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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of	)	
IMPAX LABORATORIES, INC., **a corporation;**	)	
ROUNDTABLE HEALTHCARE PARTNERS II, L.P., **a limited partnership;**	)	**Docket No. C-4511**
and	)	
TOWER HOLDINGS, INC., **a corporation.**	)	

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Impax Laboratories, Inc. ("Impax") of the voting securities of Respondent Tower Holdings, Inc. ("Tower") and Lineage Therapeutics, Inc. ("Lineage") from Respondent RoundTable Healthcare Partners II, LP ("RoundTable") (Impax, Tower, and RoundTable hereinafter collectively referred to as "Respondents"), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, 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; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such

Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

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 Impax is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 30831 Huntwood Avenue, Hayward, California 94544.

2. Respondent RoundTable is a limited partnership organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 272 E. Deerpath Road, Suite 350, Lake Forest, Illinois 60045.

3. Respondent Tower is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 215 Wood Avenue, Middlesex, New Jersey 08846.

4. 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. "Impax" means: Impax Laboratories, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Impax Laboratories, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Impax shall include Tower and Lineage.

B. "RoundTable" means: RoundTable Healthcare Partners II, L.P., its directors, officers, general partners, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by

RoundTable Healthcare Partners II, L.P, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Tower" means: Tower Holdings, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Tower Holdings, Inc. (including, without limitation, CorePharma LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

D. "Respondents" means Impax, RoundTable, and Tower, individually and collectively; *provided however*, that from the later to occur of (i) the Closing Date, or (ii) the Acquisition Date, the term "Respondents" shall mean Impax and Tower, individually and collectively.

E. "Commission" means the Federal Trade Commission.

F. "Acquirer" 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.

G. "Acquisition" means Respondent Impax's acquisition of, among other things, the voting securities of Tower pursuant to a *Stock Purchase Agreement* dated October 8, 2014, by and among Tower, Lineage Therapeutics Inc., RoundTable, and Impax.

H. "Acquisition Date" means the date on which Respondents close on the Acquisition.

I. "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").

J. "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 the Respondent and the FDA related thereto.

K. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.

L. "Categorized Assets" means the following assets related to the Divestiture Product(s):

1. all rights to all of the Applications related to the Divestiture Product(s);
2. all Product Intellectual Property related to the Divestiture Product(s) that is not Product Licensed Intellectual Property;
3. all Product Approvals related to the Divestiture Product(s);
4. all Product Manufacturing Technology related to the Divestiture Product(s) that is not Product Licensed Intellectual Property;
5. all Product Marketing Materials related to the Divestiture Product(s);
6. all Product Scientific and Regulatory Material related to the Divestiture Product(s);
7. all Website(s) owned, operated, or controlled by a Respondent related exclusively to the Divestiture Product(s);
8. the content related exclusively to the Divestiture Product(s) that is displayed on any Website owned, operated, or controlled by a Respondent that is not dedicated exclusively to the Divestiture Product(s);
9. a list of all of the NDC Numbers related to the Divestiture Product(s), and rights, to the extent permitted by Law:
    a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of the Divestiture Product(s) *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;
    b. to prohibit Respondents from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law;
    c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondents of any such cross-referencing that is discovered by a Respondent);

d. to seek cross-referencing from a customer of the Respondents' NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;

e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and,

f. to approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);

10. all Product Development Reports related to the Divestiture Product(s);

11. at the option of the Acquirer of the Divestiture Product(s), all Product Assumed Contracts related to the Divestiture Product(s) (copies to be provided to that Acquirer on or before the Closing Date);

12. all patient registries related to the Divestiture Product(s), and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the Divestiture Product(s) (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

13. a list of all customers and targeted customers for the Divestiture Product(s) and a listing of the net sales (in either units or dollars) of the Divestiture Product(s) 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 Divestiture Product(s) on behalf of the High Volume Account and his or her business contact information;

14. for each Divestiture Product that is on the market as of the Closing Date:

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;

15. at the option of the Acquirer of the Divestiture Product(s) 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 Divestiture Product(s);

16. copies of all unfilled customer purchase orders for the Divestiture Product(s), if marketed, as of the Closing Date, to be provided to the Acquirer of the Divestiture Product(s) not later than five (5) days after the Closing Date;

17. at the option of the Acquirer of the Divestiture Product(s), all unfilled customer purchase orders for the Divestiture Product(s) if marketed; and,

18. all of the specified Respondent's books, records, and files directly related to the foregoing;

provided, however, that the term "Categorized Assets" *excludes*: (i) documents relating to any Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the Divestiture Product(s); (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the Divestiture Product(s) by the Interim Monitor (if one is appointed) or the Acquirer of the Divestiture Products; (iv) information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Licensed 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 Divestiture Product(s) and to the 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 Divestiture Product(s); or (ii) for which any Respondent has a legal obligation to retain the original copies, that 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 Divestiture Product(s), the Respondents 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 Respondents provide the Acquirer with the above-described information without requiring a Respondent completely to divest itself of information that, in content, also relates to the Retained Products.

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 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.

O. "Closing Date" means the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Product Assets to an Acquirer pursuant to this Order.

P. "Confidential Business Information" means all information owned by, or in the possession or control of, a 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 a Respondent's general business strategies or practices that does not discuss with particularity the Divestiture Product(s);

2. information specifically excluded from the Divestiture Product Assets conveyed to that Acquirer;

3. information that is contained in documents, records or books of a Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Product(s) or that is exclusively related to the Retained Products; 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 to any United States, state, or foreign antitrust or competition Laws.

Q. "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 related to the foregoing. "Develop" means to engage in Development.

R. "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 an Acquirer for its use of any of a Respondent's employees' labor shall not exceed the average hourly wage rate for such employee; *provided, however,* that, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Direct Cost" means such cost as is provided in such Remedial Agreement for that Divestiture Product.

S. "Divestiture Product(s)" means the Ursodiol Products and the Pilocarpine Products, individually and collectively.

T. "Divestiture Product Assets" means the Ursodiol Product Assets and the Pilocarpine Product Assets, individually and collectively.

U. "Divestiture Product Divestiture Agreement(s)" means the following: the *Asset Purchase Agreement* by and among, Impax Laboratories, Inc., and Elan Pharma International Ltd., dated as of February 13, 2015, and all amendments, exhibits, attachments, agreements, and schedules related thereto. This agreement is contained in Non-Public Appendix I.

V. "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 all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by the Respondent specified in the definition of the particular Divestiture Product(s):

1. to research and Develop the Divestiture Products for marketing, distribution or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Divestiture Products within the Geographic Territory;
3. to import or export the Divestiture Products to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the Divestiture Products in the Geographic Territory; and,
4. to have the Divestiture Products made anywhere in the world for distribution or sale within, or import into the Geographic Territory;

provided, however, that, for any Product Licensed Intellectual Property that is the subject of a license from a Third Party entered into by a Respondent specified in the definition of the particular Divestiture Product(s) 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.

W. "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, in each such case, as related to the Divestiture Products.

X. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.

Y. "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. The term "Domain Name" *excludes* any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.

Z. "Drug Master Files" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

AA. "Elan" means Elan Pharma International Ltd., a corporation organized, existing and doing business under and by virtue of the laws of the Republic of Ireland, with its headquarters address located at Treasury Building, Lower Grand Canal Street, Dublin, Ireland. Elan Pharma International Ltd. includes Perrigo Co., a corporation organized, existing and doing business under and by virtue of the laws of the State of Michigan, with its business address located at 515 Eastern Avenue, Allegan, Michigan 19010.

BB. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.

CC. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.

DD. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the Geographic Territory from a Respondent was, or is projected to be, among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date; or (iv) the end of the last quarter following the Acquisition Date or the Closing Date.

EE. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.

FF. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

GG. "Manufacturing Designee" means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.

HH. "NDC Number(s)" means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.

II. "Orders" means this Decision and Order and the related Order to Maintain Assets.

JJ. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.

KK. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.

LL. "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.

MM. "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.

NN. "Pilocarpine Product(s)" means the following: the Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Tower (CorePharma LLC) pursuant to ANDA No. 076746, and any supplements, amendments, or revisions to that Application.

OO. "Pilocarpine Product Assets" means all rights, title and interest in and to all assets related to the Business within the Geographic Territory of Respondent Tower (CorePharma LLC) related to each of the Pilocarpine Products, to the extent legally transferable, including, without limitation, the Categorized Assets, as such assets and rights are in existence as of the date the Respondents sign the Agreement Containing Consent Orders in this matter and as are required to be maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date.

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 Application.

QQ. "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 Geographic Territory, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.

RR. "Product Assumed Contracts" means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer of the particular Divestiture Product(s) on or before the Closing Date for the particular assets related to such Divestiture Product(s) and segregated in a manner that clearly identifies the purpose(s) of each such contract):

1. that make specific reference to any Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, any Divestiture Product from a 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 any Divestiture Product;
3. relating to any Clinical Trials involving any Divestiture Product;
4. with universities or other research institutions for the use of any Divestiture Product in scientific research;
5. relating to the particularized marketing of any Divestiture Product or educational matters relating solely to any Divestiture Product(s);
6. pursuant to which a Third Party manufactures any Divestiture Product on behalf of the Respondent;
7. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of any Divestiture Product on behalf of the Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the 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 Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the 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 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 assign the Acquirer of the particular Divestiture Product(s) all such rights under the contract or agreement as are related to the Divestiture Product(s) acquired by that Acquirer, but concurrently may retain similar rights for the purposes of the Retained Product(s).

SS. "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 Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of that Divestiture Product, including all copyrights in raw data relating to Clinical Trials of that Divestiture 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 data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Divestiture Product's sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law) in connection with the acquisition of that Divestiture Product; all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

TT. "Product Development Reports" means:

1. Pharmacokinetic study reports related to any Divestiture Product;
2. Bioavailability study reports (including reference listed drug information) related to any Divestiture Product;
3. Bioequivalence study reports (including reference listed drug information) related to any Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with the FDA relating to the Application(s) related to any Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to any Divestiture Product;

7. currently used or planned product package inserts (including historical change of controls summaries) related to any Divestiture Product;

8. FDA approved patient circulars and information related to any Divestiture Product;

9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to any Divestiture Product;

10. summary of Product complaints from physicians related to any Divestiture Product;

11. summary of Product complaints from customers related to any Divestiture Product;

12. Product recall reports filed with the FDA related to any 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 any Divestiture Product;

14. reports related to any 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 any Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of any Divestiture Product;

16. analytical methods development records related to any Divestiture Product;

17. manufacturing batch records related to any Divestiture Product;

18. stability testing records related to any Divestiture Product;

19. change in control history related to any Divestiture Product; and

20. executed validation and qualification protocols and reports related to any Divestiture Product.

UU. "Product Intellectual Property" means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):

1. Patents;

2. Product Copyrights;

3. Product Trademarks;

4. Product Trade Dress;

5. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and,

6. rights to obtain and file for patents, trademarks, and copyrights and registrations related to any of the foregoing and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing.

The term "Product Intellectual Property" *excludes* the corporate names or corporate trade dress of "Impax," "RoundTable," "Tower," "Lineage" or "CorePharma" or the related corporate or partnership logos thereof, or the corporate or partnership names or corporate or partnership trade dress of any other corporations, partnerships, or companies owned or controlled by any Respondent or the related corporate or partnership logos thereof, or general registered images or symbols by which Impax, RoundTable, Tower, Lineage or CorePharma, can be identified or defined.

VV. "Product Licensed Intellectual Property" means the following:

1. Patents that are related to a Divestiture Product that a Respondent can demonstrate have been 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;

2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that the Respondent can demonstrate have been 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

3. for any Divestiture Product that is the subject of an ANDA, all Right(s) of Reference or Use that is either owned or controlled by, or has been granted or licensed to the Respondent that is related to the Drug Master File of an NDA of a Product that is the therapeutic equivalent (as that term is defined by the FDA) of any Divestiture Product.

WW. "Product Manufacturing Technology" means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, 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 Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;

2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients or packaging materials; and,

3. for those instances in which the manufacturing equipment is not readily available from a Third Party for the particular Divestiture Product, at the Acquirer's (of the particular Divestiture Product(s)) option, all such equipment used to manufacture that Product.

XX. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of any Divestiture Product in the Geographic Territory as of the Closing Date, 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 either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to any Divestiture Product.

YY. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.

ZZ. "Product Trade Dress" means the current trade dress of a Product, including, but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

AAA. "Product Trademark(s)" means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.

BBB. "Proposed Acquirer" means a Person proposed by a Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to this Order.

CCC. "Remedial Agreement(s)" means the following:

1. a Divestiture Product Divestiture Agreement; and/or

2. 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.

DDD. "Retained Product" means any Product(s) other than a Divestiture Product.

EEE. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation for an FDA audit.

FFF. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered to an 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 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 of those Divestiture Product(s) 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 processes and analytical methods related to any Divestiture 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 (including all related intellectual property) to that Acquirer or its Manufacturing Designee; and

4. providing, in a timely manner, assistance and advice to enable the Acquirer of the particular Divestiture Product(s) or its Manufacturing Designee to:

    a. manufacture such Divestiture Product(s) in the quality and quantities achieved or planned to be achieved by the Respondent (as that Respondent is specified in the definition of the particular Divestiture Product(s)), or the manufacturer and/or developer of such Divestiture Product;

    b. obtain any Product Approvals necessary for that Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell any Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and,

    c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to any Divestiture Product.

GGG. "Third Party(ies)" means any non-governmental Person other than the following: the Respondents; or, the Acquirer of particular assets or rights pursuant to this Order.

HHH. "Ursodiol Product(s)" means the following: the Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Tower (CorePharma LLC) pursuant to ANDA No. 203439, and any supplements, amendments, or revisions to that Application.

III. "Ursodiol Product Assets" means all rights, title and interest in and to all assets related to the Business within the Geographic Territory of Respondent Tower (CorePharma LLC) related to each of the Ursodiol Products, to the extent legally transferable, including, without limitation, the Categorized Assets, as such assets and rights are in existence as of the date the Respondents sign the Agreement Containing Consent Orders in this matter and as are required to be maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date.

JJJ. "Website" means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent. The term "Website" *excludes* the following: (i) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (ii) content unrelated to any of the Divestiture Products.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Divestiture Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Elan pursuant to, and in accordance with, the Divestiture Product Divestiture Agreement (which agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Elan or to reduce any obligations of Respondents under such agreements), and such agreement, if it becomes a Remedial Agreement related to the Divestiture Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that, if Respondents have divested the Divestiture Product Assets to Elan prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Elan is not an acceptable purchaser of the Divestiture Product Assets, then Respondents shall immediately rescind the transaction with Elan, in whole or in part, as directed by the Commission, and shall divest the Divestiture Product Assets within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an

Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that, if Respondents have divested the Divestiture Product Assets to Elan prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that 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 Product Assets to Elan (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

B. Prior to the Closing Date for the particular assets related to a Divestiture Product required to be divested pursuant to this Order, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest such assets to an Acquirer, and to permit that Acquirer to continue the Business related to the Divestiture Products;

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

C. Respondents shall:

1. submit to the Acquirer of the Divestiture Product(s), at Respondents' expense, all Confidential Business Information related to the Divestiture Product(s);
2. deliver all Confidential Business Information related to the Divestiture Product(s) to the 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 Acquirer, upon reasonable written notice and request, 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 being 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 other than as necessary to comply with the following:

a. the requirements of this Order;

b. Respondents' obligations to the Acquirer under the terms of any applicable 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 Divestiture Products(s), (ii) other Persons specifically authorized by that Acquirer to receive such information, (iii) the Commission, or (iv) the Interim Monitor (if any has been appointed);

6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information that is exclusively related to the marketing or sales of the Divestiture Product(s) to the marketing or sales employees associated with the Business related to those Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) of the Divestiture Products; and

7. institute procedures and requirements to ensure that the employees of each Respondent:

a. do not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information in contravention of the Orders; and,

b. do not solicit, access or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose.

D. Respondents shall provide, or cause to be provided to each 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 such Divestiture Product(s).

Respondents shall obtain all 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. 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 the relevant Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

E. At the Acquirer's option, for a period of up to two (2) years following the Closing Date, Respondents shall provide technical assistance as set forth in the Technology Transfer Standards.

F. 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 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 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. At the request of an Acquirer, Respondents shall provide the requesting Acquirer with copies of all certifications sent to the Commission and all notifications and reminders sent to Respondents' personnel related to the Divestiture Assets acquired by that Acquirer.

G. For a period of one (1) year from the Closing Date, Respondents shall not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer of the Divestiture Product(s) or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with that Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

provided, however, that Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with a Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that any Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts any Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from any Respondent.

H. Until Respondents complete the divestitures required by this Order and fully provide, or cause to be provided, the Product Manufacturing Technology related to the Divestiture Product(s) to an Acquirer,

1. Respondents shall take actions as are necessary to:

   a. maintain the full economic viability and marketability of the Businesses related to that Divestiture Product;

   b. minimize any risk of loss of competitive potential for that Business;

c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;

d. ensure the assets related to each Divestiture Product are provided to that Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business related to each Divestiture Product;

e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and,

2. Respondents shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to that Divestiture Product.

I. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer under the following:

1. any Patent owned by or licensed to a Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; and/or,

2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to a Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such 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 Products acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Products 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 Products acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Divestiture Products acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by or licensed to or from a Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

J. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist the Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Products acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Products acquired by that Acquirer.

K. For any patent infringement suit filed prior to the Closing Date in which any Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that any Respondent has prepared or is preparing to defend against as of the Closing Date related to particular Divestiture Product(s), and where such a suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Products acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of such Divestiture Products acquired by that Acquirer, that Respondent shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;

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/or,

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.

L. The purpose of the divestiture of the Divestiture Product Assets 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 related to each Divestiture Product within the Geographic Territory;

2. to create a viable and effective competitor that is independent of Respondent Impax, and Tower in the Business related to 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 all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.

B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.

C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondents' 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, until the earliest of: (i) the date the Acquirer of such Divestiture Product (or the Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and able to manufacture that Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents Impax, and Tower; (ii) the date the Acquirer 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, on such reasonable and customary terms and conditions as the Commission may set. The Interim 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 Interim Monitor's duties and responsibilities.

G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim 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 Interim Monitor.

H. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order; *provided, however*, that, beginning one hundred twenty (120) days after Respondents have filed their final report pursuant to Paragraph VII.B., and one hundred twenty (120) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each

Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents Impax and Tower.

I. Respondents may require the Interim Monitor and each of the Interim 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 Interim Monitor from providing any information to the Commission.

J. The Commission may, among other things, require the Interim Monitor and each of the Interim 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 Interim Monitor's duties.

K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

M. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

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*, that 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 Respondents' 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*, that, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

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 Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.

G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, 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 redacted documents or copies of documents are insufficient or otherwise unavailable, and for the following 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 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.

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. Unless otherwise determined by the Commission, the Divestiture Product Divestiture Agreement shall become a Remedial Agreement on the Order Date.

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 (i) every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II.A. through II.D., and (ii) every one hundred twenty (120) days thereafter until Respondents have fully complied with Paragraph II.E., Respondents shall submit to the Commission a verified written report

setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondents shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, and (ii) transitional services being provided by the Respondents to the Acquirer; and
2. a detailed description of the timing for the completion of such obligations.

C. One (1) year after the Order Date, annually for the next nine 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.

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. any proposed acquisition, merger or consolidation of a Respondent; or

C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

IX.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that 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 the 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.

X.

IT IS FURTHER ORDERED that this Order shall terminate on April 22, 2025.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: April 22, 2015

NON-PUBLIC APPENDIX I
AGREEMENTS RELATED TO THE DIVESTITURES

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