

**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;)

and)
)

ALLERGAN PLC,)
a public limited company.)

**DECISION AND ORDER
DOCKET NO. C-4713**

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

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 Clonshaugh 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

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.
- 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.
- 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.
- 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.
- EE. “FDA Authorization(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SND A”), 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.
- 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;

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.
- 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, 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.
- 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 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
 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.

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.

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
 - 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 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.
- 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 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 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).

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.

- 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.
- 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
 - 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 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 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 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
 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.

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 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 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 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 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.
- 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.
- 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 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:

- 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.

April J. Tabor
Acting Secretary

SEAL
ISSUED: September 3, 2020

NON-PUBLIC APPENDIX I

NON-PUBLIC APPENDIX II