# UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Joseph J. Simons, Chairman Noah Joshua Phillips

Rohit Chopra

Rebecca Kelly Slaughter Christine S. Wilson

| In the Matter of          | ) |                    |
|---------------------------|---|--------------------|
|                           | ) |                    |
| ABBVIE INC.,              | ) |                    |
| a corporation;            | ) | DECISION AND ORDER |
| ,                         | í | DOCKET NO. C-4713  |
| and                       | ) | DOCKET 110. C-4/13 |
|                           | ) |                    |
| ALLERGAN PLC,             | ) |                    |
| a public limited company. | ) |                    |
|                           | ) |                    |

#### **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

- 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

- 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

- 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.
- "FDA Authorization(s)" means all of the following: "New Drug Application" ("NDA"), EE. "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 seg., 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. '

8

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

2.

- 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

dwenat 14.  $\tilde{o}$   $\acute{o}$  .  $1\acute{o}\#\hat{O}1$  " $\rlap{\ }^{}$  >\* $\rlap{\ }^{}$  ># $\rlap{\ }^{}$  .& $\acute{a}_{i}!$   $\acute{Y}$  W \*

- 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.
- 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 perform(a)1 (n)2 p.5ccrr6 (s)]TJ Oufaomao2 (e)pt (e.5 (a) (l)-o)g-5 ( ( ( i)56 (

- 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 Designeerdeais M Á•r M ¾Râá!ä!R; Î."...]"¡ä. V ÞÃÍ deehe

- 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 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 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 Z m

- 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.
- 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,

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

- 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 is

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

 $(yi)-2 \ (on\ of) 3 \quad [(P)1\ (r)-2\ (oduc)-1\ (t)-2\ (s)-1\ (D) 4\ (iv\ (,(g\ R) 2\ (e)-1\ (s)-1\ (ponde)-1\ (n) 5\ (e)] TJ \quad 0.001$ 

- 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.

- 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:

21

cooperate with and assist any Proposed Acquirer or Acquirer of the Divestiture

1.

- 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 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:
  - 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;
  - 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, R4sb8ot(s)61.1 s6ruR4sb (e)han 3B,4Td

*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 effo

- 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 ,alin4 (er)-0.d Tc -0.00t(r)-2 (e)4 (r) and in aesea; a1 (m0 8.1 (99sor269.51 a19 510.30e D3 cm /Im0 D6

- 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 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:

If the Respondents have not fully complied with the obligations to assign, grant, license, A. 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  $\S 5(l)$  of the Federal Trade Commission Act, 15 U.S.C. § 45(1), 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  $\S 5(l)$  of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by a Respondent to comply with this Order.

The Commission shall select the Divestiture Trustee, subject to the consent of

B.

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

provided, however, that such agreement shall not restrict the Divestiture Trustee

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

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

## NON-PUBLIC APPENDIX I

## NON-PUBLIC APPENDIX II