitute Monitor within 10 days after notice by the staff of the Commission to Respondent AbbVie 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 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 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 Divestiture 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

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any other statute enforced by the Commission, for any failure by a Respondent to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 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 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; and
 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.
- E. 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

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shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by a Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

- F. 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 5 days after receiving notification of the Commission's approval.

- G. 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.
- H. 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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- I. 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.
- J. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 30 days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
- K. 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.
- L. 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.
- M. 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.
- N. 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 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 5 days after the Divestiture Date, Respondents shall notify Commission staff of the Divestiture Date, including electronic copies of the notification to the Secretary of the Commission at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov.

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- C. Not later than 30 days 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 30 days after the Order Date, and every 90 days thereafter until Respondents have completed all of the following: (i) the transfer and delivery of all of the Divestiture Assets to an Acquirer, (ii) the transfer and delivery of all of the Product Manufacturing Technology related to the Divestiture Products to an Acquirer, (iii) the transfer and delivery of all Confidential Business Information to an Acquirer, and (iv) the provision of Transition Packaging and/or transition services to an 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:
 - a. the transfer and delivery to an Acquirer of all of the following: (i) the Divestiture Assets, (ii) the Product Manufacturing Technology related to the Divestiture Products, (iii) the Clinical Trial(s) related to the Divestiture Products, (iv) the Confidential Business Information related to the Divestiture Product Business; and
 - b. the provision of Transition Packaging and/or transition services to the Acquirer; and
 2. a detailed description of the timing for the completion of such obligations.
- F. One year after the Order Date, annually for the next 4 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 30 days prior to:

- A. any proposed dissolution of AbbVie Inc. or Allergan plc;
- B. any proposed acquisition, merger, or consolidation of AbbVie Inc. or Allergan plc; 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-days' notice to a Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that 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 books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and
- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

XIV. Purpose

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

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- A. to ensure the continued use of such assets for the purposes of each of the Divestiture Product Businesses within the United States;
- B. to create a viable and effective competitor that is independent of Respondents in the Divestiture Product Businesses within the United States; and
- C. to remedy the lessening of competition resulting from the proposed acquisition of Respondent Allergan by Respondent AbbVie 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 September 3, 2030.

By the Commission, Commissioner Chopra dissenting and Commissioner Slaughter not participating.

NON-PUBLIC APPENDIX A

NON-PUBLIC APPENDIX B

Statement of the Commission

STATEMENT OF CHAIRMAN JOSEPH J. SIMONS, COMMISSIONER NOAH JOSHUA PHILLIPS, AND COMMISSIONER CHRISTINE S. WILSON CONCERNING THE PROPOSED ACQUISITION OF ALLERGAN PLC BY ABBVIE INC.

AbbVie Inc. (“AbbVie”), the seventh largest pharmaceutical company in the world by revenue, proposes to acquire Allergan plc (“Allergan”), the twentieth largest.¹ The parties’ portfolios are largely complementary, as AbbVie primarily develops and markets products in the immunology, oncology, and virology areas, while Allergan is focused on aesthetics and eye care. This transaction poses competitive concerns in three relevant markets: (1) drugs for the treatment of exocrine pancreatic insufficiency (“EPI”); (2) Interleukin-23 (“IL-23”) inhibitors for the treatment of moderate-to-severe Crohn’s disease; and (3) IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. In these areas, the parties are two of a limited number of firms with products on the market or in development.

The Commission has voted 3-2 to issue a complaint and accept a settlement resolving every substantial threat to competition uncovered by FTC staff and supported by the evidence, after a thorough investigation lasting ten months and involving more than forty interviews and the review of more than 430,000 documents. The proposed order remedies the competitive concerns by requiring the merging parties to divest Allergan’s EPI drugs Zenpep and Viokace to Nestlé,

S.A. (“Nestlé”) and to transfer Allergan’s assets related to the IL-23 inhibitor brazikumab back to AstraZeneca plc (“AstraZeneca”), the drug’s original developer, by terminating the AstraZeneca license to Allergan. These divestitures fully remedy any potential loss of competition from the proposed transaction.

To challenge a merger successfully under the Clayton Act, the Commission must have proof that its likely effect is “substantially to lessen competition.” We cannot meet this burden of proof just by surmising there might be harm. Likewise, when the Commission pursues divestitures to replace competition otherwise lost by a merger, we also must rely on proof. For this reason, our decisions, as to the determination of harm and the quality of both divestitures, are based on what actual evidence shows, following an extensive investigation by the Commission staff.

Our colleagues Commissioners Chopra and Slaughter, who in the past have expressed² and today reiterate their general opposition to pharmaceutical mergers, have come to a different

1 See RankingtheBrands.com, Top 50 Global Pharma Companies 2019, <https://www.rankingthebrands.com/The-Brand-Rankings.aspx?rankingID=370>.

2 Dissenting Statement of Commissioner Rohit Chopra, *In the Matter of Bristol-Myers Squibb/Celgene* (Nov. 15, 2019), https://www.ftc.gov/system/files/documents/public_statements/1554293/dissenting_statement_of_commissioner_chopra_in_the_matter_of_bristol-myers-celgene_1910061.pdf (hereinafter “Chopra Bristol-Meyers Dissent”); Dissenting Statement of Commissioner Rebecca Kelly Slaughter, *In the Matter of Bristol-Myers Squibb /Celgene* (Nov. 15, 2019), https://www.ftc.gov/system/files/documents/public_statements/1554283/17_-_final_rks_bms-celgene_statement.pdf.

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conclusion about the proposed settlement and have voted against accepting it. We respect their independent assessment of the proposed settlement. Differences of opinion facilitate healthy debate within the Commission. We value the exchange of ideas and policy perspectives, which enhances the Commission's ability to protect competition and consumers.

However, we disagree with Commissioner Chopra's characterization of the proposed settlement and of staff's investigation in this case. While we share his commitment to preserving competition in the pharmaceutical industry, we are concerned by his dissent's disregard for facts and law and its dismissal of the work of the dedicated and hardworking FTC staff. His dissent makes misleading claims about the staff's investigation, the state of competition in the pharmaceutical industry, and the Commission's enforcement record in this industry. It relies on false assertions, misapplication of law, and specious logic. It appears to have fully embraced the adage to "never let the truth get in the way of a good story" and engages in unbounded speculation, while criticizing forecasts based on rigorous investigation and grounded in evidence. Where facts conflict with theory, we follow the facts, even if they lead to an outcome we do not like.

In this statement, we attempt to set the record straight. We provide the perspective, context, logic, and facts missing from Commissioner Chopra's dissent. We also provide a response to the points raised in Commissioner Slaughter's dissent.

As occurs in every transaction, and despite the suboptimal working conditions created by the COVID-19 response, staff conducted a comprehensive and meticulous investigation of the proposed transaction and proposed divestiture buyers. As is typical, the identified competitive overlaps and required divestitures do not reflect the full scope of the Commission staff's investigation. Staff also investigated numerous other potential overlapping products and considered other possible effects that might result from the proposed combination of these companies. In addition, staff conducted extensive due diligence to evaluate the proposed divestiture buyers and the divestiture asset packages. Any assertion that the Commission did not consider every plausible theory or impact actionable under the antitrust laws is incorrect.

1. Divestiture of brazikumab to AstraZeneca

The point of a structural remedy is to replace the competition threatened by the merger. In the case of brazikumab, the IL-23 inhibitor still under development, the question is whether AstraZeneca, the drug's original developer and one of the largest pharmaceutical companies in the world, suffices to replace Allergan, a company that licensed brazikumab from AstraZeneca in 2016, has not yet brought it to market, and is about half the size of AstraZeneca.

Commissioner Chopra's dissent argues that AstraZeneca lacks Allergan's incentives to bring brazikumab to market. The evidence in this matter supports the opposite conclusion. While the dissent characterizes the drug as "Allergan's" IL-23, AstraZeneca (in cooperation with Amgen, Inc.) developed the drug, and then licensed it to Allergan. The consent terminates that license and returns the product to AstraZeneca. The structure of the divestiture incentivizes AstraZeneca to continue to develop the drug and bring it to market. The role of a divestiture is to position the divestiture buyer, here the original drug developer, to move the drug forward in the

Statement of the Commission

same fashion as would have occurred absent the merger. No drug development is without risk and there is no guarantee today that Allergan will successfully commercialize this product. The Commission can, however, ensure that AstraZeneca has the appropriate incentives to push forward with development and bring the drug to market, in the same manner Allergan would have done absent the merger. We have required specific terms to accomplish this goal.

Under the terms of the settlement, the merged firm will fund up to an agreed amount: the *total* estimated cost expected to be incurred by AstraZeneca until completion of development for brazikumab in both Crohn's disease and ulcerative colitis indications, including the development of a companion diagnostic. The specified payments are contingent on AstraZeneca's continuing to develop brazikumab in each indication. That is, AstraZeneca gets paid to develop the drug, even before it profits from its sale. Furthermore, other than a pre-existing royalty payment to the inventor of brazikumab, AstraZeneca will own all rights to revenues generated by brazikumab.

Commissioner Chopra argues that the divestiture's structure weakens AstraZeneca's incentives to bring brazikumab to market because AstraZeneca will obtain the development rights without paying anything. That is a fallacy. AstraZeneca's incentive to develop brazikumab does not depend on how much AstraZeneca paid for those rights but how much money it can make going forward. What is more, consistent with divestitures the Commission has ordered in past pharmaceutical transactions, the settlement here affirmatively pays AstraZeneca to continue to develop brazikumab.

Commissioner Chopra's dissent criticizes staff for not doing a "rigorous analysis" of whether AstraZeneca "may find it worthwhile to prioritize" the development of brazikumab over other projects. This critique is without merit. A divestiture designed to restore competition does not require absolute certainty that AstraZeneca will develop brazikumab. There is always a risk that a product in development will fail, a reality that every pharmaceutical company faces daily.

Instead, restoring competition requires that AstraZeneca's incentive for developing brazikumab be at least as strong as Allergan's. In fact, AstraZeneca has a *stronger* financial incentive to develop brazikumab than does Allergan because, under the proposed settlement, AstraZeneca will receive significant payments from Allergan that are contingent on AstraZeneca's continuing to develop the drug, and, other than a pre-existing royalty payment to the inventor of brazikumab, AstraZeneca will keep the profits for itself.

Commissioner Chopra's description of the arrangement as an "option" does nothing to support his point. What is more, the structure of the divestiture agreement is modeled on similar past arrangements, which have *succeeded* in bringing drugs to market. To resolve concerns following its investigation of Novartis's acquisition of GSK, the Commission required the divestiture of Braf-Mek Inhibitors to Array. Array was Novartis's development partner for the divested assets. As part of the divestiture, Novartis provided substantial financial support in the form of reimbursement to Array. At designated points for each trial, Novartis transitioned responsibility and provided continuing financial support to Array for completing the trials. The clinical trial for Braf-Mek Inhibitors was a success and the drug is now on-market.

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The dissent also argues that AstraZeneca is not an appropriate acquirer of Allergan's brazikumab assets because, the dissent claims, AstraZeneca has demonstrated a lack of commitment to develop brazikumab. We have seen no evidence to support that assertion.³ The only basis the dissent offers is the fact that AstraZeneca licensed the drug for development to Allergan in 2016. As a threshold matter, we reject the notions that any company that once licensed an interest in a developmental drug is inherently and forever a weaker competitor and that it must be excluded categorically from reentering the market through a government-compelled divestiture. Neither notion would make for sound policy. But leaving that policy issue aside, the point—again—is that the evidence about AstraZeneca's plans for the products and the firm's incentives to promote continued development uncovered by the investigation provide no basis for Commissioner Chopra's claim.

AstraZeneca is one of the largest pharmaceutical companies in the world (approximately 50 percent larger than Allergan is today), with total revenues exceeding \$22 billion in 2018. It has a robust portfolio with many successful products, and identifies "Respiratory and Immunology" among its three focus areas in its public financial reporting.⁴ While Commissioner Chopra makes much of AstraZeneca's decision to sell off rights to various immunology drugs four to five years ago, AstraZeneca publicly told the market just last week that it had, consistent with plans announced last year, renamed the focus area to include immunology because of the significant number of immunology products in its pipeline.⁵ That effort includes not just brazikumab, but also a number of other pipeline products.⁶ Commissioner Chopra omits these facts. While the insinuation that AstraZeneca is not interested in immunology may suit his chosen narrative, it simply is not borne out by facts.

AstraZeneca's history with brazikumab makes it a better candidate to be a divestiture buyer, not a worse one. AstraZeneca still employs the key team members, including the clinical lead, who were responsible for brazikumab during this earlier period of development. In sum, and contrary to our colleagues' fears, AstraZeneca has ample resources, significant in-house expertise, and strong financial incentives to develop brazikumab.

3 AstraZeneca's business plans, documents and presentations do not indicate that AstraZeneca has any current or future plans to relicense or flip the divestiture assets. The basis for the dissent's speculative concern is unclear.

4 See AstraZeneca, First Quarter 2020 Results (Apr. 29, 2020) at pp. 8, 28, https://1-www.astrazeneca.com/content/dam/az/PDF/2020/q1-2020/Q1_2020_results_presentation.pdf.

5 See AstraZeneca Earnings Call Transcript (Apr. 29, 2020), <https://seekingalpha.com/symbol/AZN/earnings/transcripts>. AstraZeneca also announced an agreement with the University of Oxford for the global development and distribution of a potential COVID-19 vaccine. See AstraZeneca Press Release, *AstraZeneca and Oxford University announce landmark agreement for COVID-19 vaccine* (Apr. 30, 2020), <https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-and-oxford-university-announce-landmark-agreement-for-covid-19-vaccine.html>.

6 AstraZeneca's current Respiratory & Immunology pipeline lists 29 projects and includes Fasenra (on market for severe eosinophilic asthma, but being investigated for other indications), anifrolumab (in clinical development for lupus indications), and tezepulmab (in clinical development for atopic dermatitis and other indications). See AstraZeneca's Respiratory & Immunology Pipeline, <https://www.astrazeneca.com/our-science/pipeline.html> (last visited May 5, 2020).

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Commissioner Chopra's dissent raises concerns regarding the potential that the merged firm could use rebating practices to disadvantage AstraZeneca in bringing brazikumab to the market. In the context of a merger investigation, the role of a divestiture is to restore competition to the state that it would have been absent the merger, not to provide the divestiture buyer with advantages that Allergan would not have had. Commissioner Chopra's theory is that AbbVie could use bundled rebating practices involving its Humira and Skyrizi drugs to inhibit AstraZeneca, but we lack evidence, including from AstraZeneca, that these bundling practices threaten brazikumab's ability to compete in the market. Moreover, AstraZeneca is a sophisticated company and capable of its own strategic responses to defeat any such actions by AbbVie.

2. Nestlé as a Divestiture Buyer of Zenpep and Viokace Assets

Commissioner Chopra also takes issue with the divestiture buyer of the EPI drugs, arguing that Nestlé lacks experience in the pharmaceutical industry. Commissioner Chopra's concern appears to be based on the fact that Nestlé is a food and beverage company. According to Commissioner Chopra, "[i]t strains the bounds of credulity" that Nestlé, the "maker of KitKats and Tidy Cats ... whose core business is selling packaged consumer products like candy and cat litter" could be seen as "a formidable, committed competitor for a drug that patients with pancreatic cancer, cystic fibrosis, and other serious conditions depend on." This argument, while long on alliteration, is both wrong and misleading. A company can both sell consumer products and be a formidable competitor in the pharmaceutical industry. For example, Johnson & Johnson sells Band-Aids and baby powder and is, at the same time, a major player in pharmaceutical industry. Ironically, Nestlé seems to be exactly the type of buyer Commissioner Chopra has *encouraged* in previous dissenting statements, urging the Commission to consider divestitures to new innovators, not just established pharmaceutical companies.⁷

It is true that Nestlé is the world's largest food and beverage company, with tremendous financial resources and a substantial U.S. sales infrastructure. But – and contrary to Commissioner Chopra's assertions – Nestlé is no stranger to the healthcare space. Nestlé operates Nestlé Health Science ("NHSc"), an integrated multi-billion dollar health company that focuses on nutrition products, including medical nutrition products that physicians order or recommend for patients who have certain digestive health conditions. Many of these patients use Zenpep.

The claim that Nestlé lacks significant pharmaceutical experience is simply false. Nestlé has been involved in the pharmaceutical industry for over 40 years, in various iterations. From 1977 to 2010, Nestlé owned Alcon, one of the largest eye care pharmaceutical companies in the world. It bought the company in 1977 for \$280 million and, when it finally exited the company in 2010, Nestlé stated that it "realised in excess of USD 40 billion in cash" through its gradual divestment of the company.⁸ Moreover, the dissent neglects to mention that Nestlé and L'Oreal

⁷ See Chopra Bristol-Meyers Dissent, *supra* n.2 at n.4.

⁸ Nestlé Press Release, *Nestlé to sell remaining Alcon shares to Novartis* (Jan. 4, 2010), <https://www.nestle.com/media/pressreleases/allpressreleases/alcon>.

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began the Galderma joint venture in 1981, and that Nestlé's sold Galderma in 2019, for approximately \$10.1 billion, established the largest independent global dermatology company in the world, with approximately \$2.8 billion in revenue and approximately 5,000 employees.⁹ The dissent also criticizes Nestlé for an alleged failure to bring products to market. Even assuming this criticism were accurate, this is the nature of pharmaceutical development. Not all projects succeed, and, in fact, most fail.¹⁰

Commissioner Chopra argues that, under Nestlé, Zenpep will not be able to compete against AbbVie's EPI drug Creon and that Zenpep's sales share will shrink. His dissent suggests that Zenpep will suffer the same fate as Pancreaze and Pertzye, two EPI drugs that "have less than 2% market share, even though they work just as well for most patients that use Creon and Zenpep." He argues that Pancreaze and Pertzye have low shares of sales because these drugs have little "bargaining leverage" and that Zenpep under Nestlé will likewise have little "bargaining leverage." This argument is without basis. Many factors account for differences in drugs' sales shares of a therapeutic category, including a drug's efficacy, patient experiences with the drug, and the order of introduction to the market. His dissent claims that:

But this fails to explain why Nestlé could not follow the same strategy to maintain or even increase Zenpep's share of EPI drug sales. Nestlé certainly has the resources to

Commissioner Chopra's questioning of Nestlé's ability to be a formidable competitor in pharmaceuticals also fails to acknowledge the significant pharmaceutical industry experience of Nestlé's executives. In fact, Nestlé's CEO, Mark Schneider, was previously the CEO of Fresenius Group, a global health care and pharmaceutical company. Nestlé's Chief Financial Officer, François-Xavier Roger, worked at pharmaceutical companies Takeda and Sanofi-Aventis before joining Nestlé. More importantly, the dissent ignores the leadership of NHSc, the company that will actually sell the Zenpep product. NHSc executives have significant experience running U.S. and global pharmaceutical companies, and developing and marketing branded pharmaceutical products, having held leadership roles at major pharmaceutical firms like Boehringer Ingelheim, Novartis, Pfizer, Eli Lilly, and Sanofi-Aventis.

In vetting proposed buyers, the Commission staff interview the proposed acquirer's executives, sales personnel, and corporate leadership, as well as third parties. The vetting of NHSc was no different. The investigation, including numerous interviews of doctors and health plans, found that Zenpep and Viokace are highly complementary to NHSc's existing products, as

9 Galderma Press Release, *Galderma to become the world's largest independent global dermatology company after completion of CHF 10.2 billion carve-out of Nestlé Skin Health* (Oct. 2, 2019), <https://www.galderma.com/news/galderma-become-worlds-largest-independent-global-dermatology-company-after-completion-chf-102>.

10 Stuart A. Thompson, N.Y. Times Opinion, *How Long Will a Vaccine Really Take?* (Apr. 30, 2020), <https://www.nytimes.com/interactive/2020/04/30/opinion/coronavirus-covid-vaccine.html?searchResultPosition=2> ("less than 10 percent of drug trials are ultimately approved").

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both products treat gastrointestinal (“GI”) conditions that hinder the body’s ability to extract nutrients from food. NHSc’s current products target the same patients who require EPI treatments like Zenpep, including patients with cystic fibrosis. While NHSc’s nutrition products are not pharmaceuticals, they are prescribed by doctors, used in hospitals and clinics, and covered by health insurance. Thus, NHSc already has substantial experience marketing to and interacting with the same group of healthcare providers and payors, and it has developed important relationships with these key decision-makers. But the experience does not end there. NHSc has an ongoing research and development partnership with Codexis, a protein engineering company that works with pharmaceutical firms. Building on NHSc’s established expertise in medical nutrition, this partnership seeks to develop high-performing enzymes to help patients suffering from rare metabolic and GI-related conditions. Several therapeutic enzyme candidates from this collaboration are currently in preclinical development. In addition to NHSc’s experience, its plans indicate it will commit more resources to the drugs than Allergan does today. The proposed divestiture of the Zenpep and Viokace assets will transfer Allergan’s EPI sales force and other significant assets, augmenting NHSc’s already strong capabilities and positioning it for success. NHSc plans, which staff scrutinized thoroughly, involve growing the sales team for these products substantially, and investing tens of millions of dollars to expand commercial, marketing, staffing, clinical studies and research and development activities related to Zenpep.

Commissioner Chopra claims that the divestiture of Zenpep to Nestlé will fail to restore competition in EPI drugs because Zenpep will “have little impact on Nestlé’s overall financial results” and therefore “Nestlé’s top management and board directors will not have an incentive to devote significant energy to make sure this divestiture is successful.” This claim lacks any plausible basis. As a factual matter, the Zenpep assets represent significant value even for a company of Nestlé’s size. In 2018, NHSc generated global sales of \$2.7 billion out of the total revenue of Nestlé S.A.’s worldwide sales of \$94 billion (*i.e.*, approximately 3% of Nestlé S.A.’s global sales). Approximately 47% of NHSc’s 2018 sales were in the United States. NHSc’s Strategic Advisory Committee and Management Team includes four of Nestlé’s most senior executives, including the Chairman and CEO of Nestlé S.A. Moreover, purchasing assets generating sales of \$288 million in 2019¹¹ can hardly be described as a “minor” investment. In fact, the Nestlé Board had to approve the purchase here, given the significant initial investment it required. Ultimately, NHSc will be a well-financed entrant into the pharmaceutical space.

Moreover, Commissioner Chopra appears to claim that a large company cannot be successful at selling a product unless the product will “materially impact” the company’s overall earnings. Commissioner Chopra offers no support for this claim. Like large pharmaceutical companies, large consumer products companies such as Nestlé and Procter & Gamble achieve success in selling hundreds of products in many countries around the world, even if individual products represent small shares of the company’s overall sales.

11 Allergan plc, 2019 Form 10-K at 57, https://www.sec.gov/Archives/edgar/data/1578845/000156459019003111/agn-10k_20181231.htm.

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For all of these reasons, we are confident that Nestlé is an appropriate divestiture buyer of the Zenpep and Viokace assets.

3. The Commission's Divestiture Process

Commissioner Chopra's dissent criticizes the Commission's remedy process, arguing that the staff followed a flawed process for identifying Nestlé as a divestiture buyer for the Zenpep and Viokace assets by letting the parties pick the divestiture buyer. The Commission does ask parties requiring divestitures to do the work of supplying options, though the parties do not get their pick. Our 2017 Merger Remedies Study confirmed that this practice, together with others related to designing, drafting and implementing the agency's merger remedies, generally yields effective outcomes. Indeed, with respect to the 50 orders examined using the case study methodology, which included Hertz, more than 80 percent of the Commission's orders across a wide variety of industries maintained or restored competition.

The dissent takes particular issue with the Commission's approach to remedies in pharmaceutical mergers. In citing to unsuccessful divestitures, the dissent noticeably fails to mention any pharmaceutical divestitures. That omission is material, because the findings from the pharmaceutical portion of the 2017 Merger Remedies Study support the consent in this case. The study found that when remedies entailed the divestiture of on-market pharmaceuticals produced by a contract manufacturer and did not require transferring manufacturing capability, the buyers continued to sell the divested product in every instance. This result confirms the Commission's long-standing practice of requiring divestiture of the overlap product that can be transferred to its purchaser most seamlessly and with fewest hurdles. Products made at a third-party manufacturing site, rather than those requiring a technology transfer, fall into this category. That is precisely the situation here. Currently, Allergan's products are made at a third-party manufacturing facility and those arrangements will transfer to Nestlé. Similarly, the 2017 Remedy Study also found that for all in-development products, assets were successfully transferred to the buyers. Here, AstraZeneca is uniquely familiar with the brazikumab assets as it previously developed the technology itself and, therefore, is well positioned to reintegrate the assets into its operations.

The 2017 Study also showed that respondents were now more likely to propose buyers that fully satisfy the Commission's criteria for strong, viable competitors, compared to findings from the 1999 Divestiture Study that revealed respondents sometimes proposed buyers that were marginally acceptable. The Commission made several changes in response to the 1999 findings. For example, the Commission began requiring an upfront buyer for divestitures of less than an ongoing business, thereby aligning the incentive to propose a Commission-approvable buyer with the respondents' interest in receiving Commission clearance for their deal.

In addition, staff began a more in-depth review of proposed buyers, including requiring prospective buyers to submit detailed written business and financial plans for divested assets. While the 2017 Study indicated that these measures were working, the Commission has

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continued to refine its process, including by closely examines the buyer's sources of financing, contingency planning, and ability to conduct adequate due diligence, among other factors.¹²

Staff applied its established practices to evaluate potential merger remedies in this case. Staff analyzed business plans, supply chain management and transition plans, the strategic fit of the assets with the buyers' existing business, financial projections, deal financing and incentives, experience and management expertise. The 2017 Study found that buyers that "had a complementary product line into which the divested assets could easily fit" tended to succeed. Here, the evidence we studied, including extensive consultation with experts, buyers, and prescribers, indicated that NHSc's line of medical nutrition products is a natural fit for Zenpep and Viokace as these divestiture products target the same patients and providers as its existing product line, and that brazikumab will fit nicely back into AstraZeneca's "Respiratory and Immunology" focus area.

4. Scope of the Investigation

Commissioner Chopra's claim that the Commission has a "myopic" focus on product overlaps misrepresents the scope of the investigation that staff conducted in this matter, and in other merger investigations. Commissioner Slaughter's dissent does acknowledge the scope of the investigation, but nevertheless raises concerns that it failed to investigate enough. She does not specify what additional evidence she would have sought, or how it would have informed her theory of harm.

The Commission brings cases based on evidence, not beliefs. As the Commission has stated publicly, both the Commission and its staff look well beyond product overlaps in every pharmaceutical merger review; this case was no different. The Commission staff proactively sought information from the merging parties and third parties to facilitate exploration of a wide range of theories of competitive harm, including every one mentioned in the dissents. But the evidence did not support a reason to believe that the merger would lead to competitive harms beyond the overlaps that are being remedied via divestitures. It is simply untrue to claim that theories of harm other than straightforward overlaps were ignored, and untoward to suggest they were not investigated with adequate rigor. That the dissenters may not like the result is no reason to object, much less mischaracterize the comprehensive and meticulous merger review process.

Consistent with the Horizontal Merger Guidelines, staff investigated whether the "merger will diminish innovation competition by combining two of a very small number of firms with the strongest capabilities to successfully innovate in a specific direction."¹³ Other than the harm the

12 FTC Competition Blog, *Looking back (again) at FTC merger remedies* (Feb. 3, 2017), <https://www.ftc.gov/news-events/blogs/competition-matters/2017/02/looking-back-again-ftc-merger-remedies>.

13 Horizontal Merger Guidelines§ 6.4. In Commissioner Slaughter's dissent, she raises concerns about whether the Commission analyzes and addresses innovation competition issues in pharmaceutical merger investigations. The dissent ignores the Commission's long record of addressing innovation competition concerns in pharmaceutical transactions. In recent years, for example, the Commission has taken enforcement actions to address harm to innovation competition in the Mallinckrodt, GSK/Novartis, and BMS/Celgene matters, as well as in several generic pharmaceutical mergers. See FTC Press Release, *FTC Requires Bristol-Myers Squibb Company and Celgene*

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merger would create related to the parties' ongoing development of IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis and Crohn's disease, the investigation yielded no evidence that other ongoing product development efforts would likely be altered because of a desire to diminish competition in any relevant market. Staff also evaluated in which therapeutic areas, as well as narrower disease areas and specific conditions, the parties were currently investing in research and development. A wide array of evidence gathered and reviewed by staff, including party forecasts and market analyses created in the ordinary course of business, interviews with third parties, and review of publicly available information, indicated that there is no therapeutic area, disease, or condition where the parties are two of a limited number of competitors. To the contrary, evidence indicates the parties face considerable competition in each area. The staff also investigated whether the merger eliminated competitive restraints on either AbbVie or Allergan that would allow for rebating practices that otherwise had failed due to the independence of the two companies, and did not find evidence to support such a theory.

As to other non-merger specific conduct that some have argued should be remedied through the merger review and order process, Section 7 does not afford the agency the authority to extract remedies unrelated to a proposed merger.

* * * * *

We are committed to preserving competition in pharmaceutical and medical treatment markets. Sometimes, that means blocking a merger outright. Earlier this year, for example, staff recommended that the Commission block Johnson & Johnson's proposed acquisition of Takeda's surgical patch, TachoSil, and the parties subsequently abandoned the transaction.¹⁴ But

Corporation to Divest Psoriasis Drug Otezla as Condition of Acquisition (Nov. 15, 2019), <https://www.ftc.gov/news-events/press-releases/2019/11/ftc-requires-bristol-myers-squibb-company-celgene-corporation> (alleging the acquisition would substantially lessen competition by eliminating future competition between BMS and Celgene in developing, manufacturing and selling oral products to treat moderate-to-severe psoriasis); FTC Press Release, FTC, Mallinckrodt Will Pay \$100 Million to Settle FTC, State Charges It Illegally Maintained its Monopoly of Specialty Drug Used to Treat infants (Jan. 18, 2017), <https://www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it> (blocking acquisition because Questcor "acquired the rights to its greatest competitive threat, a synthetic version of Acthar, to forestall future competition"); FTC Press Release, FTC Puts Conditions on Generic Drug Maker Lupin Ltd.'s Proposed Acquisition of Gavis Pharmaceuticals LLC (Feb. 19, 2016), <https://www.ftc.gov/news-events/press-releases/2016/02/ftc-puts-conditions-generic-drug-marketer-lupin-ltds-proposed> (requiring divestitures to ensure continued development of generic mesalimine ER capsules, which Lupin and Gavis were developing independently at the time of the merger); FTC Press Release, FTC Puts Conditions on Novartis AG's Proposed Acquisition of GlaxoSmithKline's Oncology Drugs (Feb. 23, 2015), <https://www.ftc.gov/news-events/press-releases/2015/02/ftc-puts-conditions-novartis-ag-s-proposed-acquisition> (requiring divestitures of in-development BRAF and MEK inhibitor drugs to ensure development of the BRAF and MEK inhibitors continues uninterrupted, and competition in BRAF and MEK inhibitor markets is not reduced). For an overview of the many other pharmaceutical mergers the Commission has challenged to protect innovation competition, see FTC Health Care Division Staff, Overview of FTC Actions in Pharmaceutical Products and Distribution (Sept. 2019), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/20190930_overview_pharma_final.pdf.

¹⁴ The dissent asserts that the Commission has not challenged a proposed pharmaceutical merger or acquisition, but it ignores past Commission enforcement actions challenging entire transactions and FTC attempts to challenge acquisitions in court. For example, in 2017, the Commission challenged the consummated acquisition of Synacthen by Questcor Pharmaceuticals, Inc. and required its parent company, Mallinckrodt plc, to pay \$100 million to settle

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we are also committed to predicating enforcement decisions on evidence – not just some of the evidence, but all of the evidence. Our merger challenges must stay within the scope of the law and the facts of the case in front of us. Here, the law and the facts overwhelmingly support the proposed divestiture, not the dissenters' critiques.

In his conclusion, Commissioner Chopra proposes a long list of actions the Commission should undertake to overhaul its process for reviewing mergers and divestiture proposals. Most of those steps appear unrelated to any issue involving the transaction and divestiture currently before us. Nonetheless, as Chairman Simons has indicated on numerous occasions, the Commission has been and remains willing to engage in self-critical examination.¹⁵ In fact, the Commission's predisposal to rigorous and routine self-assessment is demonstrated by the many merger retrospectives it has conducted, to determine retroactively its accuracy in calling balls and strikes; its willingness to assess with frankness and candor the efficacy of its merger remedies, as chronicled by the 2017 Mergers Remedy Study; and its no-holds-barred review of dozens of policy positions and enforcement approaches during the agency's Hearings on Competition and Consumer Protection in the 21st Century, which featured no shortage of voices critical of the FTC. While the Commission continues to strive for improvement, its empirically-based reviews do not reveal the kind of systemic failure to merger reviews and divestitures that would justify Commissioner Chopra's proposals. That said, we will continue to support the self-critical examination that typifies the agency's approach to all enforcement and policy issues.

charges that the acquisition violated the antitrust laws. *FTC et al. v. Mallinckrodt Ard Inc. et al.*, No. 1:17-cv-120 (D.D.C. Jan. 30, 2017), <https://www.ftc.gov/enforcement/cases-proceedings/1310172/mallinckrodt-ard-inc-questcor-pharmaceuticals>. In 2008, the Commission filed a complaint in federal district court challenging Ovation Pharmaceuticals, Inc.'s acquisition of the drug NeoProfen. FTC Press Release, *FTC Sues Ovation Pharmaceuticals for Illegally Acquiring Drug Used to Treat Premature Babies with Life-Threatening Heart Condition* (Dec. 6, 2008), <https://www.ftc.gov/news-events/press-releases/2008/12/ftc-sues-ovation-pharmaceuticals-illegally-acquiring-drug-used>. The recommendation to challenge Johnson & Johnson's Tachosil acquisition is only the most recent evidence of this effort. FTC Press Release, *Federal Trade Commission Closes Investigation of Johnson & Johnson's Proposed Acquisition of TachoSil from Takeda Pharmaceutical Company* (Apr. 10, 2020), <https://www.ftc.gov/news-events/press-releases/2020/04/federal-trade-commission-closes-investigation-johnson-johnsons>. As noted above, the Commission also has required extensive product divestitures in dozens of pharmaceutical company mergers. Moreover, the Commission has conducted a twenty-five year campaign to stop anticompetitive conduct in the pharmaceutical industry, resulting in a seminal Supreme Court case, and settlements that well exceed \$1 billion. For a more extensive discussion of the FTC's vast array of efforts to maintain competition in the pharmaceutical industry, see Statement of Commissioner Christine S. Wilson, *In the Matter of Bristol-Myers Squibb/Celgene* (Nov. 15, 2019), <https://www.ftc.gov/system/files/documents/public-statements/1554278/bms-celgene-wilson-statement.pdf>.

¹⁵ See, e.g., Joseph J. Simons, Keynote Address at American University Washington College of Law Conference on Themes of Professor Jonathan Baker's New Book, *The Antitrust Paradigm: Restoring a Competitive Economy* (Mar. 8, 2019), <https://www.ftc.gov/public-statements/2019/03/prepared-keynote-address-chairman-joseph-j-simons-american-university>.

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DISSENTING STATEMENT OF COMMISSIONER ROHIT CHOPRA**Executive Summary**

- The Federal Trade Commission is settling charges regarding AbbVie's unlawful takeover of Allergan. For the first time, the FTC is ordering drug divestitures to a company that does not offer any prescription drugs: Nestlé. This is risky and concerning.
- I have been unable to identify any time in the agency's history where the FTC has filed a lawsuit to block an unconsummated drug company merger. The agency's default strategy of requiring merging parties to divest overlapping drugs is narrow, flawed, and ineffective. It misses the big picture, allowing pharmaceutical companies to further exploit their dominance, block new entrants, and harm patients in need of life-saving drugs.
- Divesting assets is only an appropriate remedy if the buyer will fully replace the competition lost by a merger. But, merging parties have little incentive to sell to a strong competitor and, in fact, succeed more when the buyer fails. New entrants face high hurdles even with well-capitalized buyers. The agency must always closely vet divestiture buyers and conduct careful financial due diligence to determine whether they can or will aggressively compete. If no suitable buyers exist, the FTC should sue to block the merger outright, rather than settling.
- The Commission is too confident that Nestlé can cure this merger. Nestlé is not a pharmaceutical company. Its core focus is on food, beverages, and other grocery store items. While it has a nutrition subsidiary, this line of business does not match the capability and capacity of Allergan, which currently owns the rights to drugs that treat patients with serious pancreatic conditions. In addition, Nestlé has a checkered record in its past experiments with pharmaceuticals. If this new venture into pharmaceuticals does not succeed, it will not have a meaningful impact on Nestlé's financial results.
- To address other harmful effects of this proposed merger, the FTC is not ordering a traditional sale of assets. Instead, the agency is ordering AbbVie and Allergan to give back the rights to a major drug development project to AstraZeneca. This is a windfall for AstraZeneca, who will pay nothing for a valuable drug development project and is free to re-license the business to another company. It is unclear where this project falls in AstraZeneca's development priorities and whether the company is committed to the project over the long-term.
- The FTC should take concrete steps to move forward from this unfortunate decision and its troubling outcome. The Commission should improve its approach to analyzing mergers where new market entrants drive innovation, enhance our divestiture buyer evaluation process by including staff with financial and technical expertise, strengthen our coordination and cooperation with state attorneys general in merger investigations, and provide greater transparency to the public about the scope of merger reviews and remedies.

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I. Introduction

The current coronavirus outbreak and resulting public health and economic emergency are rightfully leading many government officials to question status quo approaches to policy, regulation, and enforcement. At the Federal Trade Commission, we should be doing the same.

I have been unable to identify any time in the agency's history where the FTC has filed a lawsuit to block an unconsummated drug company merger.¹ Instead, the FTC examines whether or not the two merging drug companies offer any competing products. If not, the agency clears the deal unconditionally, like in Takeda's recent \$62 billion takeover of Shire. If companies do have competing products, the agency requires them to divest overlapping drug product offerings to another company, like in Bristol Myers-Squibb's recent \$74 billion takeover of Celgene.

Over the years, individual Commissioners and FTC officials have questioned whether this fully remedies competitive harms.² However, the agency continues to defend its work, and, in my view, largely believes the status quo is working just fine. But, it isn't. The FTC's strategy of focusing on whether pharmaceutical companies have any overlaps in their drug product lineup is narrow, flawed, and ineffective. This strategy fails to account for how executives make decisions about their drug product portfolios, how larger portfolios can suppress new entry, and how companies use portfolios to increase bargaining leverage across the supply chain. The approach has contributed to a shrinking number of Big Pharma giants that increasingly prioritize maintaining patent monopolies over discovering new medicine.

Drug prices are exorbitant and continue to climb, price-gouging patients in life or death situations. And too many new innovators can't get off the ground to break through the barriers to entry that incumbents have created to defend their drug turf.

Today's proposed resolution to the latest pharma megamerger, AbbVie's (NYSE: ABBY) \$63 billion takeover of Allergan (NYSE:AGN), is a stark display of the agency's myopic approach. The FTC has given the green light to a merger that offers no meaningful benefits, but raises many alarm bells.

For the first time, the FTC is proposing a pharmaceutical merger settlement that divests a prescription drug business to a buyer that isn't a drug company. The settlement requires Allergan to divest drugs used to treat patients with pancreatic cancer, cystic fibrosis, and other serious pancreatic disorders. The Commission is putting its full faith in Nestlé (SIX: NESN), the maker of KitKats and Tidy Cats, to take Allergan's place in the market. The Commission is confident it

1 The FTC has filed lawsuits in other non-drug pharmaceutical markets, such as medical instruments and technology. However, those markets are distinctly different from small molecule drugs and biologics. They do not share any of the dynamics at issue in drug mergers such as the one here. As I discuss in this statement, these dynamics make the industry fraught with competitive problems not easily resolved by one-off divestitures.

2 See e.g., 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>.

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can restore competition by divesting essential medicine to a company whose core business is selling packaged consumer products like candy and cat litter.

Without a doubt, Nestlé is a large company with many capabilities – in food and beverages. Currently, the company does not offer a single prescription drug product. It strains the bounds of credulity that the Commission feels so certain that this company will be a formidable, committed competitor for a drug that patients with pancreatic cancer, cystic fibrosis, and other serious conditions depend on.

In a separate provision, AbbVie and Allergan will pull out of a licensing and development deal for a pipeline immunology drug with AstraZeneca (NYSE:AZN). AstraZeneca will pay nothing for this “divestiture” and is free to re-license the product. The FTC has put its faith in a proposal that AstraZeneca, who publicly reported a few years ago that it was retreating from immunology, will follow Allergan’s path to bring this drug to market.

Commissioners should always rely on evidence and examination, rather than ideology or intuition. We are accountable for agency decisions and for giving appropriate direction to staff. This is particularly true when it comes to merger enforcement. FTC merger settlements are supposed to restore the competition killed off from a transaction. Looking for product overlaps and then accepting risky or questionable buyers to eliminate them is not sound competition policy.

There are a number of problematic aspects with the FTC’s investigative approach to pharmaceutical industry mergers and to proposed remedies. In this statement, I will focus primarily on the issue of divestiture buyers. Accepting risky buyers that are unlikely to fully restore competition does a disservice to patients and worsens the out-of-control drug costs in our country. If no buyers are capable of restoring competition, the FTC should take steps to block the merger outright.

Below, I discuss some background information on divestiture remedies. I then describe why Nestlé and AstraZeneca are no cure for this proposed merger. I conclude with a set of concrete steps that the Commission should include in its work going forward.

II. Divestiture Remedies and Supporting Conduct Provisions

Before discussing the specific divestiture buyers approved by Chairman Simons, Commissioner Phillips, and Commissioner Wilson, we must bear in mind the challenges and distorted incentives that are inherent in the divestiture process.

Divestiture remedies to address a harmful merger can only succeed if the buyer fully restores the competition that existed prior to the merger. FTC merger settlements typically require the merging parties to divest a line of business, usually tied to specific products or geographies, to one or more approved buyers. But, given the incentives of merging parties and buyers of divested assets, the entire process can be fraught. The FTC must be especially careful.

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These practices are likely even more prevalent in industries rife with anticompetitive abuses, such as the pharmaceutical industry.³

- A. Merging companies want to sell assets to weak buyers, because these buyers will be their competitors.*

When merging companies need to divest an asset, a set of assets, or a line of business to address a reduction in competition stemming from the transaction, the combined entity is actually selling to its future competitor. The merging companies may not want to sell to the highest bidder. They have an incentive to also consider who is likely to be the weakest buyer and the easiest to dominate once the buyer takes full ownership of the divested product.

A 1999 analysis confirmed this concern, noting that merging companies “recommended marginally acceptable buyers and, on some occasions, engaged in post-divestiture strategic behavior aimed at minimizing the competitive impact of the buyer’s entry into the market.”⁴

- B. Buyers might find a bargain, but they may not have the same incentives or ability to fully restore competition.*

When merging parties are eager to consummate their transaction in as little time as possible, they often look to satisfy concerns of antitrust enforcers by quickly finding buyers for specific assets in markets where a merger would cause competitive harm. This allows prospective buyers to purchase divested assets more cheaply than they otherwise might be able to. If the asset is already generating significant cash flow, the investment may still be worthwhile even if sales decline significantly post-transfer.

Sometimes, companies may simply want to purchase an “option.” In other words, buyers might find it worthwhile to purchase an asset because it could become useful sometime in the future, even if they don’t have concrete plans to focus on it immediately.

There are many other problems that make for a bad divestiture buyer. For example, as I noted in *Praxair/Linde*, the buyer might be loading up the asset with debt, making it less likely

³ The pharmaceutical industry has long been the focus of anticompetitive conduct enforcement by the FTC, state attorneys general, and private litigants. Challenged conduct includes pay-for-delay settlements, anticompetitive product hopping, fraudulent orange book listings, and sham litigation. Both AbbVie and Allergan have been the subject of these enforcement efforts. *See, e.g., Fed. Trade Comm’n v. AbbVie Inc. et al.*, No. 14-5151, WL 8623076 (E.D. Pa. July 18, 2018); *Fed. Trade Comm’n v. Allergan plc et al.*, No. 17-cv-00312 (N.D. Cal. Feb. 22, 2019); *Fed. Trade Comm’n v. Actavis, Inc. et al.*, 570 U.S. 136 (2013); *Fed. Trade Comm’n v. Reckitt Benckiser Group plc*, No. 1:19-cv-00028 (W.D. Va. July 11, 2019); *State of California ex rel. v. Allergan plc et al.*, No. 3:17-cv-00562, WL 3251470 (N.D. Cal. June 6, 2019); *In the Matter of Biovail Corp.*, FTC File No. 011-0094 (Oct. 2, 2002); *In the Matter of Bristol-Myers Squibb Company*, FTC File No. 011-0046 (Mar. 7, 2003); *see generally*, Public Citizen, *By Any Means Necessary: How Allergan Gamed the System to Raise Drug Prices and Flood the Country with Pill* (Jan. 27, 2019), <https://www.citizen.org/news/how-allergan-gamed-the-system-to-spike-prices-and-sell-opioids/>.

⁴ FED. TRADE COMM’N, THE FTC’S MERGER REMEDIES 2006-2012, A REP. OF THE BUREAU OF COMPETITION AND ECONOMICS at 10 (2017) (referencing WILLIAM J. BAER, FED. TRADE COMM’N, A STUDY OF THE COMMISSION’S DIVESTITURE PROCESS, 8 (1999)).

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they will have the flexibility to grow the divested business and effectively compete.⁵ In addition, a buyer might have already been planning to enter the market anyway, which means that they are bolstering their own competitiveness rather than replacing competition.

C. Divestiture remedies can fail even with well-capitalized buyers and experienced management, especially when the business is not a core focus of the owner.

Rather than block a merger outright or weed out questionable buyers, the FTC sometimes rolls the dice. When rental car giant Hertz sought to get even bigger with its illegal takeover of Dollar Thrifty, the FTC entered into a settlement to address the illegal merger by ordering a divestiture of its Advantage Rent a Car business to Franchise Services of North America (FSNA) and Macquarie Capital.⁶ FSNA didn't operate a traditional airport rental car operation; it ran a U-Haul and Rent-a-Wreck business that served a different customer need.⁷ The CEO of FSNA had previous experience in traditional rental cars,⁸ and the FTC approved the buyer. But, soon after the FTC settlement, the new enterprise filed for bankruptcy.⁹

When the FTC reviewed the illegal merger of Dollar Tree and Family Dollar, it settled for divestitures to Sycamore Partners, the private equity outfit. Sycamore Partners proposed a management team with experience in the business.¹⁰ Nevertheless, the arrangement quickly failed and stores were ultimately resold to Dollar General. Instead of creating a new competitor, the big national players simply grew more powerful.

In the illegal takeover of Safeway by private equity-owned Albertson's, the FTC didn't sue to block the merger outright. Instead, the agency approved Haggen as the buyer of 146 stores.¹¹ Haggen was an experienced grocer and was backed by a financial partner, but only

5 Statement of Commissioner Rohit Chopra In the Matter of Linde AG, Praxair, Inc., and Linde PLC, Comm'n File No. 1710068, 1 (Oct. 22, 2018), https://www.ftc.gov/system/files/documents/public_statements/1416947/1710068_praxair_linde_rc_statement.pdf.

6 *In the Matter of Hertz Global Holdings, Inc.*, FTC File No. 101-0137 (July 10, 2013).

7 Franchise Servs. of North Am. Press Release, Franchise Services of North America Inc. Announces Agreement to Acquire Advantage® Rent-A-Car Business (Aug. 28, 2012) (on file with PR Newswire), <https://www.newswire.ca/news-releases/franchise-services-of-north-america-inc-announces-agreement-to-acquire-advantage-rent-a-car-business-510636941.html>.

8 *Id.*

9 David McLaughlin et al., *Hertz' Spinoff of Advantage Rent A Car Was Doomed From the Start Says Insider*, SKIFT (Nov. 30, 2013, 9:00 AM), <https://skift.com/2013/11/30/hertz-spinoff-of-advantage-rent-a-car-was-doomed-from-the-start-says-insider/>.

10 Analysis of Agreement Containing Consent Order to Aid Public Comment, In the Matter of Sycamore Partners II, L.P. et al., FTC File No. 181-0180, 4 (Jan. 28, 2019); see also Katherine Peralta and Rick Rothacker, Family Dollar's 'scheme to kill' Charlotte retailer cost thousands of jobs, suit says, THE CHARLOTTE OBSERVER (last updated June 5, 2017, 1:37 PM), <https://www.charlotteobserver.com/news/business/article153904309.html>.

11 *In the Matter of Cerberus Institutional Partners V, LP et al.*, FTC File No. 141-0108 (July 2, 2015).

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operated 18 stores. Within nine months, Haggen filed for bankruptcy.¹² Haggen would later accuse Albertson's of sabotaging the divestitures in order to steal customers from its new rival.¹³ Albertson's then bought back many of the divested stores in bankruptcy.

Despite these outcomes, the FTC published a study in 2017 and declared that its merger remedies were effective.¹⁴ It is important that we learn from these and other divestitures that did not fully restore competition.

D. Divestitures are more likely to fail when the FTC relies on speculation, rather than real- world data and robust due diligence.

During my two years as a Commissioner, I have expressed concerns that the FTC makes many of its decisions based on superficial evidence, rather than a close examination of the underlying dynamics in an industry. As a result, the agency can inadvertently miss marketplace realities.

To combat these concerns, I have strongly advocated that we increase the level of analytical rigor in our decision-making across the agency's mission, particularly when it comes to remedies. In the context of a divestiture remedy, this includes a careful assessment of divestiture buyers. Our process should more closely resemble how a lender, insurer, or equity investor might assess a corporate entity's likelihood of success.

A divestiture buyer cannot simply have management or a sales force with expertise or access to capital. Instead, a well-developed long-term strategy that fits within the overall goals of the corporation is necessary. Therefore, we must conduct due diligence that specifically explores how divested assets will fit into a buyer's broader business and long-term financial strategy. For example, we should gather specific evidence that speaks to the likelihood of a divestiture buyer quickly reselling or repurposing an asset. We should examine whether an asset may simply be a part of a branding strategy to increase sales of its other products. Of course, we must always discount the assertions of their executives and lawyers, and we must always seek to substantiate their assertions. Without this level of due diligence, we roll the dice and risk failure.

12 Hannah Madans, *Haggen bankruptcy: Failure is the 'fastest' in modern grocery store history*, THE ORANGE COUNTY REGISTER (Sept. 10, 2015, 9:08 AM), <https://www.ocregister.com/2015/09/10/haggen-bankruptcy-failure-is-the-fastest-in-modern-grocery-store-history/>.

13 Angel Gonzalez, *Haggen sues Albertsons for \$1 billion over big grocery deal*, THE SEATTLE TIMES (last updated Sept. 2, 2015, 9:00 AM), <https://www.seattletimes.com/business/retail/haggen-sues-albertsons-for-1-billion-over-big-grocery-deal/>.

14 Fed. Trade Comm'n, *The FTC's Merger Remedies 2006-2012*, A Rep. of the Bureau of Competition and Economics, 10 (2017); see also Chris Sagers, *The Limits of Divestiture as an Antitrust Remedy*, N.Y. Times: DealBook/Business & Policy (Feb. 14, 2017), <https://www.nytimes.com/2017/02/14/business/dealbook/the-limits-of-divestiture-as-an-antitrust-remedy.html>.

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Assessing the suitability of a divestiture buyer is difficult, and we must keep these challenges in mind as we evaluate the likelihood that Nestlé and AstraZeneca will fully replace Allergan's role in key product markets.

III. Nestlé Cannot Cure This Harmful Merger

Pancreatic cancer is expected to be the second leading cause of cancer-related death in America this year. It has the highest mortality rate of all major cancers.¹⁵ Cystic fibrosis is a hereditary condition that clogs a person's lungs and obstructs the function of their pancreas. Patients are typically diagnosed as babies. Chronic pancreatitis is a condition where individuals experience persistent inflammation of the pancreas that leads to permanent damage. Patients with pancreatic cancer, cystic fibrosis, chronic pancreatitis, as well as those with other conditions that affect the pancreas, may require pancreatic enzyme replacement therapy.

According to the agency's investigation, the two major prescription drugs used for pancreatic enzyme replacement therapy were AbbVie's Creon and Allergan's Zenpep, with Creon as the clear leader. While there are three other drugs that are also approved for this therapy, two of the three products are made by small pharmaceutical companies that have struggled to make inroads in capturing market share. Allergan owns the third, Viokase. There are no generic competitors.

The merger of AbbVie and Allergan would allow the merged companies to dominate the market, reducing competition in violation of the law. To cure this harm, the majority proposes that the merged AbbVie-Allergan sell the rights to Zenpep and Viokase to Nestlé. This is a risky gamble.

A. Nestlé's core business is focused on food and beverages, not prescription drugs.

Nestlé may be one of the world's largest corporations, but it is not a pharmaceutical company. As the company's mission - "Good Food, Good Life" - indicates, Nestlé is a food and beverage company. The lion's share of its revenue and profits comes from its candy products like CRUNCH and KitKat chocolate bars; coffee products like Nespresso, Nescafe, Blue Bottle, and packaged Starbucks offerings; and other items typically purchased while grocery shopping. In the United States, Nestlé is particularly successful in pet care through its subsidiary Purina, which markets Friskies, Beggin', Tidy Cats, and other brands.

Nestlé seeks to outperform its industry peers in the STOXX Global 1800 Food and Beverage Index,¹⁶ whose major components include Coca-Cola, PepsiCo, and Diageo. The company's public financial statements note that the company ties certain executive compensation

¹⁵ *Pancreatic Cancer Facts*, Hirshberg Foundation for Pancreatic Cancer Research (last visited May 4, 2020), <http://pancreatic.org/pancreatic-cancer/pancreatic-cancer-facts/>.

¹⁶ *WHY INVEST IN NESTLÉ, A winning strategy delivering results*, NESTLÉ (last visited May 5, 2020), <https://www.nestle.com/investors/creating-shareholder-value>.

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components to this metric. Neither the Board nor management have recently stated that they intend to transform Nestlé into a major player in the pharmaceutical business.

B. Nestlé's efforts on nutrition do not come close to Allergan's capabilities and capacity to compete in pharmaceuticals.

Like many other food and beverage companies, Nestlé has sought to increase its offerings that appeal to health and wellness across its businesses. For example, in its pet care business, Nestlé has launched brands like Purina ONE and Beneful, which cater to consumers looking for healthy food for their dogs. Nestlé recently launched a new Starbucks packaged coffee product with “essential vitamins.”

Nestlé also has a subsidiary called Nestlé Health Science that develops and markets “nutritional therapies,” such as vitamins, supplements, nutritional shakes, and soups. One of its top-selling products is the Boost nutritional drink.¹⁷ Like Nestlé's other lines of businesses, Nestlé Health Science is heavily engaged in traditional food marketing. For example, the company markets the Boost business by developing new varieties of the product and catering to special diets, such as lactose-free and gluten-free. Boost now offers multiple flavors, a pudding format, and special varieties for men and women.¹⁸

The Nestlé Health Science subsidiary has also invested in other vitamin and supplement businesses. Recently, it made a major investment to acquire Persona, a personalized vitamin startup.¹⁹ It also purchased Atrium Innovations for \$2.3 billion, which makes probiotics, vitamins, and meal supplements.²⁰

Nestlé and its nutrition subsidiary cannot match Allergan's experience and know-how. While this subsidiary is offering over-the-counter products to those suffering from pancreatic conditions,²¹ is marketing some of its products through doctors,²² and is run by executives with

17 Susan Caminiti, *Food giant Nestlé pivots to gain a foothold in the personal nutrition market*, CNBC: Evolve (Oct. 17, 2019, 11:23 AM), <https://www.cnbc.com/2019/10/17/nestle-pivots-to-gain-a-foothold-in-the-personal-nutrition-market.html>.

18 *Meet the Boost family*, BOOST (last visited May 4, 2020), <https://www.boost.com/products>.

19 Nestlé Press Release, Nestlé Health Science expands into personalized nutrition with acquisition of Persona™ (Aug. 22, 2019), <https://www.nestle.com/media/news/nestle-health-science-acquisition-persona>.

20 Nestlé Press Release, Nestlé extends consumer healthcare portfolio by agreeing to acquire Atrium Innovations (Dec. 5, 2017), <https://www.nestle.com/media/pressreleases/allpressreleases/nestle-acquires-atrimum-innovations>.

21 Angus Liu, *Pharma AbbVie, Allergan sell 3 drugs to win US. antitrust clearance – and send AZ, Nestlé into new realms*, FIERCEPHARMA (Jan. 27, 2020), <https://www.fiercepharma.com/pharma/abbvie-allergan-sell-3-drugs-to-win-u-s-antitrust-clearance-and-take-astra-nestle-into-new>.

22 ABOUT NESTLÉ HEALTH SCIENCE, Nestlé (last visited May 5, 2020), <https://www.nestlehealthscience.com/about-us>.

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related pharmaceutical expertise,²³ the subsidiary's capabilities pale in comparison to what Allergan is today.

Over the years, Allergan and its predecessor companies have developed and acquired a large portfolio of top-selling drugs.²⁴ Today, Allergan has “built one of the broadest pharmaceutical and device research and development pipelines in the industry.”²⁵ It takes many years for a pharmaceutical company to develop into what Allergan is today. Companies like Allergan don't build themselves into the behemoths they are by accident: they do so for the very specific purpose of achieving the scale and breadth of products across a portfolio that they can then use as leverage in negotiations with health insurers and pharmacy benefit managers. Pharmaceutical businesses have increasingly evolved this way over the last twenty years. This does not happen overnight.

There is simply no comparison between Allergan, with its strategic focus and experience in pharmaceuticals, and Nestlé's nutrition business.

C. Nestlé has a checkered record when it comes to its past experiments with pharmaceuticals.

In 2014, Nestlé became the sole owner of Galderma, a dermatology company. Galderma was originally a joint venture between Nestlé and L'Oreal until Nestlé bought back all the shares in 2014.²⁶ The venture was not particularly fruitful. Documents produced to the FTC confirm that Nestlé was unsuccessful in [REDACTED]. Under pressure from activist investor Third Point, Nestlé sold the business in 2019.²⁷

In 2011, Nestlé Health Science purchased Prometheus Laboratories.²⁸ Prometheus held the U.S. rights to an oncology drug that Nestlé sold off in 2019.²⁹ Nestlé then exited its

²³ *Corporate Governance Rep.*, NESTLÉ, 6 (2019), <https://www.nestle.com/sites/default/files/2020-03/2019-annual-review-corp-governance-compensation-financial-statements-en.pdf>.

²⁴ Acquisitions had long been the strategy for Allergan, which now includes Watson, Actavis, Warner Chilcott and Forest Laboratories. See PUBLIC CITIZEN, *By Any Means Necessary: How Allergan Gamed the System to Raise Drug Prices and Flood the Country with Pill*, 7 (Jan. 27, 2019), <https://www.citizen.org/news/how-allergan-gamed-the-system-to-spike-prices-and-sell-opioids/>.

²⁵ *We Are Allergan*, ALLERGAN (last visited May 1, 2020), <https://www.allergan.com/about/about-allergan>.

²⁶ See *Consolidated Financial Statements of the Nestlé Group 2014*, NESTLÉ, 6 2 (Feb. 18, 2015), <https://www.nestle.co.nz/sites/g/files/pydnoa371/files/aboutus/documents/2014-financial-statements.pdf>.

²⁷ Gautam Naik, *Attention shifts to Nestlé's \$29B L'Oreal stake after sale of skin health unit*, S&P Global: Market Intelligence (July 18, 2019), <https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/52918238>.

²⁸ Nestlé Press Release, *Nestlé Health Science acquires leading US gastrointestinal diagnostics company* (May 24, 2011), <https://www.nestle.com/media/pressreleases/allpressreleases/nestle-health-science-acquires-leading-us-gastrointestinal-diagnostics-company>.

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investment in Prometheus later that year.³⁰ In 2010, Nestlé also exited its eye care business.³¹ Typically, Nestlé has justified these and other exits on the basis of a periodic strategic review of whether or not the acquired business fit into the company's core strategy. This raises the risk of whether Zenpep might find itself facing similar considerations of whether it fits into the company's core strategy in the future.

D. Other competitors with a small prescription drug footprint have failed to gain traction in this market, which suggests that Nestlé faces an uphill battle relative to Allergan.

Today, only four companies sell prescription pancreatic enzyme replacements: AbbVie's Creon, Allergan's Zenpep and Viokace, Vivus' Pancreaze, and Digestive Care's Pertzye. Because all of the products have similar clinical effectiveness, sales are heavily dependent on whether the drug is listed as "preferred" by a patient's insurance company, since patients typically pay lower co-pays for drugs with preferred status.

The market leader, Creon, is the only medication approved for treatment of five exocrine pancreatic insufficiency medical diagnoses (also known as "indications") in adults. Allergan's Zenpep and Digestive Care's Pertzye have approval for only three of Creon's five indications.³² This may give Creon a competitive advantage, since the eligible patient population that can be treated with Creon is larger than the population that can be treated with Zenpep. This also may give AbbVie more leverage to bargain for preferred positions on an insurance company's list of covered drugs.

Currently, Allergan aggressively markets its portfolio of drugs to make sure its drugs are preferred by insurance companies. The evidence in the investigation shows [REDACTED]

Chairman Simons, Commissioner Phillips, and Commissioner Wilson argue that Nestlé can simply copy Allergan's strategy, even though it will only have one drug to market compared to the many that Allergan offers today.

29 Sarah de Crescenzo, *Nestlé Sells Gut-Health Test Maker Prometheus Labs, Layoffs Expected*, XCONOMY (July 10, 2019), <https://xconomy.com/san-diego/2019/07/10/nestle-sells-gut-health-test-maker-prometheus-labs-layoffs-expected/>.

30 *Id*; see also Corrine Gretter, *Nestlé Sells Prometheus Laboratories in Trim of Health Portfolio*, BLOOMBERG L. (July 11, 2019, 10:50 AM), <https://news.bloomberglaw.com/mergers-and-antitrust/nestle-sells-prometheus-laboratories-in-trim-of-health-portfolio>.

31 Nestlé Press Release, Nestlé completes sale of Alcon to Novartis (Aug. 26, 2010), <https://www.nestle.com/media/pressreleases/allpressreleases/nestle-completes-sale-of-alcon-to-novartis>.

32 Eurand Pharm., Ltd, Zenpep (pancrelipase) Delayed-Release Capsules, BLA 022210 (Aug. 27, 2009); Digestive Care Inc., Pertzye (pancrelipase) Delayed-Release Capsules, BLA 022175 (May 17, 2012); AbbVie Inc., Creon (pancrelipase) Delayed-Release Capsules, BLA 020725 (Apr. 30, 2009).

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Unsurprisingly, smaller pharmaceutical companies that don't offer an expansive list of drugs have less bargaining leverage. Pancreaze and Pertzye have less than 2% market share,³³ even though they work just as well for most patients that use Creon and Zenpep. This reality relegates companies like them to market their products on a more limited basis, with the hopes that another drug company may one day take them over. Nestlé, which will not have much bargaining leverage, may find itself losing more share to Creon and suffering the same fate as Pancreaze and Pertzye.

Chairman Simons, Commissioner Phillips, and Commissioner Wilson claim that Nestlé has “budgeted” funds for marketing and future development. This is not a promise but is instead a sales pitch. I prefer to approach these assertions with skepticism and evaluate them against how they fit into the buyer's overall financial incentives.

E. Nestlé manages its business to maximize its overall profits. Even if the Zenpep business shrinks, it will have little impact on Nestlé's overall financial results.

When taking a risk of divesting a drug to food and beverage company, it is particularly important to determine whether success or failure will make a meaningful difference in Nestlé's overall financial performance - especially for a company that is seeking to enter a market outside of its core capabilities and strategic focus. In my view, the Commission primarily focused on whether Nestlé would have the personnel and manufacturing capabilities to offer Zenpep. However, I am concerned that we did not conduct sufficient financial due diligence.

After conducting my own analysis of financial information from Nestlé, it is clear that the purchase of these divested businesses is fairly minor. In fact, the purchase was not even significant enough to disclose the financial details to Nestlé's investors. While other transactions and business developments have been carefully examined in management calls with analysts, the company has been mostly silent on this transaction, potentially due to the fact that the acquisition is much smaller than its other transactions. Based on my review, evidence suggests that even if Zenpep lost significant share to a combined AbbVie and Allergan, it would not materially impact Nestlé's overall earnings per share.

I can also conclude that Nestlé's top management and board directors will not have an incentive to devote significant energy to ensure that this divestiture is successful. Based on my assessment, it is more likely to prioritize revitalizing its Perrier and San Pellegrino sparkling water brands, investing further in pet care, and increasing sales of its Starbucks packaged coffee business. All of these would make more financial sense than allocating significant time and effort to make Zenpep a true success. In addition, based on Nestlé's approach to mergers and acquisitions, I also believe that there is a significant risk that the Zenpep business will be resold.

33 *Data for Digestive Enzymes (2018 - 2019)*, IQVIA (on file with IQVIA); see also *Analysis of Agreement Containing Consent Orders to Aid Public Comment, in the Matter of AbbVie Inc. and Allergan plc*, FTC File No. 191-0169, 2 (May 5, 2020).

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F. Supplemental order provisions could have reduced the risk of Nestlé as the divestiture buyer.

While I believe there would be many buyers that may have been superior to Nestlé,³⁴ the Commission could have taken steps to increase the chance that Nestlé would succeed in taking Allergan's place over the long term. These provisions could be designed after thorough due diligence on Nestlé's corporate governance, executive compensation, mergers and acquisition strategy, and capital allocation strategy.

For example, the Commission could have sought amendments to the company's senior management compensation agreements that incentivize investment and attention to Zenpep. The Commission could have sought binding assurances that Nestlé senior management would not resell assets without prior Commission approval. The Commission could have sought terms that give the nutrition subsidiary more independence when seeking outside financing to grow the business. Other supplemental provisions could also bolster senior management's commitment to long-term success of the divestiture.

Given Nestlé's core focus, track record, and the financial aspects of this deal, I have serious doubts that Nestlé will be able to replace the competition killed off by AbbVie and Allergan's merging. The combined company has essentially selected a new competitor that it will clearly be able to crush in the market, and the FTC has given the go-ahead. This is too risky and is a mistake.

IV. AstraZeneca Has an Option to Compete, Not a Commitment to Compete

Injectable biologic drugs that affect the body's immune system can be used to treat a host of conditions and disorders. Unsurprisingly, such drugs can be very expensive for companies to develop and for affected patient populations to afford. Under the FTC's status quo approach of analyzing pharmaceutical mergers, the agency determined that Allergan had an immunologic pipeline drug in development that could one day rival those currently marketed by AbbVie.

Since AbbVie also has a pipeline drug very similar to Allergan's in development, the FTC is proposing that the merging companies renegotiate a development deal with AstraZeneca.

Both AbbVie and Allergan are developing "IL-23" inhibitors³⁵ to treat moderate-to-severe Crohn's disease and ulcerative colitis.³⁶ These two diseases are caused by chronic

34 Merging parties typically propose a buyer to the Commission rather than the Commission selecting a buyer from a list of bidders that parties are willing to sell to.

35 IL-23 is a pro-inflammatory cytokine that is secreted by white blood cells. Allergan's version of the IL-23 inhibitor is called brazikumab, and AbbVie's is called Risankizumab. See *Immunology Pipeline: Risankizumab*, ABBVIE (last visited May 4, 2020), <https://www.abbvie.com/our-science/pipeline/risankizumab.html>; *Gastroenterology Pipeline: Brazikumab*, ALLERGAN (last visited May 4, 2020), <https://www.allergan.com/research-and-development/pipeline>.

36 Analysis of Agreement Containing Consent Orders to Aid Public Comment, *In the Matter of AbbVie Inc. and Allergan plc*, FTC File No. 191-0169, 1 (May 5, 2020).

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inflammation in the digestive track and have similar symptoms: severe diarrhea, abdominal pain, fatigue, and weight loss. Both can be debilitating and lead to life-threatening complications.

The parties are two of only four companies developing IL-23 inhibitors for Crohn's disease and ulcerative colitis.³⁷ AbbVie's IL-23 inhibitor Skyrizi is expected to be approved in [REDACTED] to treat Crohn's disease and in [REDACTED] to treat ulcerative colitis. Allergan is expected to launch its IL-23 inhibitor in 2025 for Crohn's disease and in 2026 for ulcerative colitis.³⁸

These unusual deal terms make me question whether AstraZeneca will have the incentive to fully replace competition lost from the merger or to complete the development process. I share the view of some industry analysts who believe this deal is a massive windfall for AstraZeneca.³⁹ The company will pay nothing and gets to keep the \$250 million upfront payment it received a few years ago from Allergan.⁴⁰ Now, it can re-license the project again, which could further delay needed competition in the immunology space.

A. AstraZeneca has only recently re-focused on the immunology space, which suggests it may not prioritize the development of brazikumab.

In 2015, AstraZeneca made a strategic decision to focus on a narrow set of core therapy areas that did not include immunology.⁴¹ At that time it began selling off rights to various drugs in its immunology portfolio. Brazikumab was part of that effort. In 2016, it licensed its research and development of brazikumab to Allergan.⁴² Prior to that, in 2015, AstraZeneca divested its non-U.S. global rights to Entocort (a medicine for ulcerative colitis and Crohn's Disease). AstraZeneca decided to discontinue its work on brazikumab because the project is "outside [of] AstraZeneca's three main therapy areas."⁴³ AstraZeneca licensed brazikumab to Allergan, and Allergan took over the work in exchange for a \$250 million upfront payment and royalties paid

³⁷ *Id.*, 2.

³⁸ *AstraZeneca acquires global rights to brazikumab following AbbVie's pending acquisition of Allergan*, PHARMACEUTICAL TECHNOLOGY (Feb. 3, 2020), <https://www.pharmaceutical-technology.com/comment/brazikumab-allergan/>.

³⁹ Jacob Plieth, *Astra's retrospective brazikumab cashback*, EVALUATE VANTAGE (Jan. 27, 2020), <https://www.evaluate.com/vantage/articles/news/snippets/astras-retrospective-brazikumab-cashback>.

⁴⁰ AstraZeneca Press Release, *Medimmune out licenses potential medicine for inflammatory diseases to Allergan* (Oct. 3, 2016), <https://www.astrazeneca.com/media-centre/press-releases/2016/medimmune-out-licenses-potential-medicine-for-inflammatory-diseases-to-allergan-03102016.html#>.

⁴¹ AstraZeneca Press Release, *AstraZeneca sharpens focus on main therapy areas through agreement with gastroenterology specialist Tillotts Pharma for Entocort* (July 9, 2015) <https://www.astrazeneca.com/media-centre/press-releases/2015/astrazeneca-tillotts-pharma-entocort-gastroenterology-09072015.html#>.

⁴² AstraZeneca Press Release, *supra*, note 40.

⁴³ AstraZeneca Press Release, *supra*, note 40.

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to AstraZeneca.⁴⁴ While AstraZeneca is apparently now re-focusing on immunology, these facts raise questions about its long-term commitment to the field.

The Commission proposes to resolve competitive concerns from the overlap between Allergan's brazikumab and AbbVie's Skyrizi by requiring Allergan to terminate the 2016 licensing agreement with AstraZeneca. AstraZeneca will take back all intellectual property it previously licensed to Allergan, as well as all the intellectual property Allergan has developed in relation to brazikumab since acquiring the license to the product. In addition, Allergan will assign the contracts related to manufacturing and clinical development of brazikumab to AstraZeneca and transfer ownership of all clinical study materials and clinical data.

AstraZeneca will not make an upfront payment for brazikumab, as would normally be expected in a Commission-approved divestiture. Instead, the money is flowing in the opposite direction: Allergan will reimburse AstraZeneca up to [REDACTED] of AstraZeneca's development costs related to Brazikumab [REDACTED].

B. Given the deal structure of the “divestiture,” AstraZeneca has weaker incentives than Allergan to bring brazikumab to market and to compete successfully.

The Commission's proposed remedy is not a divestiture in a traditional sense, because there is no purchase of assets. Allergan is merely terminating a 2016 licensing agreement that Allergan entered into with AstraZeneca for the rights to take over development work of brazikumab. Thus, the Commission's remedy merely grants AstraZeneca the right to continue the development of a product that it previously decided to get rid of, with funding from Allergan.

One analyst correctly noted that this arrangement is “essentially a ‘free’ new pipeline option.”⁴⁵ In other words, if AstraZeneca wants to prioritize brazikumab, it can, but it doesn't have to. It is not a true capital commitment like Allergan's. AstraZeneca clearly had good cause to believe that Allergan would be better positioned to commercialize brazikumab than it did when it entered into the 2016 licensing agreement. This is not unlike a situation where someone pays \$300 for a ticket to a desirable concert performance, but then gives it away. When we make a substantial purchase like that, we are revealing our preferences that we value that good, service, or investment. This can demonstrate that the purchase is a priority ranking above other items we might purchase. Using this analogy, someone who gets a free ticket is much more likely to be a no-show than someone who paid for it. And if the ticket's market price is \$300, there is also a risk that the person getting it for free will simply resell it for a \$300 profit.

I am always concerned when a buyer is selected outside of a typical, competitive bidding process. Theoretically, AstraZeneca may find it worthwhile to prioritize this project over others.

⁴⁴ *Id.*

⁴⁵ Nick Paul Taylor, *Allergan axes AstraZeneca deal, clearing path for AbbVie merger*, FIERCEBIOTECH (Jan. 27, 2020, 7:57 AM), <https://www.fiercebiotech.com/biotech/allergan-axes-astrazeneca-deal-clearing-path-for-abbvie-merger>.

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In my view, the FTC's investigation did not include a rigorous analysis of all of AstraZeneca's development projects and the metrics AstraZeneca uses to prioritize such initiatives. Absent this evidence and analysis, we have little to rest on when claiming that AstraZeneca will fill the shoes of Allergan, except for self-interested assertions by the parties benefiting from this settlement.

Of course, there is a risk that the current owner of a drug development project will not succeed. However, we must take steps to ensure that any prospective buyer has the same or higher chance of success.

Unfortunately, the Commission did not require an alternative deal structure that would have increased the likelihood of AstraZeneca's entry. The deal structure could have easily been altered in ways that would better reveal AstraZeneca's preferences over other potential projects.

C. There are no supplemental conduct provisions to ensure that AstraZeneca will bring brazikumab to market.

The unusual deal structure is enough to disqualify AstraZeneca as a credible replacement for Allergan. Even though the Commission insisted on pushing forward with AstraZeneca, the agency did not take steps to increase AstraZeneca's chances of success by including supplemental conduct provisions tailored to the features of competition in the market.

As discussed earlier, the FTC often includes supplemental conduct provisions to increase the likelihood that a divestiture buyer can replace the competitive intensity lost by a merger. For example, AstraZeneca is not subject to the Commission's order, and the Commission is not requiring AstraZeneca to prioritize the brazikumab project over other opportunities.

The Commission could have also taken steps to reduce a key barrier to entry and expansion for AstraZeneca by restricting AbbVie and Allergan's contracting and rebating practices. This would make it more likely that AstraZeneca would exercise its option to develop and bring brazikumab to market.

Importantly, in the immunology space, a key feature of competition is the ability for a market player to engage in "portfolio contracting" and "bundled rebates" across its portfolio of drugs. The evidence in the investigation suggests that AbbVie currently uses its bargaining leverage from its blockbuster drug Humira to preference its other immunology drugs. For example,

[REDACTED]

AbbVie's rebating practices are suspicious in their own right, and certain aspects of these practices might be unlawful. But, rebating is undoubtedly a fixture of the competitive environment in immunology that might act as a barrier to entry and expansion for other drugmakers with less bargaining leverage.

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One potential way to increase the likelihood that AstraZeneca would fully replace lost competition and bring brazikumab to market would be to restrict certain contracting practices by the combined AbbVie and Allergan.

In certain instances, the FTC and Department of Justice (DOJ) have prohibited contracting practices that make entry and expansion difficult for a divestiture buyer.⁴⁶ For example, in 2016, the DOJ determined that AnheuserBusch InBev's (ABI) acquisition of SABMiller would increase ABI's incentive and ability to disadvantage its remaining brewery rivals by limiting or impeding the distribution of their beers.⁴⁷ ABI's practices typically included incentives for independent wholesale distributors to sell exclusively or near exclusively ABI beers. To remedy that concern, ABI was required to divest SABMiller's entire U.S. business, including SABMiller's ownership interest in MillerCoors, the right to brew and sell certain SABMiller beers in the United States, and the worldwide Miller beer brand rights. ABI was also prohibited from engaging in contracting practices designed to limit the ability and incentives of independent beer distributors to sell and promote the beers of ABI's rivals.⁴⁸ It is unclear whether this supplemental conduct provision fully restored competition, though it is certainly better than allowing the divestiture to proceed without meaningful safeguards.

The FTC pursued a similar approach in its 2012 order resolving competitive concerns stemming from the merger of CoStar Group, Inc. and LoopNet, Inc.⁴⁹ The FTC imposed supplemental conduct provisions that prohibited the merged firm from restricting customers' ability to support the divested product or requiring customers to buy any of its products as a condition for receiving other products.⁵⁰ Again, we do not know whether this belt-and-suspenders approach fully restored the competition lost by the merger, but it is certainly less risky than allowing a divestiture buyer to be squashed by the combined company.

While provisions like these could have ameliorated some of the concerns with AstraZeneca, I ultimately conclude that simply allowing AstraZeneca to get a windfall without skin-in-the-game is problematic in its own right.

IV. Conclusion

AbbVie and Allergan are no strangers to the Federal Trade Commission. Both companies are pioneers in intellectual property abuse and anticompetitive practices. The FTC has battled

46 *United States v. Anheuser-Busch InBEV SA/NV, et al.*, No. 1:16-cv-01483 (Oct. 22, 2018); *In the Matter of Simon Property Group, Inc.*, FTC File No. 101-0061 (Jan. 13, 2011); *In the Matter of CoStar Group, Inc., Lonestar Acquisition Sub, Inc., and LoopNet, Inc.*, FTC File No. 111-0172 (Aug. 29, 2012); *In the Matter of Perrigo Company and Paddock Laboratories, Inc.*, FTC File No. 111-0083 (June 21, 2012).

47 *United States v. Anheuser-Busch InBEV SA/NV, et al.*

48 *Id.*

49 *In the Matter of CoStar Group, Inc., Lonestar Acquisition Sub, Inc., and LoopNet, Inc.*

50 *Id.*

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both companies for years, including one case that went to the Supreme Court and another that achieved a record-breaking monetary judgment.⁵¹

But in this matter, we took a far different approach. Just days after the President declared a state of emergency due to the current global pandemic, the FTC's Bureau of Competition entered into a settlement with AbbVie and Allergan. [REDACTED], eliminating any realistic possibilities of correcting the deficiencies in the settlement.

The FTC must learn from this experience and let go of the status quo. The Commissioners should take several steps to move forward.

(1) *Dramatically increase rigor and Commission supervision of innovation-merger investigations, especially in industries where new market entrants drive innovation.*

I share Commissioner Rebecca Kelly Slaughter's concerns about investigations into innovation effects of mergers. It is difficult to quantify the harms associated with suppressed entry of new life-saving innovations or breakthrough technologies. When pharmaceutical industries assemble multiple dominant products or when technology companies combine multiple sources of data, this affects how those firms can exert bargaining leverage across the supply chain. It also reduces the ability for new firms to raise capital for entry.

However, in my view we do not have a robust approach to assess how a merger can choke off the entry of startups and nascent businesses. I have observed that when we do uncover evidence that a transaction may lead to these effects, we do not give it the appropriate weight.

As Commissioners, we must substantially increase our supervision to ensure we are meeting our obligations to the public to protect competition. Specifically, the Commission should:

- Request that the Inspector General conduct a programmatic review of our merger investigations in biomedical, consumer technology, and other innovation markets.
- Hold formal Commission meetings on large merger investigations in these sectors prior to any proposed remedy negotiated between staff and merging parties.
- Analyze "stealth consolidation" in the pharmaceutical sector, in accordance with Commissioner Christine S. Wilson's statement in February of this year.⁵²

⁵¹ In 2018, after years of hard-fought litigation, a federal court awarded the FTC a \$448 million monetary judgment – the highest ever in a litigated antitrust case – after finding that AbbVie broke the law by filing sham patent infringement lawsuits against potential generic competitors. *Fed. Trade Comm'n v. AbbVie et al.*, 329 F. Supp. 3d 98 (E.D. Pa. 2018). For years, the FTC and Allergan battled in court over so-called pay-for-delay settlements, where pharmaceutical companies gave payoffs to generic companies to stay off the market. The case was ultimately decided by the Supreme Court. *Fed. Trade Comm'n v. Actavis, Inc. et al.*, 570 U.S. 136 (2013). (In 2015, Actavis purchased Allergan, and the combined company took Allergan's name. The CEO of Actavis, Brent Saunders, continues to be the CEO of Allergan).

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- Require the Bureau of Competition to obtain a vote of the Commission before closing investigations or granting early termination of the Hart-Scott-Rodino waiting period for large mergers, particularly in sectors where innovation is critical for the public interest.⁵³
- (2) *Enhance our analytical capabilities when assessing prospective divestiture buyers and when crafting remedies for anticompetitive mergers and conduct.*

During the Senate confirmation process, Chairman Simons outlined his desire to reduce the failure rate of remedies in merger settlements.⁵⁴ I completely agree with this objective.

The FTC Bureau of Competition's Compliance Division is one of the most important offices in the entire agency. The office assesses prospective divestiture buyers, creates remedies, and ensures compliance with Commission orders. The Compliance Division largely consists of attorneys. While the division has strong capabilities when it comes to assessing many of the legal dimensions of a transaction, including the transfer of contracts and intellectual property, the Commission has not augmented the division with other needed skill sets related to the financial and technical dimensions.

For example, in the United Kingdom, the Competition and Markets Authority established a highly respected group focused on remedies. The group is interdisciplinary and includes individuals with backgrounds in law, auditing and accounting, financial analysis, investment banking, management consulting, and other analytically minded skill sets.⁵⁵ It is clear that this group is a tremendous asset to the Competition and Markets Authority's competition policymaking.

The Commission would also benefit from those with diverse backgrounds and technical expertise. To increase analytical rigor and reduce risk of divestiture remedy failure, the Commission should:

- Support the Compliance Division with additional professionals with experience in transactional due diligence and other technical skill sets.

52 Statement of Commissioner Christine S. Wilson joined by Commissioner Rohit Chopra, Concerning Non-Reportable Hart-Scott Rodino Act Filing 6(b) Orders (Feb. 11, 2020), https://www.ftc.gov/system/files/documents/reports/6b-orders-file-special-reports-technology-platform-companies/statement_by_commissioners_wilson_and_chopra_re_hsr_6b_0.pdf.

53 For example, shortly after the new Commission took office in 2018, the Bureau of Competition was able to grant unconditional clearance to Takeda's \$62 billion takeover of Shire without seeking a Commission vote.

54 Federal Trade Commissioner Confirmations Before The Senate Commerce, Science and Transportation Committee, 115th Cong. (Feb. 14, 2018).

55 Adam Land, *Introducing our Remedies, Business and Financial Analysis team*, COMPETITION AND MARKETS AUTHORITY (Aug. 17, 2018), <https://competitionandmarkets.blog.gov.uk/2018/08/17/introducing-our-remedies-business-and-financial-analysis-team/>.

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- Increase the proportion of financial analysts in the Bureau of Economics and elevate their role in investigations.

(3) *Increase coordination and cooperation with state attorneys general in merger review.*

When law enforcement agencies do not effectively cooperate and coordinate, companies seeking to consummate unlawful mergers can take advantage of the gaps. Given their concurrent jurisdiction, the state attorneys general are key partners in competition enforcement.

Coordination and cooperation can include sharing documentary evidence, conducting joint interviews and investigational hearings, and pooling resources on expert analysis. The FTC should do more to strengthen these partnerships. To advance this goal, the Commission should:

- Ensure that Commission staff verify that merging parties have complied with subpoenas and other reasonable information requests from state regulators prior to finalizing any settlement negotiations.
- Update agreements and policies governing joint investigations with state attorneys general on merger review.⁵⁶
- Assist state policymakers who are seeking to institute state laws on merger control and pre-merger notification.

(4) *Provide greater transparency to the public about the scope of FTC merger reviews.*

Under agency rules, the Commission must solicit public comments on its administrative settlements regarding unlawful mergers. The agency publishes an Analysis to Aid Public Comment that describes the investigation. However, the FTC provides sparse information in this document. I previously raised this concern in *Fresenius/NxStage*.⁵⁷

Greater transparency can increase confidence that the Commission was thorough and independent in its investigation, while still respecting laws and regulations governing confidentiality. It can also offer other merging parties clearer expectations of how it can fully cooperate. The Commission should:

- Publish a more detailed discussion of the analyses conducted regarding potential anticompetitive effects when proposing a settlement.

⁵⁶ *Protocol for Coordination in Merger Investigations*, Fed. Trade Comm'n (last visited May 5, 2020), <https://www.ftc.gov/tips-advice/competition-guidance/merger-investigations>; see also *Press Release, Fed Trade Comm'n, Federal Antitrust Agencies and State Attorneys General Announce Protocol for Joint Federal/State Merger Investigations* (Mar. 11, 1998), <https://www.ftc.gov/news-events/press-releases/1998/03/federal-antitrust-agencies-and-state-attorneys-general-announce>.

⁵⁷ Dissenting Statement of Commissioner Rohit Chopra In the Matter of Fresenius Medical Care AG & Co. KGaA and NxStage Medical, Inc., FTC File No. 171-0227, 4 (Feb. 19, 2019) <https://www.ftc.gov/public-statements/2019/02/statement-commissioner-chopra-matter-fresenius-medical-care-ag-co-kgaa>.

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- Disclose the data sets relied upon to justify a remedy (or lack thereof).
- Provide the public with more details about the assessment of any proposed divestiture buyers.
- Outline the Commission's assessment of entry conditions post-transaction.

Today's uncertain times reveal that the mission of the FTC has never been more relevant. The agency must evolve, and the Commission must take concrete actions to improve agency decision-making to ensure the agency is advancing this mission.

DISSENTING STATEMENT OF COMMISSIONER REBECCA KELLY SLAUGHTER

Today, the Commission proposes a consent agreement with AbbVie and Allergan to settle claims that the parties' pending merger will substantially lessen competition in three relevant markets: (1) drugs for the treatment of exocrine pancreatic insufficiency, a condition that makes it impossible to digest food properly; (2) Interleukin-23 ("IL-23") inhibitors for the treatment of moderate-to-severe Crohn's disease; and (3) IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. AbbVie's \$63 billion acquisition of Allergan—a merger of two of the largest pharmaceutical companies in the world, both of which have previously been the subject of allegations of anticompetitive conduct—has rightfully garnered substantial public attention. Commission staff painstakingly reviewed and analyzed large volumes of information, and I commend them for their work on this investigation, especially in light of the challenging and unprecedented circumstances of the past several months. As I have said in the past, however, I remain concerned about the Commission's approach to pharmaceutical mergers. In this case specifically, I do not believe the proposed settlement adequately remedies a range of competitive issues that this acquisition poses. I share the concerns Commissioner Chopra has articulated in detail about the proposed divestitures and the absence of meaningful benefits to consumers, and I write separately only to add a few additional thoughts on the question of innovation harms.

Analysis of the effects of a merger on innovation is a standard practice for the Commission in all merger matters, and I think that it deserves particularly substantial and vigorous investigation when it comes to transactions between pharmaceutical companies. At a time when we are all enduring increasingly difficult news about family members, friends, and neighbors near and far with serious health concerns because of the global coronavirus pandemic, we are keenly aware of the need for companies to innovate by creating and manufacturing products for testing, prevention, and treatment. As pharmaceutical companies frequently cite the

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need to invest in research and development to justify exorbitant drug prices,¹ innovation consequences of pharmaceutical mergers merit particular scrutiny.

Vigorous enforcement of the antitrust laws helps protect and promote the competitive environment that supports strong incentives for research and development and leads to greater innovation.² Innovation also helps lead to better outcomes for consumers in the form of lower prices, higher quality, and more choices. Thus, it is essential to scrutinize closely whether a merger is likely to diminish innovation competition by incentivizing the merged firm to curtail its innovative efforts, including investment in research and development, below the level that would prevail in the absence of the merger.

The explicit inclusion of a section on innovation effects in the 2010 Horizontal Merger Guidelines was a significant step in formalizing the recognition that a merger could harm innovation.³ Since the 2010 Guidelines, the Commission has brought several cases that include allegations of harm to innovation.⁴ To conduct a thorough analysis of innovation competition, it is essential to seek both past evidence of innovation in an industry, but also information about what parties and other stakeholders in the industry predict about future competition. When considering the competitive effects on innovation, we must be particularly mindful of Section 7's instructing us to prevent monopolies and oligopolies in their "incipiency" and the Supreme Court's emphasis that the Clayton Act deals with "probabilities, not certainties."⁵

More importantly, the Commission must seek to gather this kind of evidence at the earliest stage possible in an investigation and from the most relevant sources possible to ensure the most thorough record. In addition, we need to cast a broad net for third parties and other industry participants to consult. In this case, staff deserves credit for its consideration of, and investigation into, the transaction's effect on the parties' research and development programs and investments, as well as on innovation competition that was more in-depth than what I have seen in previous pharmaceutical mergers.⁶

1 Yoni Blumberg, *Here's why many prescription drugs in the US cost so much – and it's not innovation or improvement*, CNBC (Jan. 14, 2019), <https://www.cnbc.com/2019/01/10/why-prescription-drugs-in-the-us-cost-so-much.html>.

2 See Giulio Federico, Fiona Scott Morton & Carl Shapiro, *Antitrust and Innovation: Welcoming and Protecting Disruption*, Innovation Pol'y & Econ. 125, 26 (2019), <http://faculty.haas.berkeley.edu/shapiro/disruption.pdf>.

3 See U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines § 6.4 (2010).

4 See, e.g., *In the Matter of Altria Group/JUUL Labs*, Docket No. 9393 (Apr. 1, 2020); *In the Matter of Illumina Inc./Pacific Biosciences of California, Inc.*, Docket No. 9387 (Dec. 12, 2019); *In the Matter of CDK Global and Auto /Mate*, Docket No. 9382 (Mar. 20, 2018); *In the Matter of Verisk/Eagle View*, Docket No. 9363 (Dec. 16, 2014); *FTC v. Steris Corporation*, No. 15-cv-1080, (N.D. Ohio Sept. 24, 2015).

5 *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962).

6 See *Dissenting Statement of Commissioner Rebecca Kelly Slaughter In the Matter of Bristol-Myers Squibb and Celgene*, Fed. Trade Comm'n (Nov. 15, 2019), https://www.ftc.gov/system/files/documents/public_statements/1554283/17_-_final_rks_bms-celgene_statement.pdf; *Closing Remarks of Commissioner Rebecca Kelly Slaughter*,

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Nevertheless, I am concerned that the initial scope of the investigation curtailed the Commission's ability to obtain and consider all relevant evidence. For example, crucial pieces of evidence should be made available early in the investigation and pursuant to a Second Request. Because Second Requests are enforceable in court for a party's lack of substantial compliance, information produced under that process provides the Commission with a materially different level of confidence that it has received the relevant information needed to determine whether a transaction is likely to harm competition. Furthermore, in these types of cases, it is incumbent on the Commission to seek and on parties to produce evidence from the individuals best positioned to understand the scientific significance of particular research and development projects, as well as contemporaneous evidence that was generated at the time and not documents created in anticipation of an agency challenge.

Based on my review of the record before the Commission, and in light of AbbVie's public representations about its plans to curtail Allergan's ongoing research programs,⁷ I cannot share the majority's confidence that the innovation effects of this merger are competitively benign.

I appreciate that the investigative analysis in this case on the question of innovation harms is movement in the right direction. Going forward, however, I hope our investigations will address these issues more comprehensively at the very start of an investigation.

FTC Hearing #4: Innovation and Intellectual Property (Oct. 24, 2018), https://www.ftc.gov/system/files/documents/public_statements/1418279/slaughter_-_closing_remarks_at_ip_innovation_hearing_10-24-18.pdf.

⁷ Eric Sagonowsky, *AbbVie, nearing the end of Humira's historic run, scoops up a struggling Allergan for \$63B*, FiercePharma (June 25, 2019), <https://www.fiercepharma.com/pharma/no-allergan-split-abbvie-buys-struggling-drugmaker-for-63b>.

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 AbbVie Inc. (“AbbVie”) and Allergan plc (“Allergan”) designed to remedy the anticompetitive effects resulting from AbbVie’s proposed acquisition of Allergan. The proposed Decision and Order (“Order”) contained in the Consent Agreement requires Allergan to divest all rights and assets related to its Zenpep and Viokase products to Nestlé S.A. (“Nestlé”). The proposed Order also requires that Allergan return its rights and assets related to brazikumab to AstraZeneca plc (“AstraZeneca”).

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 a Scheme of Arrangement under Irish law, AbbVie will acquire all of the voting securities of Allergan from its shareholders for approximately \$63 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. markets for (1) prescription drugs for the treatment of exocrine pancreatic insufficiency (“EPI”); (2) Interleukin-23 (“IL-23”) inhibitors for the treatment of moderate-to-severe Crohn’s disease; and (3) IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in these markets as a result of the proposed Acquisition.

THE PARTIES

Headquartered in North Chicago, Illinois, AbbVie researches, develops, manufactures, and sells prescription pharmaceutical products and biologic products in several therapeutic areas, including immunology, oncology, virology, neuroscience, and women’s health. Among other products, AbbVie sells a product to treat EPI and is developing an IL-23 inhibitor to treat moderate-to-severe Crohn’s disease and ulcerative colitis. Like AbbVie, Allergan researches, develops, manufactures, and sells prescription pharmaceutical products in the United States. Among its products, Allergan also sells a product to treat EPI and is developing an IL-23 inhibitor to treat moderate-to-severe Crohn’s disease and ulcerative colitis.

THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS**Drugs for the Treatment of Exocrine Pancreatic Insufficiency**

EPI is a condition that results from a deficiency of pancreatic enzymes. Patients who have EPI cannot properly digest fats, proteins, and carbohydrates in the foods they eat and, as a

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result, may suffer from malnutrition and have uncomfortable gastrointestinal symptoms when they eat. EPI is treated using pancreatic enzyme products. Pancreatic enzyme products contain the active ingredient pancrelipase, a mixture of the digestive enzymes amylase, lipase, and protease that is extracted from the pancreas of a pig.

Only four companies sell prescription pancreatic enzyme product in the United States: AbbVie, Allergan, Vivus Inc. (“Vivus”), and Chiesi USA, Inc. (“Chiesi”). AbbVie is the clear market leader with its product, Creon, and Allergan is the second-largest supplier, with its product, Zenpep. Vivus sells Pancreaze and Chiesi sells Pertzye. Allergan also sells a second pancreatic enzyme product, Viokase, although its sales in the United States are much more limited. Together, AbbVie and Allergan have a share of more than 95 percent of the market for drugs to treat EPI.

Interleukin-23 Inhibitors for the Treatment of Moderate-to-Severe Crohn’s Disease and for the Treatment of Moderate-to-Severe Ulcerative Colitis

Ulcerative colitis and Crohn’s disease are the most common causes of chronic inflammation of the digestive track. Both diseases have similar symptoms—severe diarrhea, abdominal pain, fatigue, and weight loss—and both can be debilitating and lead to life-threatening complications. The location of the inflammation is the primary difference between the two diseases: ulcerative colitis is a continuous inflammation of the colon, affecting only the innermost lining, while Crohn’s disease can occur anywhere between the mouth and the anus, has healthy parts of the digestive tract between inflamed parts, and can occur in all layers of the bowel walls. Because the diseases are similar, drugs that are effective in treating ulcerative colitis are also typically effective in treatment Crohn’s disease (and vice versa), but the United States Food and Drug Administration (“FDA”) requires that companies seeking ulcerative colitis and Crohn’s disease indications for drugs conduct separate clinical studies and submit separate applications to market drugs for each indication.

A variety of drugs are approved to treat ulcerative colitis and Crohn’s disease, but the effectiveness for most drugs is limited. IL-23 inhibitors are a new class of drugs to treat both diseases. Johnson & Johnson’s Stelara is the only IL-23 inhibitor currently approved to treat moderate-to-severe Crohn’s disease and ulcerative colitis in the United States. Stelara is both an IL-23 inhibitor and an Interleukin-12 inhibitor. Only three other companies—AbbVie, Allergan, and Eli Lilly and Company—have IL-23 inhibitors in late-stage development for ulcerative colitis and Crohn’s disease. Allergan is developing brazikumab and AbbVie is developing Skyrizi.

THE RELEVANT GEOGRAPHIC MARKET

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. Drugs to treat EPI and drugs to treat moderate-to-severe ulcerative colitis and Crohn’s disease 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.

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COMPETITIVE EFFECTS OF THE ACQUISITION

The proposed Acquisition would likely result in substantial competitive harm to consumers in the markets for prescription drugs for the treatment of EPI, IL-23 inhibitors for the treatment of moderate-to-severe Crohn's disease, and IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. Together, AbbVie and Allergan account for more than 95 percent of the market for drugs to treat EPI, and they are two of a limited number of companies in late-stage development with IL-23 inhibitors to treat moderate-to-severe ulcerative colitis and Crohn's disease.

ENTRY CONDITIONS

Entry in the relevant markets 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.

THE CONSENT AGREEMENT

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring the combined company to divest Allergan's Zenpep and Viokase business, including its regulatory approvals, intellectual property, contracts, and inventory to Nestlé, and Allergan's brazikumab business to AstraZeneca. AbbVie and Allergan also must transfer all business information, research and development information, regulatory, formulation, and manufacturing reports related to the divested products, as well as provide access to knowledgeable employees to assist in the transfer. The provisions of the Consent Agreement ensure that Nestlé and AstraZeneca become independent, viable, and effective competitors in the U.S. markets.

Nestlé is the world's largest food and beverage company, operating in more than 190 countries around the world. While the company is most well-known for its chocolate products, it also operates Nestlé Health Science, an integrated health company that focuses on nutrition products, including enteral feeding products that are used in hospitals and at home by patients who are unable to chew or swallow food. Nestlé's existing business includes products that are highly complementary to the divestiture assets. Nestlé has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition.

AstraZeneca is a global research-based pharmaceutical company specializing in researching, developing, manufacturing, and marketing prescription products. AstraZeneca was responsible for conducting some of the early phase clinical studies for brazikumab, but out-licensed the product to Allergan in 2016. AstraZeneca is a well-qualified buyer for brazikumab because, as the original innovator of the product, it already has experience developing

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brazikumab prior to out-licensing it to Allergan, and, further, the key team members who were previously responsible for brazikumab's development are still employed by the company and will take responsibility for the developing the product. With its resources, capabilities, and previous experience with brazikumab, AstraZeneca is well positioned to successfully develop and commercialize the product and thereby replace the competition that otherwise would have been lost through the proposed Acquisition.

AbbVie and Allergan must accomplish the divestitures no later than ten days after consummating the proposed Acquisition. If the Commission determines that Nestlé or AstraZeneca are not acceptable acquirers, or that the manner of the divestitures is not acceptable, the proposed Order requires AbbVie and Allergan to unwind the sale of rights and assets and then divest the affected product to a Commission-approved acquirer within six months of the date the Order becomes final. The Commission has agreed to appoint a Monitor to ensure that AbbVie and Allergan 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 rights and assets to the buyers. The proposed Order further allows the Commission to appoint a trustee in the event that AbbVie and Allergan 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.

Complaint

IN THE MATTER OF

**ARKO HOLDINGS LTD.,
GPM SOUTHEAST, LLC,
GPM PETROLEUM, LLC,
AND
EMPIRE PETROLEUM PARTNERS, LLC**

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-4726; File No. 201 0041
Complaint, August 25, 2020 – Decision, October 5, 2020*

This consent order addresses the \$415 million acquisition of certain assets of Empire Petroleum Partners, LLC by Arko Holdings Ltd., GPM Southeast, LLC, and GPM Petroleum, LLC. The complaint alleges that the Acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition for the retail sale of gasoline in seven local markets in Indiana, Michigan, Maryland, and Texas, and by substantially lessening competition for the retail sale of diesel fuel in three local markets in Indiana, Michigan, and Texas. Under the order respondents must divest certain retail fuel assets in seven local markets in Indiana, Michigan, Maryland, and Texas.

Participants

For the *Commission*: Steven R. Couper and Nicolas Stebinger.

For the *Respondents*: Stephen M. Pepper, Greenberg Traurig LLP; Edward G. Biester III, Duane Morris LLP.

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 Arko Holdings Ltd., through its indirectly controlled subsidiaries GPM Southeast, LLC, and GPM Petroleum, LLC, entered into an agreement to acquire retail fuel outlets and other interests from Empire Petroleum Partners, LLC, 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 Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and that a proceeding in respect thereof would be in the public interest, hereby issues this Complaint, stating its charges as follows.

I. RESPONDENTS**GPM**

1. Respondent Arko Holdings Ltd. (“Arko”) is a corporation organized, existing, and doing business under, and by virtue of, the laws of Israel, with its executive offices and principal