1510011

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

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	)	
EALTHCARE PARTNERS II, L.P.,	)	**Docket No. C-**
a limited partnership;	)	
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GS, INC.,	)	
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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

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").

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 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 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

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, 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 Respondents' 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, but is not limited to [87 0 Tatiom t[p.nfitPsoTj /Tp 0 T04 Tw [(e)3,5look4 Tw [(e)4(

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

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; ;

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 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;

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

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,

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

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.

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

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

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

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;

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

divest expeditiously and at no minimum price. The divestiture shall be made in

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),ey2de(5(mmis)2(D)4(iv)2(e)tf5 4(r)a41(es(5 t(r

X.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the Order Date.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED:

NON-PUBLIC APPENDIX I
AGREEMENTS RELATED TO THE DIVESTITURES

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