

The Commission having thereafter considered the matter and having 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, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Pfizer 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 235 East 42nd Street, New York, New York 10017.
2. Respondent Hospira 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 275 North Field Drive, Lake Forest, Illinois 60045.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER

I.

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

- A. “Pfizer” means: Pfizer Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Pfizer Inc. (including, without limitation, Perkins Holding Company, and Innopharma, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Pfizer shall include Hospira.

- E. “Acquirer(s)” means the following:
1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
 2. a Person approved by the Commission to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. “Acquisition” means Respondent Pfizer’s acquisition of fifty percent (50%) or more of the voting securities of Hospira. Respondents entered an *Agreement and Plan of Merger* on February 5, 2015, to effect the Acquisition, among Pfizer Inc., Perkins Holding Company, and Hospira Inc., that was submitted to the Commission.
- G. “Acquisition Date” means the date on which the Acquisition is consummated.
- H. “Acetylcysteine Products” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Respondent Pfizer pursuant to the following Applications:
1. ANDA Number 203-853;
 2. ANDA Number 204-674; and,
 3. any supplements, amendments, or revisions to these Applications.
- I. “Acetylcysteine Product Divestiture Assets” means the following assets and rights of Pfizer, as such assets and rights are in existence as of the date Pfizer signs the Agreement Containing Consent Orders in this matter and as are maintained by Pfizer in accordance with the Order to Maintain Assets until the Closing Date:
1. all rights to all of the Applications related to the Acetylcysteine Products; and,
 2. all rights to any profits, royalties or other financial interests related to the

- L. “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, without limitation, the United States Food and Drug Administration (“FDA”).
- M. “Alvogen” means Alvogen Group, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 10 Bloomfield Avenue, Building B, Pine Brook, NJ 07058, or any of its wholly-owned subsidiaries.
- N. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent and the FDA related thereto. The term “Application” 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 a Respondent and the FDA related thereto.
- O. “Business” means the research, Development, manuf(0(A)]TJ 99Tu 0 Td (“)TjD)2(r)3(u)-10(gu4

8. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
9. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date, a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
 - a. to require Respondents

FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

13. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date, a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
14. for each specified Divestiture Product, a list of all active pharmaceutical ingredient suppliers listed on any Application of a Retained Product that is the therapeutic equivalent (as that term is defined by the FDA) of that Divestiture Product;
15. for each specified Divestiture Product that is a Contract Manufacture Product:
 - a. a list of the inventory levels (weeks of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler or distributor) as of the Closing Date; and
 - b. anticipated reorder dates for each customer as of the Closing Date;
16. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;
17. -2(t10(a)4(s))4(s)17.

Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of any Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, the specified Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the specified Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the specified Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

Q. “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.

R. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, 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.

S. “Clindamycin Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Respondent Hospira pursuant to the following Applications:

1. ANDA Number 62-801;
2. ANDA Number 62-800;
3. ANDA Number 62-943; and,
4. any supplements, amendments, or revisions to these Applications.

T. “Clindamycin Product Assets” means all rights, title and interest in and to all assets related to the Business within the Geographic Territory of Hospira related to each of the Clindamycin Products, to the extent legally transferable, including, without limitation, the following:

1. at the Acquirer’s option, any equipment that is specialized for use in the manufacture or fi5 -(t)-2((th)2(e-)4(A40(D40(D)]TJ 0 Tc 0 Tw 2.486 0 Td -))Tj -0.004 Tc 0.0

- U. “Closing Date” means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- V. “Confidential Business Information” means all information owned by, or in the possession or control of, any Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes* the following:
1. information relating to any Respondent’s general business strategies or practices that does not discuss with particularity the Divestiture Products;
 2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
 3. information that is contained in documents, records or books of any Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
 4. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating

Y. “Development” means all preclinical and clinical drug development activities (including formulation), 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 relatl(f)3(f)4(t)-2(i)-2(ne5(2 r)3(e)4Tj 0.44 0)-4(e)]e/itent ap

4. the Voriconazole Product Assets.

DD. “Divestiture Product Core Employees” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Contract Manufacture Product.

EE. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) under a Remedial Agreement with rights to sublicense to:

1. all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondents:
 - a. to research and Develop the specified Divestiture Product(s) for marketing, distribution or sale within the Geographic Territory;
 - b. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the Geographic Territory;
 - c. to import or export the specified Divestiture Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the specified Divestiture Products in the Geographic Territory; and
 - d. to have the specified Divestiture Product(s) made anywhere in the World for distribution or sale within, or import into the Geographic Territory; and,
2. to use the ADD-V Technology, the ADD-Vantage® Vial, and ADD-Vantage® Trademark solely for the purposes of use in the Business specifically related to the Clindamycin Products;

provided however, that for any Product Licensed Intellectual Property or Product Manufacturing Technology that is the subject of a license from a Third Party entered into by a Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to that Respondent.

FF. “Divestiture Product Releasee(s)” means the following Persons:

1. the Acquirer for the assets related to a particular Divestiture Product;
2. any Person controlled by or under common control with that Acquirer; and
3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.

GG. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.

HH. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration;

- TT. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- UU. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- VV. “Patent(s)” means all patents, 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 Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- WW. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- XX. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- YY. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other 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 of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.
- ZZ. “Product Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):
1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from the Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
 2. pursuant to which the Respondent had or has as of the Closing 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 the specified Divestiture Product;
 3. relating to any Clinical Trials involving the specified Divestiture Product;

4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished Product on behalf of the Respondent;
7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to the Respondent;
9. pursuant to which a Third Party is licensed by the Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the specified Divestiture Product to the Respondent including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), the 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 specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

AAA. "Product Copyrights" means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical

12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from 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;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;
17. manufacturing batch records related to the specified Divestiture Product;
18. stability testing records related to the specified Divestiture Product;
19. change in control history related to the specified Divestiture Product; and
20. executed validation and qualification protocols and reports related to the specified Divestiture Product.

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

1. a complete and accurate list containing the name of each Divestiture Product Core

used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and,

2. in those instances in which any Respondent (i) owns, licenses or controls the rights to the Drug Master File of a Product that is the subject of an NDA (“NDA Product”) that is the therapeutic equivalent

basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists,

Order final and effective;

3. any 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, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by that Respondent(s) to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

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“Retained Product” means any Product(s) other than a Divestit4d(an)-4(a)-400(a)4(ppr)3(ov6((-TJ 0.0

1. designating employees of the Respondent(s) knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the

relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

D. Respondents shall:

1. submit to each Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
 - 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;
3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Interim Monitor (if any has been appointed) 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 books, records, and files directly related to the Divestiture Products acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture

E. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondents shall provide, or cause to be provided to that Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to any Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondents shall obtain any consents from Third Parties required to comply with this provision. No Respondent shall enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

F. Respondents shall:

1. upon reasonable written notice and request from the Acquirer to Respondents, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Supply Cost, for a period of time sufficient to allow the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondents, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) of the relevant Respondent (as that Respondent is identified in the definition of the respective Divestiture Product) from Persons other than Respondents;
2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s) supplied by a Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the supplying Respondent 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 Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP.

This obligation may be made contingent upon the Acquirer giving that Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that a 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 that Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however,* that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties,

information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

- H. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of their 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 one (1) year after the Closing Date. Respondents shall provide a copy of the notification to the relevant Acquirer. Respondents shall maintain complete records of all such notifications at Respondents' registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent

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acquired by that Acquirer. Each Respondent shall also covenant to that Acquirer that as a condition of any assignment or license from that Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, diDiv7 Td [(i).r the pu2(, o 1ppl)-12(yaTd ()20(y)20(t)-2(102 Tc -0.0

2. waive conflicts of interest, if any, to allow that Respondent’s outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of that Respondent’s outside counsel related to that Divestiture Product.

N. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology (for the Contract Manufacture Products) and the related obligations imposed on the Respondents by this Order is:

1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory; and
2. to create a viable and effective competitor, that is independent of Respondents in the Business of each Divestiture Product within the Geographic Territory; and,
3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission’s Complaint in a timely and sufficient manner.

III.

IT IS FURTHER ORDERED that:

A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Interim Monitor”) to assure that the Respondents expeditiously comply with all of their obligations and perform id2((e

1. The Interim Monitor shall have the power and authority to monitor 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 Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Interim Monitor shall serve until the date of completion by the Respondents of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and, with respect to each Divestiture Product that is either a Clindamycin Product, Melphalan Product, or a Voricanazole Product, until the earliest of: (i) the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and able to manufacture the Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondents of its intention to abandon its efforts to manufacture that Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that, the Interim Monitor's service shall not exceed five (5) years from 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.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents

G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities

IV.

IT IS FURTHER ORDERED that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Product 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 Respondents to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee’s powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of

the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee'

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondents may require the Divestiture Trustee and each of the Divestiture(i)-2(ve)4(s)-1(t)-2(i)-2

purposes:

- A. To assure such Respondent's compliance with any Remedial 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
- B. 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 the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, however, that pursuant to this Paragraph V, the 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 relevant Acquirer (but shall not be deemed to have violated this requirement if that 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.

VI.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. For each Divestiture Product that is a Contract Manufacture Product, Respondents shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to

- E. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- F. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VII.

IT IS FURTHER ORDERED that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fulfilled their obligations under the Order, Respondents shall submit to the Commission a letter certifying the date on which they have fulfilled their obligations under the Order.

VIII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B.

**NON-PUBLIC APPENDIX I
AGREEMENTS RELATED TO THE DIVESTITURES**

[Redacted From the Public Record Version, But Incorporated By Reference]